San Francisco
Department of Public Health

Daniel Lurie
Mayor

CBHS PHARMACY SERVICES MANUAL

2026

CBHS PHARMACY SERVICES
1380 Howard Street, Room 130
San Francisco, CA 94103
628-754-9110

City and County of San Francisco
Department of Public Health
Daniel Lurie, Mayor

Behavioral Health Services

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CBHS Pharmacy Services
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Material published in this 2026 edition of the CBHS Pharmacy Services Manual contains information that was **current as of January 15, 2026**.

For updated policies/procedures and treatment guidelines please visit:

http://www.sf.gov/resource/2024/behavioral-health-services-policies-and-procedures

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Behavioral Health Services

Introduction
The CBHS Pharmacy Services Manual is updated and printed annually to help support BHS providers in medication-related services. Welcome to our 2026 edition.

About CBHS Pharmacy Services
The CBHS Pharmacy Services team provides pharmaceutical services and medication expertise to support clinicians and BHS clients in the wellness and recovery model of care. We support system of care programs and serve as a safety net to clients to ensure continuous access to mental health medications.

OUR MISSION: TO ADVANCE WELLNESS BY DELIVERING INNOVATIVE PATIENT-CENTERED CARE WITH CLINICAL EXPERTISE

OUR VISION: TO BE A LEADER IN PROVIDING PHARMACY SERVICES IN AN INTEGRATED HEALTH NETWORK

OUR VALUES: LEAD, LEARN, COLLABORATE, SERVE, EDUCATE

Prescription Benefits
Behavioral Health Services (BHS) offers prescription benefits for BHS clients with Healthy San Francisco (HSF) when prescriptions are written by a BHS prescriber following BHS formulary guidelines. These services are provided through our pharmacy benefits manager (PBM), MedImpact. BHS clients covered by insurance that includes prescription benefits (e.g. Medi-Cal, Medi-Cal Managed Care, MediCare-MediCal) receive prescription coverage through their insurance plan, and not through the BHS PBM service. Clients with Medicare A-B must enroll in a Medicare D drug plan for prescription coverage.

The Affordable Care Act mandates uninsured clients enroll in insurance; those eligible for Medi-Cal must enroll in Medi-Cal. Covered California offers expanded health coverage for those whose income is too high to qualify for Medi-Cal. Clients who do not qualify for any coverage must enroll in HSF.

For HSF clients of CBHS to receive prescription benefits through MedImpact, the **following are required**:

- **Prescriptions are for psychiatric medications listed in the BHS Formulary** and prescribed by approved prescribers and dispensed according to BHS Formulary guidelines. Some medications may require a prior authorization request (PAR). If so, follow the current BHS protocol to obtain a PAR. Questions about the formulary or guidelines may be directed to any of our clinical pharmacists by calling CBHS Pharmacy Services at (628) 754-9110.

- **Provide the patient's MRN** to the pharmacy to access prescription benefits.
- **For BHS Providers (Non-PPN): All prescriptions are entered via Epic.**

Laboratory Services:

BHS offers laboratory services through Laboratory Corporation of America (LabCorp). BHS can only pay for laboratory tests that are on the BHS laboratory formulary, unless special arrangements have been made in advance. For clinics, laboratory tests may be ordered electronically via Epic. Non-clinic programs use a BHS LabCorp Requisition form, ordered via CBHS Pharmacy.

Questions regarding tests approved on the laboratory formulary, and other general questions regarding BHS laboratory use policies may be directed to CBHS Pharmacy Services at (628) 754-9110. For more details, see the Laboratory Section of this manual.

Drug Information Service

CBHS Pharmacy provides clinical psychopharmacology telephone consultations for BHS psychiatrists, staff and San Francisco County providers including primary care clinicians. This service is available Monday through Friday, except holidays, from 9:00 a.m. to 4:30 p.m. To access this service email druginfo.bhs@sfdph.org (preferred) or call the CBHS Pharmacy at (628) 754-9110 and indicate that the call involves a drug information request.

Resources to be found in “Medication Resources” via this link: sf.gov/resource/2024/medication-guidelines

Medication Resources

Attention-Deficit/Hyperactivity Disorder (ADHD) Prescribing Resources

- Safer Prescribing of Stimulant and Non-Stimulant Medication Guideline

Antidepressant/Mood Stabilizers Prescribing Resources

- Safer Prescribing of Antidepressant Medication Guideline
- Safer Prescribing of Mood Stabilizer Medications Guideline

Antipsychotic Prescribing Resources

- Safer Prescribing of Antipsychotic Medications Guideline
- Atypical antipsychotic metabolic side effects patient handout
- Anticholinergics patient flier - English

Sedative-Hypnotic Prescribing Resources

- Safer Prescribing of Sedative-Hypnotics and Related Medications Guideline

Substance Use Disorders Prescribing Resources

- Medications for Alcohol Use Disorder Guideline
- Cannabis Use Disorder Medication-Assisted Treatment Guideline
- Medications for Nicotine Use Disorders Treatment Guideline
- Medications for Opioid Use Disorder Guideline
    - Naloxone Guideline
    - Direct to Inject Buprenorphine Guideline
    - Methadone for Treatment of OUD in Opioid Treatment Programs

Child Youth and Family Prescribing Resources

- Safer Use of Psychotropic Medications in Children and Adolescents Guideline

Other Resources

- Adult Blood Pressure Monitoring Guidelines
- Hypertension Patient Toolkit - English

I. Directories

San Francisco
Department of Public Health

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FAX: (628) 754-9571

BEHAVIORAL HEALTH SERVICES
Daniel Lurie, Mayor

RESOURCES DIRECTORY

Behavioral Health Access Center (BHAC)	888-246-3333
Healthy San Francisco	415-615-4555 www.healthysanfrancisco.org
Health Insurance Counseling and Advocacy Program (HICAP)	415-677-7520 800-434-0222 www.hicap.org
Laboratory Corporation of America (LabCorp)	800-888-1113 www.labcorp.com
Medi-Cal	
Eligibility (AEVS)	800-456-2387
Fax TAR	877-270-8779
Provider Service	800-541-5555
Website	www.medi-cal.ca.gov
Medicare	
Medicare Part D Website	www.medicare.gov
Medicare UPIN listing	*See Below*
MedImpact	877-403-6032
San Francisco Health Plan	www.sfhp.org
Pharmacy Information	415-547-7810
Provider Relations	415-547-7818 ex: 7084
Stericycle (Hazardous Waste Pick-up)	866-783-7422
Treatment Access Program (TAP)	415-503-4730

*https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/UniquePhysicianIdentificationDirectory.html

How to find the BHS Public Website

Website:

http://www.sf.gov/departments/department-public-health/behavioral-health

BHS Drug Information Consultation Service

The Drug Information Consultation Service responds to drug information questions regarding mental health drug therapy and related questions. This service is available free of charge to all BHS prescribers and staff, and to San Francisco County providers.

Mission

- Provide clinical psychopharmacology consultation for BHS psychiatrists and staff, and to providers in San Francisco County (including physical health care providers)
- Develop and support evidence-based drug use policy through comprehensive literature analysis and reviews

Consultations include:

- Dosing and designing drug regimens
- Evaluation of drug interactions
- Assessment of adverse drug effects
- Information on drug stability
- Drug use in pregnancy and lactation
- Practice guidelines and treatment algorithms
- Requests for primary literature
- Literature analysis and evaluation

Hours of Service

9:00am to 4:30pm Monday through Friday (except holidays)

Drug information requests may be submitted via:

- Email (preferred): **druginfo.bhs@sfdph.org**
- Telephone: **(628) 754-9110**. This is the main line for the CBHS Pharmacy; please indicate that the call is specifically for a drug information request.

Requests should include the following information:

1. Your name and profession
2. Location
3. Phone or pager number and fax number
4. Time limitations
5. Question
6. Patient-specific information such as current drug regimen (including dosages), recent lab values, diagnosis, etc.

Response time depends on the complexity of the question, acuteness of the patient's problem, and staff resources. Please indicate when you need a response in your request. Our goal is to complete requests within one to five business days. The response you receive will be verbal or in writing via fax or mail. Due to staffing limitations, we are not a STAT service.

Staff

Pharmacy students with clinical pharmacist supervision frequently staff the service. The coordinator of the Drug Information Consultation Service is Mark D. Watanabe, PharmD, PhD. Dr. Watanabe is a board-certified psychiatric pharmacist and is licensed as an Advanced Pharmacist Practitioner in California.

MEDICATION INFORMATION – CARLAT REPORT

www.thecarlatreport.com

Login: michelle.geier@sfdph.org Password: 1380howard

II. CBHS Prescription Procedures

BHS Pharmacy Prescription Benefits Overview

Purpose:

To outline available BHS prescription benefits based on client's insurance status

**** Clients with Medicare must enroll in a Medicare D drug plan for prescription coverage**

Client's Insurance	CBHS Benefit
Healthy San Francisco BHS clients enrolled in Healthy San Francisco	Full coverage for BHS Formulary prescriptions
Medi-Cal Medi-Cal (no share of cost) Medi-Cal with Share of Cost	No Prescription Coverage SOC may be covered by BHS, retail pharmacies must contact MedImpact
Medicare D Medicare only	Pay up to $25 per prescription for co-pays for psychiatric medications Full coverage for BHS Formulary over-the counter medications
Medi-Cal + Medicare Dual eligible Medicare and Medi-Cal	Pay up to $10 per prescription for co-pays for psychiatric medications
Healthy Workers San Francisco Health Plan	No prescription coverage by BHS benefit Prescription coverage by SFHP; pay up to $10 per prescription for co-pays for psychiatric medications
Other Health Coverage Kaiser, other private insurance	No prescription coverage
Temporary New clients activated with temporary number, or by a member activation request	Full coverage for BHS Formulary prescriptions for 30 days

BHS Prescription Information

For BHS clients with Healthy San Francisco (HSF), the following applies:

❖ **Client Prescription Benefit Activation with MedImpact (Member Activation Form)**

- All clients are automatically eligible to receive prescription benefits 7 days after Avatar registration.

- **If medications are needed in less than 7 days**, prescription benefits must be manually activated.
  - To manually activate, the **Member Activation Form** must be completed and submitted. See form for detailed instructions (see following page).
  - Member activation occurs between the hours of 8:30 AM – 5:00 PM, Monday – Friday (excluding holidays).

❖ **Duration/Refill**

- Non-Scheduled medications: 90-day supply maximum
  - Maximum of 6 months worth of refills allowed
- Scheduled Medications: 35-day supply maximum
- Refills available when 75% of a 0–20-day supply has been used or when 82% of a 21 day or more supply has been used.
- Anything outside these parameters will require prior approval from Pharmacy Services by calling (628) 754-9110.

❖ **Lost/Stolen Medications**

- BHS psychiatrist or another authorized prescriber must call the dispensing pharmacy or note “lost medication” on prescription. The dispensing pharmacy will then call MedImpact for approval.
- Limited to once per calendar year for all medications (controlled and non-controlled medications).

❖ **Vacation/Travel Supply of Medications**

- BHS psychiatrist or another authorized prescriber must call the dispensing pharmacy or note “vacation supply” on prescription. The dispensing pharmacy will then call MedImpact for approval.
- One additional refill of the original quantity is the maximum amount that can be concurrently dispensed
- Clozapine and buprenorphine prescriptions are not included

❖ **Medi-Cal and Other Third Party Insured Clients**

- For clients with third party prescription coverage (including Medi-Cal and Medicare), the dispensing pharmacy must bill the third-party insurer.
- For Medi-Cal clients, all non-electronic prescriptions must be executed on tamper-resistant pads.
- If you are seeing a client with third party prescription coverage (including Medi-Cal and Medicare), please contact the third party for questions concerning their formulary and prior approval process.

CSF Member Activation Request

City and County of San Francisco
Department of Public Health
COMMUNITY BEHAVIORAL HEALTH SERVICE

Email to MedImpact: grouprequest@medimpact.com
Fax to MedImpact at 858-578-2135

CBHS MEDIMPACT ACTIVATION FORM

NOTE: activation can only be obtained Monday through Friday 8:30-5:00pm (Excluding holidays)
This activation form is used to allow prescription services for new clients within 7 days of admission to a CBHS program

If no response (return fax or email) within 60 minutes
Call CBHS Pharmacy Services at 628-754-9110

CBHS Clinic Name:		**Site #**	
Requester:		Phone No.: - -	Return Fax No.: - -
Email:		Title:	Date: / /
Effective Date: / /		***End Date:*** / /	
MEMBER INFORMATION			
MRN# (required):		**SSN#:**	
Client Last Name	**Client First Name**	**Client Middle Name**	
Gender M / F		**DOB (If not available use 1/1/1911)** / /	
Comments:			

My signature below affirms that I have authority to authorize MedImpact, and I do authorize MedImpact, to perform, implement or change the services or products described herein.

X _____ Date: / /

Signature of Authorized Plan Representative Required

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BEHAVIORAL HEALTH SERVICES
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Kaiser Permanente Members

This is a memorandum to BHS providers regarding the procedures to be followed when prescribing medications or ordering medication-related laboratory tests for BHS clients who are Kaiser Permanente members. **Kaiser clients must fill prescriptions and receive blood draws at a Kaiser facility.**

Please follow the recommendations below before sending clients to Kaiser for pharmacy or laboratory services.

1. Provide the client with a copy of the Kaiser letter (on next page), filled-in with client name, Kaiser number, and date of birth. **Client should bring this letter to each pharmacy and laboratory visit.** Keep a copy in the client's chart.

2. Submit prescriptions electronically via Epic. Always indicate in the Notes to Pharmacist that client has an "**Authorized Outside Referral**".

    a. Electronic prescriptions sent to Kaiser will automatically be put on file and will not automatically be filled. To fill the prescriptions, one of the following must be performed:
        i. For clients that can wait 24 hours for their prescription and familiar with the Kaiser system: instruct the client to use the Kaiser app or www.kp.org to request their prescription be filled. It may take up to 4 hours for the prescriptions to become available on the app or website.
        ii. For clients that have difficulty navigating the app or website or for prescriptions that need to be picked up that day: call the Call Center (1-888-218-6245) and state that you need to speak to a pharmacist for an "urgent" medication. Inform the pharmacist that the prescription needs to be picked-up today.

3. Provide to client a filled-in lab requisition, with client name, Kaiser number, provider's information (full name, NPI number, telephone number, fax number, and address) so provider may receive lab results. Always indicate on the lab requisition that client has an "**Authorized Outside Referral**".

4. **Note that Kaiser clients insured through Medi-Cal must follow the Medi-Cal drug formulary. Kaiser clients insured through other means (i.e. Medicare, Medicare/Medi-cal, employment, self-pay, etc.) will follow the Kaiser formulary.**

If the client has problems getting prescriptions filled or laboratory work done, providers may contact CBHS Pharmacy Services at (628) 754-9110 for further assistance.

KAISER PERMANENTE

TO:

Kaiser Number:

Date of Birth: / /

Beginning July 1, 2001, your Kaiser Permanente supplemental prescription drug plan will no longer cover medications prescribed by non-Plan physicians. However, Kaiser Permanente has decided to make a coverage exception for certain prescriptions. Plan pharmacies will continue to fill those prescriptions that are prescribed by a County psychiatrist (or County-assigned psychiatrist) for their covered Kaiser Permanente patients who participate in certain County treatment programs.

Please bring this letter, with your prescription, to a Kaiser Permanente Plan pharmacy. For qualified prescriptions, you will be charged your regular drug plan copayment.

In addition, if your psychiatrist orders laboratory tests related to your psychiatric medications, the tests will be covered by Kaiser Permanente when you bring your physician order and this letter to a Kaiser Permanente laboratory.

Please remember that this exception applies only for your formulary psychiatric medications and related laboratory tests, and is subject to change at any time.

Sincerely,

Kaiser Foundation Health Plan

Remember...
Please bring this letter with you to the pharmacy or lab each visit, to help remind our staff that your prescription may qualify for this coverage exception.

Antidepressants	HSF	BHS	LHH	MCal Rx
amitriptyline	F	F	F	F
bupropion	F	F	F	F
bupropion SR (Wellbutrin SR)	NF	F	F	F
bupropion XL (Wellbutrin XL)	F	F	F	F
citalopram	F	F	F	F
clomipramine	F	F	NF	F
desipramine	F	F	F	F
desvenlafaxine ER	NF	NF	NF	F
doxepin	F	F	F	F
duloxetine	F	F	F	F
escitalopram	F	F	F	F
fluoxetine	F	F	F	F
fluvoxamine	F	F	NF	F
imipramine	F	F	F	F
isocarboxazid	NF	F	NF	NF
levomilnacipran ER	NF	NF	NF	NF
mirtazapine	F	F	F	F
nefazodone	F	F	NF	NF
nortriptyline	F	F	F	F
paroxetine hcl	F	F	F	F
phenelzine	F	F	NF	NF
protriptyline	F	F	NF	F
sertraline	F	F	F	F
tranylcypromine	NF	F	NF	NF
trazodone	F	F	F	F
venlafaxine XR	F	F	F	F
vilazodone	NF	NF	NF	NF
vortioxetine	NF	NF	NF	LR

Antipsychotics	HSF	BHS	LHH	MCAL
aripiprazole tablet	F	F	F	F
aripiprazole oral solution	PAR	PAR	F	F
aripiprazole ODT	NF	NF	F	F
aripiprazole ER injection	NF	PAP	F	F
aripiprazole lauroxil ER inj	NF	PAP	NF	F
asenapine	NF	NF	NF	F
brexpiprazole	NF	NF	NF	NF
cariprazine	NF	NF	NF	NF
chlorpromazine	F	F	F	F
clozapine	F	F	F(psych)	F
fluphenazine	F	F	F	F
fluphenazine decanoate	F	F	F	NF
haloperidol	F	F	F	F
haloperidol decanoate	F	F	F	F
iloperidone	NF	NF	F	F
lurasidone	NF	NF	F	F
loxapine	F	F	NF	F
molindone	NF	F	NF	F
olanzapine	F	F	F	F
olanzapine ODT	F	NF	F	F
olanzapine long acting inj	NF	PAP	NF	NF
paliperidone	NF	NF	F	F
paliperidone inj (Sustena)	NF	PAP	F	NF
paliperidone inj (Trinza)	NF	PAP	F	NF
perphenazine	F	F	F	F
quetiapine	F*	F*	F	F
quetiapine XR**	F	F	F	F
risperidone	F	F	F	F
risperidone ODT	F	F	F	F
thioridazine	F	F	NF	F
thiothixene	F	F	F	F
trifluoperazine	F	F	NF	F
xanomeline/trospium	NF	NF	NF	NF
ziprasidone	F	F	F	F

Sedatives/ Hypnotics	HSF	BHS	LHH	MCal Rx
alprazolam	NF	NF	NF	NF
chloral hydrate concentrate	F	F	NF	NF
chlordiazepoxide	F	F	NF	QL
clonazepam	F	F	F	F
daridorexant	NF	NF	NF	NF
diazepam	NF	NF	F	AL
eszopiclone	NF	NF	NF	NF
flurazepam	NF	F	NF	F
hydroxyzine HCl (Atarax)	F	F	F	F
hydroxyzine pam (Vistaril)	NF	F	NF	F
lemborexant	NF	NF	NF	NF
lorazepam	F	F	F	F
midazolam	NF	NF	F	QL/AL
temazepam	F	F	F	RF
ramelteon	NF	NF	NF	QL/AL
suvorexant	NF	NF	NF	NF
tasimelteon	NF	NF	NF	NF
zaleplon	F	F	NF	PAR
zolpidem	F	F	F	RF

Miscellaneous	HSF	BHS	LHH	MCAL
amantadine	F	F	F	AL
atomoxetine	NF	NF	NF	AL
benztropine	F	F	F	AL
buprenorphine	F	F	F	QL
buprenorphine inj (Brixadi)	RF	RF***	NF	F
buprenorphine inj (Sublocade)	RF	RF***	NF	F
buprenorphine/naloxone tabs	F	F	F	QL
buprenorphine/naloxone films	F	F	F	QL
buspirone	F	F	F	F
carbamazepine	F	F	F	F
clonidine	F	F	F	F
clonidine patch	F	F	F	F
diphenhydramine	F	F	F	F
disulfiram	F	F	NF	F
divalproex	F	F	F	F
divalproex sprinkles	F	F	F	F
divalproex ER	F	F	F	F
folic acid	F	F	F	F
guanfacine	NF	F	NF	F
guanfacine ER	NF	NF	NF	F
lamotrigine	F	F	F	F
liothyronine (T3)	F	F	NF	NF
lithium carbonate	F	F	F	F
lithium carbonate (Eskalith CR)	F	F	F	NF
lithium carbonate ER (Lithobid)	F	F	F	F
modafinil	NF	NF	NF	NF
naloxone	F	F	F	F
naltrexone (oral)	F	F	F	F
ondansetron tab	RF	F	F	F
ondansetron ODT	RF	F	F	F
prazosin	F	F	F	F
trihexyphenidyl	F	F	F	AL
valproic acid	F	F	F	AL

Legend	
F = Formulary	PAR = Prior Authorization Required
RF = Restricted Formulary	MCAL = billed to Medi-Cal FFS (see MCAL formulary)
NF = Non-Formulary	AL = age limits
PAP = Patient Assistance Program	QL = quantity limits
LR = labeler restriction	
CBHS = Community Behavioral Health Services	
HSF= Healthy San Francisco (Community Oriented Primary Care)	
LHH = Laguna Honda Hospital	
MCAL= Medi-Cal (Fee-for-Service)	

FORMULARY ALIGNMENT AND PRESCRIBING

In concert with integration efforts in the San Francisco Health Network, the BHS and COPC (Healthy San Francisco) Formulary Committees continue to work to improve formulary alignment. Each core psychiatric drug class contains several full formulary ("F") options which have been selected as preferred drugs by the BHS and COPC Formulary Committees.These cross-formulary medications should be used as first-line treatment. Using cross-formulary medications will facilitate patient access to medications, particularly for those individuals who transition between COPC and CBHS providers.

*25mg, 50mg tablets restricted to ages <18 and >60
**50 mg NF
***must fill through CBHS pharmacy

DPH Formulary Comparison: Stimulant Medications

December 1, 2025

Stimulants	HSF	BHS	LHH	Medi-Cal
amphetamine salts IR (Adderall)	F	F	NF	RF
amphetamine salts XR (Adderall XR)	F (psych)	F	NF	RF
amphetamine salts XR (Mydayis)	NF	NF	NF	NF
amphetamine XR (Dyanavel XR)	NF	NF	NF	NF
amphetamine XR ODT (Adzenys-XR ODT)	NF	NF	NF	NF
dexmethylphenidate	NF	NF	NF	NF
dexmethylphenidate XR	NF	NF	NF	RF
dextroamphetamine IR	F	F	NF	RF
dextroamphetamine ER	F (psych)	F	NF	NF
dextroamphetamine IR liquid	NF	NF	NF	NF
lisdexamfetamine	NF	NF	NF	RF
methylphenidate IR (Ritalin IR)	F	F	F	RF
methylphenidate IR chewable	NF	NF	NF	NF
methylphenidate IR oral solution	NF	NF	NF	RF
methylphenidate CD (Metadate CD)	NF	NF	NF	NF
methylphenidate ER (Metadate ER)	F (psych)	F	NF	NF
methylphenidate ER (Concerta)	F (psych)	F	NF	RF
methylphenidate XR suspension (Quillivant XR)	NF	NF	NF	NF
methylphenidate XR chewable (Qullichew ER)	NF	NF	NF	NF
methylphenidate LA (Ritalin LA)	NF	NF	NF	NF
methylphenidate SR (Ritalin SR)	F (psych)	F	NF	NF
methylphenidate transdermal patch	NF	NF	NF	NF

SAN FRANCISCO MENTAL HEALTH PLAN FORMULARY

BHS	Medi-Cal Rx	Antidepressants	Commonly Available Strengths	*Max Daily Dosage	Dosage Form
F	F	amitriptyline	10, 25, 50, 75, 100, 150	300	TAB
F	F	bupropion	75, 100	450	TAB
F	F	bupropion SR	100, 150, 200	400	TAB
F	F	bupropion XL	150, 300	450	TAB
F	F	citalopram	10, 20, 40	40	TAB
F	F	clomipramine	25, 50, 75	250	TAB
F	F	desipramine	10, 25, 50, 75, 100, 150	300	TAB
NF	F	desvenlafaxine ER	25, 50, 100	100	TAB
F	F	doxepin	10, 25, 50, 75, 100, 150	300	CAP
F	F	duloxetine	20, 30, 60	120	CAP
F	F	escitalopram	5, 10, 20	20	TAB
F	F	fluoxetine	10, 20, 40	80	CAP
F	F	fluvoxamine	25, 50, 100	300	TAB
F	F	imipramine	10, 25, 50	300	TAB
F	NF	isocarboxizid	10	60	TAB
NF	NF	levomilnacipran ER	20, 40, 80, 120	120	CAP
F	F	mirtazapine	15, 30, 45	45	TAB
NF	F	mirtazapine ODT	15, 30, 45	45	TAB
F	NF	nefazodone	50, 100, 150, 200, 250	600	TAB
F	F	nortriptyline	10, 25, 50, 75	150	CAP
F	F	paroxetine	10, 20, 30, 40	60	TAB
F	NF	phenelzine	15	90	TAB
F	F	protriptyline	5, 10	60	TAB
F	F	sertraline	25, 50, 100	200	TAB
F	NF	tranylcypromine	10	60	TAB
F	F	trazodone	50, 100, 150	400	TAB
F	F	venlafaxine XR	37.5, 75, 150	225	CAP
NF	NF	vilazodone	10, 20, 40	40	TAB
NF	F	vortioxetine	5, 10, 15, 20	20	TAB

BHS	Medi-Cal Rx	Antipsychotics	Commonly Available Strengths	*Max Daily Dosage	Dosage Form
F	F	aripiprazole	2, 5, 10, 15, 20, 30	30	TAB
NF	F	aripiprazole ODT	10,15	30	ODT
PAP	F	aripiprazole ER injection	300, 400	400	INJ
PAP	F	aripiprazole lauroxil ER injection	441, 662, 882	882	INJ
NF	F	asenapine	5, 10	20	TAB
NF	NF	brexpiprazole	0.25, 0.5, 1, 2, 3, 4	4	TAB
NF	NF	cariprazine	1.5, 3, 4.5, 6	6	CAP
F	F	chlorpromazine	10, 25, 50, 100, 200	2000	TAB
F	F	clozapine	12.5, 25, 50, 100, 200	900	TAB
F	F	clozapine ODT			
F	F	fluphenazine	1, 2.5, 5, 10	40	TAB
F	NF	fluphenazine decanoate	25mg/ml		INJ
F	F	haloperidol	0.5, 1, 2, 5, 10, 20	30	TAB
F	F	haloperidol decanoate	50mg/ml, 100mg/ml		INJ
NF	F	iloperidone	1, 2, 4, 6, 8, 10, 12	24	TAB
NF	F	lurasidone	20, 40, 80, 120	160	TAB
F	F	loxapine	5, 10, 25, 50	250	CAP
F	F	olanzapine	2.5, 5, 7.5, 10, 15,20	20	TAB
NF	F	olanzapine ODT	5,10,15,20	20	TAB
PAP	NF	olanzapine long acting injection	150, 210, 300, 405	405	INJ
NF	NF	paliperidone	1.5, 3, 6, 9	12	TAB
PAP	NF	paliperidone inj (Sustenna)	39, 78, 117, 156, 234	234	INJ
PAP	NF	paliperidone inj (Trinza)	273, 410, 546, 819	819	INJ
F	F	perphenazine	2, 4, 8, 16	64	TAB
F**	F	quetiapine	25, 50, 100, 200, 300, 400	800	TAB
F	F	quetiapine XR	50,100, 150, 200, 300, 400	800	TAB
F	F	risperidone	0.25, 0.5, 1, 2, 3, 4	8	TAB
F	NF	risperidone ODT	0.5, 1, 2, 3, 4	8	ODT
F	F	thiothixene	1, 2, 5, 10, 20	60	CAP
F	F	trifluoperazine	1, 2, 5, 10	40	TAB
F	F	ziprasidone	20, 40, 60, 80	200	CAP

F = Formulary
NF = Non-formularly; may be covered through Medi-Cal with a PA
PAP = Patient Assistance Program (not paid for by SF Mental Health Plan)
PAR = Prior Authorization Required

RF = Restricted formulary (RF* = must be filled at CBHS Pharmacy)
QL = Quantity limit
AL = Age limit

CBHS Pharmacy **628-754-9110**
MedImpact **800-788-2949**
Medi-Cal **800-541-5555**

All oral dosage forms (tablet, capsule and liquid) and strengths are covered unless otherwise indicated.
*Max Daily Dosage and commons daily dosage are provided as an abitrary reference, each patient must be individually titrated to tolerance and response.
**25mg, 50 mg tablets restricted to ages <18 and >60

Last updated April 2026

SAN FRANCISCO MENTAL HEALTH PLAN FORMULARY

BHS	Medi-Cal Rx	Anxiolytics/Sedatives/Hypnotics	Commonly Available Strengths	*Max Daily Dosage	Dosage Form
NF	NF	alprazolam	0.25, 0.5, 1, 2	4	TAB
F	NF	chlordiazepoxide	5, 10, 25	300	CAP
F	QL	clonazepam	0.5, 1, 2	4	TAB
NF	RF	diazepam	2, 5, 10	60	TAB
F	F	diphenhydramine	25, 50	400	CAP
NF	NF	eszopiclone	1, 2, 3	3	TAB
F	QL/AL	flurazepam	15, 30	30	CAP
F	F	hydroxyzine HCl (Atarax)	10, 25, 50	400	TAB
F	F	hydroxyzine pamoate (Vistaril)	25, 50	400	CAP
F	QL/AL	lorazepam	0.5, 1, 2	10	TAB
NF	QL/AL	ramelteon	8	8	TAB
NF	NF	suvorexant	5, 10, 15, 20	20	TAB
NF	NF	tasimelteon	20	20	CAP
F	QL/AL	temazepam	7.5, 15, 22.5, 30	30	CAP
F	PAR	zaleplon	5, 10	20	CAP
F	RF	zolpidem	5, 10	10	TAB
NF	NF	zolpidem CR	6.25, 12.5	12.5	TAB

BHS	Medi-Cal Rx	Stimulants	Commonly Available Strengths	*Max Daily Dosage	Dosage Form
F	RF	amphetamine salts (Adderall)	5, 7.5, 10, 12.5, 15, 20, 30	40	TAB
F	RF	amphetamine salts (Adderall XR)	5, 10, 15, 20, 25, 30	60	CAP
NF	NF	dexmethylphenidate (Focalin)	2.5, 5, 10	20	TAB
NF	RF	dexmethylphenidate XR (Focalin XR)	5, 10, 15, 20, 25, 30, 35, 40	40	CAP
F	RF	dextroamphetamine IR	5, 10	40	TAB
F	NF	dextroamphetamine ER	5, 10, 15	40	CAP
NF	NF	dextroamphetamine IR liquid	5mg/5mL	40	SOLN
NF	RF	lisdexamfetamine (Vyvanse)	10, 20, 30, 40, 50, 60, 70	70	CAP
F	RF	methylphenidate IR	5, 10, 20	60	TAB
NF	NF	methylphenidate IR chewable	2.5, 5, 10	60	TAB
NF	NF	methylphenidate IR oral solution	5mg/5mL, 10mg/5mL	60	SOLN
NF	NF	methylphenidate CD (Metadate CD)	10, 20, 30, 40, 50, 60	60	CAP
F	NF	methylphenidate ER (Metadate ER)	10, 20	60	TAB
F	RF	methylphenidate ER (Concerta)	18,27, 36, 54	72	TAB
NF	NF	methylphenidate XR suspension (Quillivant XR)	5mg/mL	60	SUS
NF	NF	methylphenidate LA (Ritalin LA)	10, 20, 30, 40	60	CAP
F	NF	methylphenidate SR (Ritalin SR)	20	60	TAB
NF	NF	methylphenidate transdermal patch	10, 15, 20, 30	30	PATCH

BHS	Medi-Cal Rx	Miscellaneous	Commonly Available Strengths	*Max Daily Dosage	Dosage Form
F	F	amantadine	100	400	CAP
F	F	amlodipine	2.5, 5, 10	10	TAB
F	F	atenolol	25, 50, 100	100	TAB
NF	RF	atomoxetine	10, 18, 24, 40, 60, 80, 100	100	CAP
F	F	atorvastatin	10,20,40,80	80	TAB
F	F	benztropine	0.5, 1, 2	6	TAB
F	F	bethanechol	5, 10, 25, 50	400	TAB
F	F	buprenorphine	2, 8	16	TAB
RF*	F	buprenorphine inj (Brixadi)	8 mg/0.16, 16 mg/0.32, 24 mg/0.48, 32 mg/0.64, 64 mg/0.18, 96 mg/0.27, 128 mg/0.36	128	INJ
RF*	F	buprenorphine inj (Sublocade)	100 mg/0.5, 300 mg/1.5	300	INJ
F	F	buprenoprhine/naloxone	2/0.5, 8/2 (add'l doses available)	16	TAB
F	F	buprenoprhine/naloxone	2/0.5, 4/1, 8/2	16	FILM
F	F	buspirone	5, 10,15, 30	60	TAB
F	F	carbamazepine	100, 200	1200	TAB
F	F	clonidine	0.1, 0.2, 0.3	0.4	TAB
F	F	clonidine patch	0.1, 0.2, 0.3	0.4	PATCH
F	NF	cyproheptadine	4	32	TAB
F	F	disulfiram	250, 500	500	TAB
F	F	divalproex (Depakote)	125, 250, 500	60mg/kg/day	TAB
F	F	divalproex ext release (Depakote ER)	250, 500	60mg/kg/day	TAB
F	F	divalproex sprinkles (Depakote Sprinkles)	125	60mg/kg/day	CAP
F	F	docusate sodium	100, 250	500	CAP
F	F	folic acid	0.4, 0.8, 1		TAB
F	F	guanfacine	1, 2	4	TAB
NF	NF	guanfacine ER	1, 2, 3, 4	7	TAB
F	F	gabapentin	100, 300, 400, 600, 800	3600	CAP/TAB
F	F	lamotrigine	25, 100, 150, 200		TAB
F	F	levothyroxine (T4, Synthroid)	multiple doses	0.3	TAB
F	NF	liothyronine (T3, Cytomel)	0.005, 0.025, 0.05	0.1	TAB
F	F	lithium carbonate	150, 300		CAP
F	NF	lithium carbonate SR (Eskalith-CR)	450		TAB
F	F	lithium carbonate ER (Lithobid)	300		TAB
F	F	metformin	500, 850, 1000	2550	TAB
F	F	metformin ER	500, 750	2000	TAB
NF	NF	modafinil	100, 200	400	TAB
F	NF	multivitamin			TAB
F	F	naloxone	4mg/0.1ml, 2mg/2ml, 0.4mg/ml		SPRY/SYR/VL
F	F	naltrexone (oral)	50	50	TAB
F	F	nicotine transdermal patch	7, 14, 21		PATCH
F	F	nicotine gum	2,4		GUM
F	F	ondansetron	4, 8	24	TAB
F	F	ondansetron ODT	4, 8	24	SL TAB
NF	F	oxcarbazepine	150, 300, 600	2400	TAB
F	F	prazosin	1, 2, 5	15	CAP
F	F	propranolol	10, 20, 40, 60, 80	120	TAB
F	NF	psyllium powder			POW
F	F	rosuvastatin	5, 10, 20, 40	40	TAB
F	F	trihexyphenidyl	2, 5	15	TAB
F	F	valproic acid	250	60mg/kg/day	CAP

F = Formulary
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PAR = Prior Authorization Required

RF = Restricted formulary (RF* = must be filled at CBHS Pharmacy)
QL = Quantity limit
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CBHS Pharmacy **628-754-9110**
MedImpact **800-788-2949**
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All oral dosage forms (tablet, capsule and liquid) and strengths are covered unless otherwise indicated.
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**25mg, 50 mg tablets restricted to ages <18 and >60

Last updated April 2026

III. Medicare Part D Prescription Drug Plan

RESOURCE FOR CLIENTS WITH MEDICARE D PLANS

HICAP (Health Insurance Counseling Advocacy Program) is available to assist our clients with their Medicare Part D plans. They are a program funded through State and Federal grants with a focus on helping seniors and disabled adults (including our behavior health clients) who are Medicare beneficiaries or pending Medicare coverage.

Clients can call to set up a one-on-one appointment to meet with a State Register HICAP Counselor to evaluate and compare their Part D plan. The HICAP counselors utilize the Medicare website and enter the client's medication list and explain the options to the clients who then chose a plan. Clients should bring a complete list of their prescription medications for the appointment, along with their Medicare card and Identification.

The program is run by appointment-only and does not function through walk in appointments due to site and counselor availability. They have several locations throughout San Francisco County.

Please call for appointments at 1-800-434-0222 or locally at 415-677-7520

For clients who may not be able to travel to HICAP offices, HICAP may be able to provide services at our clinics by special arrangement.

San Francisco County HICAP Office
601 Jackson Street, 2nd Floor
San Francisco, CA 94133
(415) 677-7520

Link for HICAP website: http://hicap.org/

LINET MEDICARE

Medicare's LINET Program gives temporary drug coverage to people who qualify for Medicare's low-income subsidy (LIS), also called Extra Help, and either: both Medicare and Medicaid (Medi-Cal) or both Medicare and Supplemental Security Income (SSI). Currently, Humana administers the LINET Program.

2026 California Medicare Part D Prescription Drug Benchmark Plans
Accepts Low Income Subsidy (premium & deductible are $0 with 100% LIS)

PLAN NAME	MONTHLY PREMIUM	COVERAGE IN THE GAP?	PRIOR AUTHOR-IZATION	HELP DESK	FORMULARY WEBSITE	GENERAL WEBSITE
Wellcare Classic **(PDP)**	$0	**Effective January 1, 2026:** Coverage gap is replaced by annual OOP maximum of $2,100.	1-888-550-5252 Electronic PA: https://www.covermymeds.com/main/prior-authorization-forms/wellcare/ Form (fax): https://www.wellcare.com/California/Forms/Request-PDP-Prescription-Drug-Coverage	Wellcare Medicare Plans: 1-866-899-3945 (TTY 711) Wellcare Prescription Drug Plans: 1-888-550-5252 (TTY 711)	https://www.wellcare.com/California/2023-Preferred-Drug-List-Search-PDP/PDP-Preferred-Drug-List-Search-23320-Book-03	https://www.wellcare.com/california
HealthSpring Assurance Rx (PDP)	$0		1-877-813-5595 Electronic PA: https://www.express-scripts.com/medicare/prescription-drug-coverage-review-form/?wform=physician&article=CorpPhysMedicare PDF (fax):	1-877-642-8212 (TTY 711)	https://www.healthspring.com/static/docs/medicare/plans/2026/formulary-assurance.pdf	https://www.healthspring.com/medicare/shop-plans/part-d

IV. Laboratory

PATIENT SERVICE CENTERS

SAN FRANCISCO

LABORATORY SERVICES

Laboratory Corporation of America (LabCorp)	Telephone	Fax
148 Noe Street (Duboce Triangle)	415-487-8960	415-487-3510
490 Post Street, Suite 419 (Union Square)	415-837-0782	415-788-7839
2233 Post Street, Suite 105 (Mt. Zion Hospital Area)	415-928-0199	415-771-6730
2100 Webster Street, Suite 420 (Pacific Heights)	415-674-1662	415-674-1865
728 Pacific Avenue, Suite 401 (Chinatown)	415-576-1017	415-576-1016
2622 Ocean Avenue (West Portal)	415-469-9710	415-469-9776
1 Daniel Burnham Court, Suite 391C (Polk Gulch)	415-409-2563	415-474-2264
1440 Southgate Avenue, Suite 2 (Daly City)	650-992-2986	650-757-6848

Hours of operation vary by facility. They are generally open in the early part of the day.

Facility-specific information may be found at:

locations.labcorp.com/ca/san-francisco/

CBHS Formulary Laboratory Tests

LabCorp Test Number	LabCorp Test Name	LabCorp Description
007476	Amitriptyline (Elavil), Serum	Amitriptyline
322758	Metabolic Panel (8), Basic	Metabolic Panel (8), Basic (Na,K,Cl,Ca,CO_2,Glu,BUN,Cr)
004556	Human Chorionic Gonadotropin (hCG), β-Subunit, Qualitative	Human Chorionic Gonadotropin (hCG), β-Subunit, Qualitative
004036	Pregnancy Test, Urine	Pregnancy Test, Urine (Beta HCG, Urine)
701985	Buprenorphine MAT 2, Ur (Urine Drug Screen) **See Labcorp.com test menu for details on cutoffs and confirmation**	Urine Drug Screen, 18 drugs: (buprenorphine, alcohol biomarkers (EtG, EtS), amphetamines, barbiturates, benzodiazepines, cocaine metabolite, phencyclidine, cannabinoids (THC), heroin metabolite (6-AM), opiates, oxycodones, tapentadol, fentanyl, methadone, propoxyphene, tramadol, carisoprodol, gabapentin
007419	Carbamazepine	Carbamazepine, Serum or Plasma
005009	CBC With Differential/Platelet	Complete Blood Count (CBC) With Differential
028142	CBC, Platelet, No Differential	Complete Blood Count (CBC) Without Differential
706465	Clomipramine	Clomipramine, Serum or Plasma
706440	Clozapine	Clozapine, Serum or Plasma
322000	Metabolic Panel (14), Comprehensive	Metabolic Panel (14), Comprehensive (Na,K,Cl,Ca,CO_2,Glu,BUN,Cr, [BUN:Cr],Alb,Glub,[Alb:Glub],TBili,AlkPhos, AST,ALT,GGT,TP)
003012	Creatinine, 24-Hour Urine	Creatinine, 24-Hour Urine
007765	Desipramine	Desipramine, Serum or Plasma
007609	Doxepin	Doxepin, Serum or Plasma
002014	Folate (Folic Acid)	Folate (Folic Acid), Serum
001958	GGT	γ-Glutamyl Transferase (GGT)
001453	Hemoglobin A1c	Hemoglobin (Hb) A1c, whole blood
322755	Hepatic Function Panel (7)	Hepatic Function Panel (7) (Alb,TBili.,DBili.,AlkPhos,AST,ALT,TP):
144052	Hepatitis C Virus (HCV) Genotyping	Hepatitis C Genotyping, Sequence-based Determination
083935	HIV p24 Antigen/Antibody With Reflex to Confirmation	Human Immunodeficiency Virus 1/O/2 (HIV-1/O/2) Antigen/Antibody (Fourth Generation) Preliminary Test With Cascade Reflex to Supplementary Testing
007468	Imipramine	Imipramine, Serum or plasma
001321	Iron and TIBC	Iron and Total Iron-binding Capacity (TIBC)
303756	Lipid Panel	Lipid Panel
007708	Lithium	Lithium, Serum
001537	Magnesium, Serum	Magnesium
007393	Nortriptyline	Nortriptyline, serum or plasma
007401	Phenytoin	Phenytoin, Serum or Plasma
004465	Prolactin	Prolactin
005199	Prothrombin Time (PT)	Prothrombin Time (PT)
005207	PTT, Activated	Partial Thromboplastin Time (PTT), Activated
182879	QuantiFERON®-TB Gold Plus	Interferon-gamma Release Assay (IGRA) for Mycobacterium tuberculosis
012005	Syphilis: RPR With Reflex to RPR Titer and Ab	Syphilis: RPR With Reflex to RPR Titer and Treponemal Antibodies, Traditional Screening and Diagnosis Algorithm
140103	Testosterone, Free and Total	Testosterone, Free, Direct With Total Testosterone
004226	Testosterone, Total	Testosterone, Total

000620	Thyroid Profile With TSH	Thyroid Profile With TSH
224576	TSH+Free T4	Thyroid-stimulating Hormone (TSH) and Free T4
001057	Uric Acid	Uric Acid, Serum (preferred) or plasma
003772	Urinalysis, Complete	Urinalysis, Complete With Microscopic Examination
007260	Valproic Acid	Valproic Acid, Serum or Plasma
144025	Viral Hepatitis Screening and Diagnosis (HBV, HCV)	Hepatitis B Surface Antigen (HBsAg) Screen, Qualitative; Hepatitis B Surface Antibody, Qualitative; Hepatitis B Core Antibody, Total with reflex to IgM; Hepatitis C Virus (HCV) Antibody with reflex to Quantitative Real-time PCR
001503	Vitamin B12	Vitamin B12, Serum

Prior Authorization Required Laboratory Tests

The following tests are not covered by CBHS unless an allowable psychiatric condition/s exist/s

To qualify for prior authorization approval contact CBHS Pharmacy 628-754-9110

LabCorp Service Code	Test/Panel	LabCorp Description
017996	Ethanol, Blood	Ethanol, Whole Blood
811083	Bupropion (Wellbutrin)	Bupropion and Hydroxybupropion, Serum or Plasma
071712	Clonazepam (Klonopin(R)),Serum	Clonazepam
001370	Creatinine	Creatinine
120766	C-Reactive Protein, Cardiac	C-Reactive Protein (CRP), High Sensitivity (Cardiac Risk Assessment)
004515	Estradiol	Estradiol
004309	FSH, Serum	Follicle-stimulating Hormone (FSH)
070482	Haloperidol (Haldol(R)) Serum	Haloperidol, Serum or Plasma
004283	Luteinizing Hormone(LH), S	Luteinizing Hormone (LH)
004044	Metanephrines, Pheochromocyt	Metanephrines, Pheochromocytoma Evaluation
811513	Olanzapine (Zyprexa)	Olanzapine, Serum or Plasma
811133	Paroxetine (Paxil)	Paroxetine, Serum or Plasma
706838	Fluoxetine (Prozac(R)), Serum	Fluoxetine, Serum or Plasma
716563	Risperidone (Risperdal(R)), S	Risperidone
002188	Triiodothyronine (T3)	Triiodothyronine (T3)
001974	Thyroxine (T4) Free, Direct, S	Thyroxine (T4), Free, Direct
071688	Trazodone, Serum	Trazodone
123208	VMA, Random Urine	Vanillylmandelic Acid (VMA), Random Urine

PANELS – Lab Ordering Guidance

Panel	LabCorp Service Code	Test/Panel
Atypical Antipsychotic Metabolic Monitoring	322000	Metabolic Panel (14), Comprehensive
	001453	Hemoglobin A1c
	303756	Lipid Panel
Carbamazepine Monitoring (Female)	007419	Carbamazepine
	005009	CBC With Differential/Platelet
	322000	Metabolic Panel (14), Comprehensive
	004556	Human Chorionic Gonadotropin (hCG), β-Subunit, Qualitative
	000620	Thyroid Profile With TSH
Carbamazepine Monitoring (Male)	007419	Carbamazepine
	005009	CBC With Differential/Platelet
	322000	Metabolic Panel (14), Comprehensive
	000620	Thyroid Profile With TSH
Lithium Monitoring (Female)	322758	Metabolic Panel (8), Basic
	005009	CBC With Differential/Platelet
	004556	Human Chorionic Gonadotropin (hCG), β-Subunit, Qualitative
	007708	Lithium
	000620	Thyroid Profile With TSH
Lithium Monitoring (Male)	322758	Metabolic Panel (8), Basic
	005009	CBC With Differential/Platelet
	007708	Lithium
	000620	Thyroid Profile With TSH
New Client	701985	Buprenorphine MAT 2, Ur (Urine Drug Screen)
	005009	CBC With Differential/Platelet
	322000	Metabolic Panel (14), Comprehensive
	001453	Hemoglobin A1c
	303756	Lipid Panel
	012005	Syphilis: RPR With Reflex to RPR Titer and Ab
	000620	Thyroid Profile With TSH
Urine Drug Screen (Buprenorphine Medication Assisted Treatment Monitoring 2, Urine) **See Labcorp.com test menu for details on cutoffs and confirmation**	701985	Urine Drug Screen, 18 drugs: buprenorphine, alcohol biomarkers (EtG, EtS), amphetamines, barbiturates, benzodiazepines, cocaine metabolite, phencyclidine, cannabinoids (THC), heroin metabolite (6-AM), opiates, oxycodones, tapentadol, fentanyl, methadone, propoxyphene, tramadol, carisoprodol, gabapentin
Valproic Acid / Depakote Monitoring (Female)	005009	CBC With Differential/Platelet
	322000	Metabolic Panel (14), Comprehensive
	004556	Human Chorionic Gonadotropin (hCG), β-Subunit, Qualitative
	007260	Valproic Acid
Valproic Acid / Depakote Monitoring (Male)	005009	CBC With Differential/Platelet
	322000	Metabolic Panel (14), Comprehensive
	007260	Valproic Acid

Common ICD-10 Codes for Laboratory Test Orders

Note Medical Necessity Coverage Limitations

Complete list available through CMS

~~LABORATORY TEST~~	~~ICD-10 CODE~~	~~DESCRIPTION~~
A1C	Z79.899	Long term current use of other medication
	E11.9	Diabetes Mellitus
Blood Glucose	Z79.899	Long term current use of other medication
	E11.9	Diabetes Mellitus
CBC	Z79.899	Long term current use of other medication
HCG	Z33.1	Pregnancy
Lipids	Z79.899	Long term current use of other medication
Thyroid – TSH, FT4	Z79.899	Long term current use of other medication
	various	Bipolar I Disorder
	various	Anxiety States
	various	Other Extrapyramidal Diseases and Abnormal Movement Disorders
	G47.9	Difficulty sleeping
	R41.82	Altered Mental Status
	R63.5	Abnormal Weight Gain
	R63.4	Abnormal Weight Loss
Medication Monitoring	Z51.81	Encounter for therapeutic drug level monitoring

** Last Updated October 2018

V. Forms

PRIOR AUTHORIZATIONS

Effective January 1, 2022 clients enrolled in Medi-Cal San Francisco Health Plan and Medi-Cal Anthem Blue Cross have their prescription drug coverage under the Medi-Cal Rx program. The Medi-Cal Rx formulary now applies to individuals in both plans plus Medi-Cal fee for service.

Use the table below for reference and specific plan contact information:

Prescription Plan	Plan/Medical Group Name	Plan/Medical Group Phone Number	Plan/Medical Group FAX number
CBHS/Healthy San Francisco	CSF01	1-800-788-2949	1-858-790-7100
Medi-Cal San Francisco Health Plan	Medi-Cal Rx	1-800-977-2273	1-800-869-4325
Medi-Cal Anthem Blue Cross	Medi-Cal Rx	1-800-977-2273	1-800-869-4325

Prior Authorization requests can be submitted as follows:

- **CBHS/Healthy San Francisco**
  - Complete and FAX the two-page Prior Authorization Request form shown on pages 28 and 29
- **Medi-Cal San Francisco Health Plan OR Medi-Cal Anthem Blue Cross**
  - Prior authorization requests may be submitted to **Medi-Cal Rx** through one of five ways:
    1. ***CoverMyMeds® (CMM) PA*** – The CMM PA submission channel allows pharmacies to initiate PAs and prescribers to initiate and submit PAs, with covered alternatives and approvals given in real time. More information can be found in Reference Materials at www.medi-calrx.dhcs.ca.gov/provider/forms/ in the *Medi-Cal Rx: CoverMyMeds How-To Guide* or on the CMM website: www.covermymeds.com.
    2. ***Medi-Cal Rx Secured Provider Portal*** – Registered pharmacy providers and prescribers will be able to log in to the Secured Provider Portal at www.medi-calrx.dhcs.ca.gov/provider/login to submit, inquire about, cancel, or add additional information to existing PAs as well as attach documents to any PAs in progress.
    3. ***FAX submission*** – The FAX number is 1-800-869-4325. Pharmacy providers and prescribers can submit a PA request via FAX by utilizing the following approved forms: 50-1, 50-2, 61-211, or the *Medi-Cal Rx PA Request Form* in Reference Materials at www.medi-calrx.dhcs.ca.gov/providers/forms/.
    4. ***NCPDP Transaction using Pharmacy POS System*** – A National Council for Prescription Drug Programs (NCPDP) transaction will use the pharmacy Point of Sale (POS) system to submit a PA request. Pharmacies must go to the Secured Provider Portal at www.medi-calrx.dhcs.ca.gov/provider/ to upload attachments or FAX additional information into the Medi-Cal Rx Customer Service Center (CSC) when needed if submitting via a pharmacy POS system.
    5. ***Mail*** – Pharmacy providers and prescribers may also submit a PA via mail to the following address:

       Medi-Cal Rx Customer Service Center
       ATTN: PA Request
       P.O. Box 730
       Rancho Cordova, CA 95741-0730

PRESCRIPTION DRUG PRIOR AUTHORIZATION REQUEST FORM

Plan/Medical Group Name: _____ **Plan/Medical Group Phone#:** (_____)_____
Plan/Medical Group Fax#: (_____)_____

Instructions: Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization request.

Patient Information: This must be filled out completely to ensure HIPAA compliance

First Name:	Last Name:	MI:	Phone Number:
Address:	City:	State:	Zip Code:
Date of Birth:	☐ Male ☐ Female	Circle unit of measure Height (in/cm): _____ Weight (lb/kg):_____	Allergies:
Patient's Authorized Representative (if applicable):		Authorized Representative Phone Number:	

Insurance Information

Primary Insurance Name:	Patient ID Number:
Secondary Insurance Name:	Patient ID Number:

Prescriber Information

First Name:	Last Name:	Specialty:
Address:	City:	State: Zip Code:
Requestor (if different than prescriber):	Office Contact Person:	
NPI Number (individual):	Phone Number:	
DEA Number (if required):	Fax Number (in HIPAA compliant area):	
Email Address:		

Medication / Medical and Dispensing Information

Medication Name:

☐ New Therapy ☐ Renewal
If Renewal: Date Therapy Initiated: Duration of Therapy (specific dates):

How did the patient receive the medication?
☐ Paid under Insurance Name:_____ Prior Auth Number (if known):_____
☐ Other (explain):

Dose/Strength:	Frequency:	Length of Therapy/#Refills:	Quantity:

Administration:
☐ Oral/SL ☐ Topical ☐ Injection ☐ IV ☐ Other:

Administration Location:
☐ Patient's Home ☐ Long Term Care
☐ Physician's Office ☐ Home Care Agency ☐ Other (explain):_____
☐ Ambulatory Infusion Center ☐ Outpatient Hospital Care _____

PRESCRIPTION DRUG PRIOR AUTHORIZATION REQUEST FORM

Patient Name:	ID#:

Instructions: Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization request.

1. Has the patient tried any other medications for this condition? ☐ **YES (if yes, complete below)** ☐ **NO**

Medication/Therapy (Specify Drug Name and Dosage)	**Duration of Therapy** (Specify Dates)	**Response/Reason for Failure/Allergy**

2. List Diagnoses:	**ICD-9/ICD-10:**

3. <u>Required clinical information</u> - Please provide all relevant clinical information to support a prior authorization review.

Please provide symptoms, lab results with dates and/or justification for initial or ongoing therapy or increased dose and if patient has any contraindications for the health plan/insurer preferred drug. Lab results with dates must be provided if needed to establish diagnosis, or evaluate response. Please provide any additional clinical information or comments pertinent to this request for coverage (e.g. formulary tier exceptions) or required under state and federal laws.

☐ Attachments

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature:_____ **Date:**_____

Confidentiality Notice: The documents accompanying this transmission contain confidential health information that is legally privileged. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of these documents is strictly prohibited. If you have received this information in error, please notify the sender immediately (via return FAX) and arrange for the return or destruction of these documents.

Plan Use Only: Date of Decision:_____

☐ Approved ☐ Denied Comments/Information Requested: _____

VI. Policies and Procedures

BHS Policies and Procedures

City and County of San Francisco
Department of Public Health
San Francisco Health Network
BEHAVIORAL HEALTH SERVICES

1380 Howard Street, 5th Floor
San Francisco, CA 94103
(628)754-9500
FAX (628)754-9585

Policy/Procedure Title: **BHS Clinic Medication Rooms**

Issued By:

DocuSigned by:
Maximilian Rocha
EB51A346C32641B...

Maximilian Rocha, LCSW
Director of Systems of Care

Date: April 9, 2025

Manual Number: 3.01-04
References:
California Business and Professions Code
Code of Federal Regulations
California Code of Regulations

Technical revision. Replaces 3.01-4 of September 7,2021

Equity Statement: The San Francisco Department of Public Health, Behavioral Health Services (BHS) is committed to leading with race and prioritizing intersectionality, including sex, gender identity, sexual orientation, age, class, nationality, language, and ability. BHS strives to move forward on the continuum of becoming an anti-racist institution through dismantling racism, building solidarity among racial groups, and working towards becoming a Trauma-Informed/Trauma Healing Organization in partnership with staff, members, communities, and our contractors. We are committed to ensuring that every policy or procedure, developed and implemented, lead with an equity and anti-racist lens. Our policies will provide the highest quality of care for our diverse members. We are dedicated to ensuring that our providers are equipped to provide services that are responsive to our members' needs and lived experiences.

Purpose:

This policy and procedure is intended to serve as a guideline for compliance with state and federal laws and regulations as well as to ensure medication safety in the clinic setting.

Scope:

This policy applies to BHS and BHS-affiliated clinics that store or maintain medications on site and their staff working there.

Definitions: For the purposes of this policy, the following definitions, based on pharmacy law and/or Behavioral Health Services practice environment, will apply:

a. **Prescription Refill**: The remaining quantity of fills for a particular member prescription at the pharmacy. Prescription refills records are stored on file at a pharmacy. A medication request by the member or clinic must be received by the pharmacy to initiate a refill.

b. **Medication Request**: A request made by the member or clinic for a particular member medication to be filled by the pharmacy.

c. **Medication Renewal**: The prescriber issuance of an additional order for a particular member medication once refills of that medication are depleted.

d. **Medication Dispensing**: The preparation, packaging, labeling, documenting, or transfer of a medication from a bulk supply (e.g. physician supply) by authorized medical personnel to the member for which the medication was prescribed.

e. **Medication Distribution**: The distribution of a patient's own medications to the patient. These are medications that were prescribed to the patient, delivered to the clinic by a pharmacy, and stored at the clinic on behalf of the patient. This may include subsequent delivery of the patient's medication to the patient by authorized clinic staff.

f. **Medication Administration**: The directly observed administration of medications to a member (e.g. orally or via injection) by authorized medical personnel during the course of a clinic visit.

g. **Receiving Medications**: The act of accepting a medication delivery from a pharmacy or wholesale distributor. Types of medications being received may be member-specific or may be a physician supply (e.g. for emergency use).

h. **Medication Room:** A secure location for medication storage of patient's own med, a physician's supply, or a clinic supply that ensures the proper storage and security of medications as outlined in this policy. This definition does not include the mobile storage of emergency medication.

Policy:

1. RESPONSIBILITY

a. BHS and BHS-affiliated clinic staff shall be in compliance with this policy and procedure, and with state and federal laws and regulations for medications including the accessing, ordering, receiving, storage, prescribing, dispensing, administration and disposal of medications.

b. The clinic Medical Director and Program Director have shared responsibility to ensure that the clinic staff and premises are in compliance. The Program Director has responsibility in the general support of the medication room including security and upkeep of the premises, and non-medical staff receiving and distributing/delivering of medications. The Medical Director has responsibility to ensure compliance by medical staff for medication room policies and procedures, and laws and regulations.

2. ACCESS

a. All prescription medications and medication injection equipment (syringes, needles) will be stored in a securely locked medication room or cabinet with access limited to medical personnel authorized to prescribe, dispense or administer medication. (CCR, Title 9, § 1810.435 (b) (3)) Designated medical staff will be identified in writing by the clinic and posted in the medication room. Non-medical staff may only enter medication rooms when an operational reason exists and when authorized medical personnel are present.

b. Keys (keys, key cards, key codes) that open medication rooms and cabinets are issued only to authorized medically licensed personnel assigned to work at these sites. These staff members must secure possession of the keys and must return the keys to the Medical Director when no longer assigned to the clinic. Under no circumstance shall staff members share keys with anyone

else. Medical Directors and program managers should maintain an active list of authorized personnel with keys, including name and provider type (e.g. -- physician, psychiatry technician)

c. Any lost medication room keys must be immediately reported to the Medical Director, who will work with the appropriate program and facilities personnel to ensure only authorized staff will have access.

3. RECEIVING MEDICATIONS

a. The clinic shall only receive medication deliveries when authorized medical staff is present. Medications delivered to the clinic must be received by authorized personnel, then promptly and appropriately stored in the medication room.

b. If medications are received by non-medical staff, such as front desk clerk, the front desk clerk shall immediately notify authorized medical staff so that medications are promptly stored in the medication room. Packages shall never be left unattended. Every clinic that receives and stores medications must keep records of their acquisition and disposition *(B&P Code 4081.4105,4180).* A chain of custody chronologically documenting the receipt, dispensing, administration, and/or disposal of all medications shall be maintained.

c. Clinics must log the receipt of all member medications *(CCR, Title 22 73361*). Copies of the pharmacy's delivery log may serve as the receipt log. The records shall be retained for at least 3 years. *(CCR, Title 22 73361)*. Incoming member medication logs must contain all the following information:
    i. Medication name
    ii. Strength and quantity
    iii. Name of the member
    iv. Date ordered (date medication request made to pharmacy)
    v. Date received
    vi. Name of issuing pharmacy

d. To document "date ordered" for the receipt of member medications, facilities shall do one of the following:
    a. Retain copies of medication requests sent to the pharmacy or
    b. Print and retain the medication lists from the electronic health record, noting date and requested medications or
    c. Record medication requests using the Member Medication Request Log (Attachment 1)

e. Clinics must log the receipt of all physician's own use medications *(CCR, Title 22 73361).* A copy of delivery log sent with the delivery, may serve as the receipt log. The records shall be retained for at least 3 years. Incoming medication logs must contain all of the following information:
    i. Medication name
    ii. Strength and quantity
    iii. Name and signature of person receiving medication delivery
    iv. Date ordered
    v. Date received
    vi. For prescription medications, name of ordering physician
    vii. Name of issuing pharmacy

g. Member medications received at a clinic from a pharmacy must be properly labeled with *(CA B&P Code 4076)*:
    i. Name of the member
    ii. Name and strength of the medication; if generic name, include name of manufacturer
    iii. Description of the medication (color, shape, any identification code)
    iv. Directions for use
    v. Condition or purpose of the medication, if indicated
    vi. Date of issue.
    vii. Medication quantity
    viii. Expiration date of the medication
    ix. Name of the prescriber
    x. Initials of the dispensing individual
    xi. Name, address and phone number of the dispensing pharmacy
    xii. FDA side effects statement label *(21 CFR 209)*
    xiii. Any applicable auxiliary labels

h. Prescription labels may be altered only by persons legally authorized to do so.

4. STORAGE

a. The medication room/storage area shall be located on premises.
b. The medication room/storage area shall be secure, clean, and orderly. Drugs are organized in a manner that prevents crowding and confusion. The facility shall have a schedule or procedure for cleaning and upkeep of the premises.
c. Controlled substance floor stock or physician supply medications must be stored in a separately locked cabinet in the medication room. CCR, Title 22, §73367(a)
d. Medications labeled and intended for external use only (topical) shall be stored separately from oral and injectable medications. Germicidals, cleaning agents and test reagents are stored separately from all drugs.
e. Drugs stored at room temperature are kept between 59° and 86°F. (CCR, Title 9, §1810.435(b) (3)) Room temperatures shall be logged each working day on the Room Temperature Log form (Attachment 2). For any out-of-range temperatures, contact CBHS Pharmacy immediately for instructions and document actions taken on the Room Temperature Log form. Room temperature logs shall be retained for at least 3 years.
f. Drugs requiring refrigeration are stored in a refrigerator between 36° and 46°F. (CCR, Title 9, §1810.435(b) (3)) Refrigerator temperatures shall be logged each working day on the Refrigerator Temperature Log form (Attachment 3). Contact CBHS Pharmacy immediately for instructions for any out-of-range temperatures and document actions on the Refrigerator Temperature Log form. Refrigerator temperature logs shall be retained for at least 3 years.
g. Drugs shall not be stored in a refrigerator with any food or lab specimens. (CCR, Title 9, § 1810.435 (b) (3))

h. Vaccines: vaccine storage, use, and documentation must be in compliance with Center for Disease Control Guidelines, and in alignment with other applicable programs supplying the vaccine (e.g. Vaccine for Children).

    1. If any vaccines are stored in refrigerators, refrigerator temperatures must be logged at the beginning and end of each working day. Vaccines cannot be stored in dormitory-style refrigerators which have a combined refrigerator and freezer in the same compartment.

    2. Vaccines in multidose vials that do not require reconstitution can be administered until the expiration date printed on the vial or vaccine packaging if the vial has been stored correctly and the vaccine is not visibly contaminated, unless otherwise specified by the manufacturer.

i. Multiple dose injectable medications will be initialed and have the expiration date recorded on the label when opened, with the exception of certain vaccines. Once opened, multiple dose vials expire in 28 days. Any open vial that appears to be contaminated or discolored shall be discarded and not used.

j. Drug containers shall not be cracked, soiled or without secure closures.

k. Expired, contaminated, or deteriorated prescription medications, over-the-counter (OTC) medications, and/or medical supplies are not available for use and shall be properly disposed of.

l. Medication expiration dates will be checked and documented on a monthly basis by a designated person with legal access to the medication room. The Monthly Expired Medication Review form (Attachment 4) may be used to document completion. Records shall be retained for at least 3 years.

m. Medication samples and drug vouchers are not allowed in clinics.

n. Paper prescription pads are stored in a secure location inaccessible to members.

5. HANDLING OF MEMBERS' OWN MEDICATIONS

a. Members' own prescription medications that have been dispensed by a pharmacy may be stored in the clinic medication room, if necessary to support the member's wellness and recovery, and be supported by documentation, e.g. – documented medication order or in the medical record,
b. Members' own medications are properly stored, clearly labeled, and with internal use medications separated from external use.
c. No more than an 8-week supply of member's own medications should be stored in the clinic medication room.
d. If a member does not claim his or her medications within 8 weeks of receipt by the clinic, they may be considered as medications abandoned by the member.
e. Abandoned, expired, or discontinued medications shall, if possible, be first sent back to the dispensing pharmacy for the billing to be reversed. If the issuing pharmacy does not accept returned dispensed medications, medications shall be disposed of as hazardous medication waste.
f. Members' own medications shall only be distributed to the specific member for whom it was prescribed and labeled. Member's own medications shall not be administered or "shared" with other members.

g. Re-packaging of a member's own medications (e.g. - specialty packaging, such as bubble packs) can only be performed by a pharmacy or the member. (BPC code 4052.7)
h. "Automatic medication refills" (i.e. refills sent by the pharmacy automatically without needing to be requested) shall not be utilized for member's medications stored in the clinic medication room in compliance with CMS requirements mandating member consent for all prescription deliveries, new or refill. (2014 Call Letter) (42 CFR §423.504)
i. Delivering medication: this refers to staff handing an unaltered bubblepack, bag or vial of medication delivered from the pharmacy, along with any medication information, to a patient who had their medication delivered to the clinic's address. This is the equivalent of handing a patient any other items that are mailed to the clinic and is within the scope of any healthcare worker at the clinic.

6. PHYSICIAN'S SUPPLY MEDICATIONS

a. "Physician's Supply Medications" refers to a physician's supply of medications for the physician's use in clinic *(B&P Code 4119.5 and 4170)*.

b. A physician's own supply of medications may be stored in the medication room. Medications should be prescribed by the physician, and use should be limited to acute or emergency need of medications. Prescribers should use a local community pharmacy to provide non-acute, standard medications to members.

c. Usage shall be documented on the Physician's Supply Medication Log sheet. (Attachment 6).

d. Each medication use shall be logged separately with a running inventory of the quantity used and quantity remaining for that particular medication. The records shall be retained for at least 3 years. Logs must contain all of the following information:

    i. The date and time the medication was administered
    ii. The source of the medication
    iii. The expiration date, lot and/or vial number of the medication
    iv. The name of the member receiving the medication
    v. The name, dosage and quantity of the medication given
    vi. The route of administration for medication (if other than oral)
    vii. The signature of authorized staff who administered the medication

e. Requests for Physician's Supply Medications shall be placed using the BHS Drug and Supply Request form (Attachment 5). Orders shall be placed by designated medical staff and need to include a copy of the Physician's Supply Medication Log sheet for proof of use or expiration of the medication requested.

f. For Controlled Substances, medication quantities must be reconciled at least daily on the Physician's Supply Medication Log (Attachment 6) and shall be retained for at least three years. Controlled Substances are stored separate from non-controlled medications and locked.

7. STORAGE OF MEDICATIONS FOR PUBLIC HEALTH BENEFIT

a. County-sponsored or State-sponsored programs may provide medications for clinics to distribute for public health benefit. For example, the DHCS-sponsored Nasal Distribution Project provides nasal naloxone, a life-saving medication, to assist in the opiate epidemic. (https://www.dhcs.ca.gov/individuals/Pages/Naloxone_Distribution_Project.aspx)

b. On-site storage of medication obtained through these programs are permitted after review and approval by the clinic Medical Director and the BHS Pharmacy Director. These medications are not required to be stored within a medication room. However, if stored in a medication room, they must be stored separately from other medications and must follow any additional guidelines set out by the sponsoring program.

8. MEDICATION ADMINISTRATION

a. Medications may only be administered to members by authorized personnel upon an order by a lawfully authorized prescriber. BHS personnel who are authorized to administer medications under their scope of practice include: physicians, physician assistants, nurse practitioners, registered nurses, licensed vocational nurses, licensed psychiatric technicians and pharmacists.

b. Authorized personnel administering a medication are responsible for:

   i. Knowing a drug's usual dosage range, indications, side effects, toxicity, stability, expiration date and the member's hypersensitivity or allergies.
   ii. Ensuring that the fundamentals of medication administration are followed: right member, right drug, right dose, right route, and right time.

c. Prior to drug administration, establish the member's identity by using two distinct member identifiers (e.g. asking the member to state their name and date of birth).

d. For injectable medication administration:

   i. Use universal and bloodborne pathogen precautions
   ii. Use safety needles

e. Documentation by the person administering the medication(s) shall be in compliance with Medical Records Policy 3.10-02, (CCR, Title 22 § 73313(f), 73351, 73353) and include:

   i. Medication, dosage, frequency and route
   ii. Date and time of administration
   iii. Site/location of any injection
   iv. The lot and/or vial number if medication was dispensed from a multi-dose container
   v. Any unusual or adverse response to the medication

f. Injectable medications administered in clinic need to be documented on the electronic MAR of the electronic health record when available. This may be in addition to documenting in a progress note, but a progress note alone is not sufficient.

g. Member medications shall not be "shared" or utilized as floor stock medications under any circumstance. Member medications shall only be administered to the specific member for whom it was prescribed and labeled.

9. DRUG AND SHARPS DISPOSAL

a. General requirements: Every clinic that maintains a stock of drugs must keep records of their acquisition and disposition *(B&P Code 4081.4105,4180).* All medications shall be disposed in accordance with applicable federal, state, and local regulations for disposal of chemicals and potentially dangerous or hazardous substances.
b. Medications for disposal may include:
    i. Medications which are not taken with the member upon termination of services
    ii. Medications abandoned by the member
    iii. Discontinued medications
    iv. Expired, contaminated or deteriorated medications
c. Proper medication disposal
    i. Members' medications may be returned to the dispensing pharmacy for disposal or disposed of at the clinic through the use of a licensed medical waste disposal service (e.g. -- Stericycle) or destruction container (e.g. -- RxDestroyer).
    ii. Solid dosage form medications (e.g. -- pills, capsules) are removed from their original containers before disposal.
    iii. Non-Controlled Substances
        a. Non-Controlled pharmaceutical waste shall be placed in the **white waste container with the blue top** that is puncture resistant and sealable when full. This container is labeled "Pharmaceutical Waste" and shall be stored in the medication room.
        b. The waste shall be removed by a licensed medical waste disposal company.
    iv. Controlled Substances
        a. Controlled substances shall be placed in the "RxDestroyer" which is a white, puncture resistant container with a red top and sealable when full. This container is labeled "RxDestroyer" and shall be stored in the medication room. RxDestroyer should only be used for destruction of controlled substances. All other pharmaceutical waste must be destroyed by placing in the blue and white pharmaceutical waste container as described above.
        b. Directions for using "RxDestoyer"
            i. Load medications into the bottle
            ii. Tightly replace cap
            iii. Gently shake to mix solution over medications. The bottle contains a solution that will dissolve medications on contact. Active medication ingredients are absorbed or neutralized by activated charcoal.
            iv. Note that the outer shells of capsules or patch materials will not dissolve
            v. Bottle is full when contents are 2 inches from the cap. Do not overfill.
            vi. When full, the full container shall be discarded into regular trash receptacle.
    v. Personnel conducting disposal
        a. Only individuals with authorized access to the medication room may dispose of expired or returned medications.

b. Disposal and documentation of disposal of non-controlled medications shall be conducted by a pharmacist or registered nurse employed by the facility. In the absence of a pharmacist and registered nurse, by licensed medical staff authorized to access the medication room.
c. Disposal and documentation of disposal of controlled medications shall be conducted by both a pharmacist and registered nurse. In the absence of a pharmacist and/or registered nurse, by two licensed medical staff authorized to access the medication room.

vi. Disposal shall be documented on a Medication Destruction Log (Attachment 7). The log shall be retained for at least 3 years and include the following information:
a. Name of the member
b. Medication name and strength
c. Quantity destroyed
d. Prescription number
e. Date of destruction
f. Name and signature of witness (two signatures if controlled substance)

d. Member Confidentiality
i. Member identifiers are protected health information (PHI), include the member's name, medical record number, address, and date of birth. (Refer to San Francisco Department of Public Health Privacy and Data Security Policies)
ii. Labels or documents containing PHI are disposed of by placing in confidential waste or by physically removing or fully obscuring with a permanent marker.

d. Sharps containers:
i. Shall be stored in a secure location not accessible to members. Containers are disposed of in accordance with applicable federal, state, and local regulations for disposal of chemical and potentially dangerous or hazardous substances. The method of disposal may include the use of a contracted medical waste disposal service.

10. MEDICATION ROOM COMPLIANCE CHECKLIST

a. The Clinic Medical Director will appoint appropriate staff to manage monitoring of medication storage and handling, and to conduct the quarterly Medication Room Audit. The results of the audit shall be reviewed by the clinic Medical Director.

b. The Medication Room Compliance Checklist (Attachment 8) form shall be used to complete the Medication Room Audit. It must be completed each quarter (every three months) by a pharmacist or other authorized medical staff.

c. Plans of Correction: Any areas of non-compliance shall be promptly addressed through a plan of correction developed by the clinic Medical Director, who will be responsible for its implementation. BHS Director of Pharmacy may be consulted for questions arising from a plan of correction. Areas of non-compliance should be addressed before the next quarterly audit.

d. Compliance checklists and any plans of correction shall be retained for at least three years.

Contact Person:

Director, BHS Pharmacy Services

Distribution:
BHS Policies and Procedures are distributed by BHS Quality Management and Regulatory Affairs

Administrative Manual Holders
BHS Programs
SOC Managers
BOCC Program Managers
CDTA Program Managers

City and County of San Francisco
Department of Public Health
San Francisco Health Network
BEHAVIORAL HEALTH SERVICES

Client Medication Request Log (Via Non-Fax Modality)

Client Name	Medication			Name of Pharmacy	Date Ordered	Date Received[1]
	Name	Strength	Quantity			

[1]Document date received if the issuing pharmacy does not provide a delivery log

Client Medication Request Logs must be retained for **three years**.

Medication Room Temperature Log - Fahrenheit

Month/Year: _____ Days 1-15

Clinic Name:

Completing this temperature log: Check the temperature in the medication room EACH WORKING DAY. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, and your initials. Once the month has ended, save each month's completed for 3 years.

If temperature is out of range, contact dispensing pharmacy or CBHS Pharmacy Services (415-255-3659) immediately at and document action taken on this form.

Staff Initials															
Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Exact Time															

*Write any unacceptable temperatures (above 86°F or below 59°F) in these boxes. Then take action!

Acceptable Temperatures																
	Danger! Temperatures above 86°F are too warm! Write any unacceptable temperatures on the boxes above and call CBHS Pharmacy Services immediately!															
	86°F															
	85°F															
	84°F															
	83°F															
	82°F															
	81°F															
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	62°F															
	61°F															
	60°F															
	59°F															
	Danger! Temperatures below 59°F are too cold! Write any unacceptable temperatures on the boxes above and call CBHS Pharmacy Services immediately!															

Attachment 2

Medication Room Temperature Log - Fahrenheit

Month/Year: _____ Days 16-31

Clinic Name:

Completing this temperature log: Check the temperature in the medication room EACH WORKING DAY. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, and your initials. Once the month has ended, save each month's completed for 3 years.

If temperature is out of range, contact dispensing pharmacy or CBHS Pharmacy Services (415-255-3659) immediately at and document action taken on this form.

Staff Initials																
Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Exact Time																

*Write any unacceptable temperatures (above 86°F or below 59°F) in these boxes. Then take action!

	Danger! Temperatures above 86°F are too warm! Write any unacceptable temperatures on the boxes above and call CBHS Pharmacy Services immediately!																
Acceptable Temperatures	**86°F**																
	85°F																
	84°F																
	83°F																
	82°F																
	81°F																
	80°F																
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	60°F																
	59°F																
	Danger! Temperatures below 59°F are too cold! Write any unacceptable temperatures on the boxes above and call CBHS Pharmacy Services immediately!																

Attachment 2

Temperature Log for Refrigerator — Fahrenheit

Month/Year:_____ **Days 1–15**

Program Name:

Completing this temperature log: Check the temperature in the refrigerator compartment of your storage unit at minimum of EACH WORKING DAY. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, and your initials. Once the month has ended, save each month's completed form for 3 years.

If temperature is out of range, contact dispensing pharmacy or CBHS Pharmacy Services immediately at 415-255-3659 and document action taken on this form.

Staff Initials																													
Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Exact Time																													
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm

***Write any unacceptable temps (above 46°F or below 36°F) on these lines. Then take action!** ↳ _____

Danger! Temperatures above 46°F are too warm! Write any unacceptable temperature on the lines above* and call BHS Pharmacy Services immediately!

Acceptable Temperatures																													
	46°F																												
	45°F																												
	44°F																												
	43°F																												
	42°F																												
	41°F																												
	40°F																												
	39°F																												
	38°F																												
	37°F																												
	36°F																												
	35°F																												

Danger! Temperatures below 36°F are too cold! Write any unacceptable temperature on the lines above* and call BHS Pharmacy Services immediately!

Temperature Log for Refrigerator — Fahrenheit

Month/Year:_____ **Days 16–31**

Program Name:

If temperature is out of range, contact dispensing pharmacy or CBHS Pharmacy Services immediately at 415-255-3659 and document action taken on this form.

Completing this temperature log: Check the temperature in the refrigerator compartment of your storage unit at a minimum of EACH WORKING DAY. Place an "X" in the box that corresponds with the temperature, the time of the tempera-ture reading, and your initials. Once the month has ended, save each month's completed form for 3 years.

Staff Initials																														
Day of Month	16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Exact Time																														
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm

***Write any unacceptable temps (above 46°F or below 36°F) on these lines. Then take action!**

Danger! Temperatures above 46°F are too warm! Write any unacceptable temperature on the lines above* and call BHS Pharmacy Services immediately!

Acceptable Temperatures																														
46°F																														
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Danger! Temperatures below 36°F are too cold! Write any unacceptable temperature on the lines above* and call BHS Pharmacy Services immediately!

City and County of San Francisco
Department of Public Health
BEHAVIORAL HEALTH SERVICES

Monthly Expired Medication Review

Program:_____ **Year:_____**

Month	Staff Member	Date Completed
January		
February		
March		
April		
May		
June		
July		
August		
September		
October		
November		
December		

All **medications and medical supplies** stored in the medication room must be **checked monthly** for **contamination, deterioration, and/or expiration** and shall be logged appropriately for destruction. Retain Logs for **3 years**.

City and County of San Francisco
Department of Public Health
BEHAVIORAL HEALTH SERVICES

Drug and Supply Request Form

Clinic Name & Address:_____

Ordered By (Name-Please Print):_____

Fax requests to CBHS Pharmacy Services at **415-255-3754**

Date Ordered:_____
Dated Shipped:_____

OTC MEDICATIONS

DRUG	STRGTH	QUANTITY	ORDERED	REC'D
Acetaminophen tablets	500mg	100/UD		
Antacid Liquid		12 fl oz		
Bacitracin Ointment, foil pack		12/pk		
Bisacodyl tablets	10mg	100/btl		
Diphenhydramine capsules	25mg	24/ btl		
Docusate Sodium capsules	250mg	100/btl		
Fiber		10 oz – each		
Folic acid	400mcg	100/btl		
Glucose gel	15gm	1tube		
Ibuprofen tablets	200mg	24/ btl		
Lice Shampoo		2 oz – each		
Multi Vitamins		100/btl		
Senna tablets	8.6mg	100/ btl		
Sunblock, Ultra Sheer Dry Touch, SPF 45		3 oz - each		
Thiamine tablets	100mg	100/ btl		

OTC MEDICATIONS (INTEGRATED HEALTH HOMES AND HOPE SF SITES ONLY)

DRUG	STRGTH	QTY	ORDERED	REC'D
A and D Ointment	-	113g/Tube		
Acetaminophen Children's Susp	160 mg/5 ml	118ml/Bottle		
Acetaminophen Tabs	325 mg	100/Bottle		
Alum, Mag Hydrox w/ Simeth Oral Soln	400 mg-400 mg-40 mg/10 ml	355ml/ Bottle		
Analgesic Cream	-	85g/Tube		
Artificial Tears Solution	-	15 ml/Bottle		
Aspirin (EC) Tabs	81 mg	100/Bottle		
Aspirin (EC) Tabs	325 mg	100/Bottle		
Bacitracin, Neomycin, Polymyxin B Ointment	-	28g/Tube		
Benzocaine & Menthol Loz	15 mg & 3.6 mg	16/Box		
Bismuth, Pink Susp	525 mg/15 ml	236ml/Bottle		
Bismuth, Pink tablets	262 mg	40/Box		
Calamine Lotion	-	177ml/bottle		
Calcium w Vit D Tablets	400 mg/200 mg	100/Bottle		

Drug and Supply Request forms must be retained for **three years.**

Attachment 5

Drug and Supply Request Form

Calcium Carbonate Tablets	1000 mg	160/Bottle		
Carbamide Peroxide Earwax Removal Aid	6.5%	15 ml/Bottle		
Chlorpheniramine Tablets	4 mg	100/Box		
Clotrimazole Topical Cream	1%	30g/Tube		
Clotrimazole Vaginal Cream	1%	45g/Tube		
DHS Shampoo	-	240 ml/Bottle		
Diphenhydramine Tablets	25 mg	24/Bottle		
Diphenhydramine Elixir	12.5 mg/5 ml	118ml/Bottle		
Eugenol Toothache Relief	85%	3.7ml/Bottle		
Ferrous Sulfate Tablets	325 mg	100/Bottle		
Guaifenesin Oral Soln	100 mg/5 ml	118ml/Bottle		
Guaifenesin & Dextro Oral Soln	200 mg – 20 mg/20 ml	118ml/Bottle		
Hemorrhoidal Ointment	-	56g/Tube		
Hemorrhoidal Suppository	-	12/Box		
Hydrocortisone Cream	1%	28g/Tube		
Ibuprofen Tabs	200 mg	24/Bottle		
Ibuprofen Children's Susp	100 mg/5 ml	120ml/Bottle		
Loperamide Caplets	2 mg	24/Box		
Magnesium Hydroxide Oral Soln	1200 mg/15 ml	355 ml/Bottle		
Minerin Absorption Base	-	120 gm		
Mineral Oil Enema	100%	133ml/Bottle		
Multivitamin Tablets (Adult)	-	100/Bottle		
Multivitamin Tablets (Pediatric Chewable)	-	100/Bottle		
Phenylephrine Tablets	10 mg	36/Box		
Plan-B One Step	1.5 mg	1/Box		
Prenatal Vitamin Tablets	-	100/Bottle		
Psyllium Husk Packet	3.4 g	30Pack/Box		
Saline Nasal Spray	-	44 ml/Bottle		
Selenium Sulfide Shampoo	1%	325 ml/Bottle		
Senna Tablets	8.6 mg	100/Bottle		
Sodium phosphate- sodium biphosphate Rectal Soln	6 g-16 g/100 ml	135 ml/Bottle		
Tolnaftate Cream	1%	14g/Tube		
Vitamin B1 Tablets	100 mg	100/Bottle		
Vitamin B6 Tablets	100 mg	100/Bottle		
Vitamin C Tablet	1000 mg	100/Bottle		

Drug and Supply Request forms must be retained for **three years.**

City and County of San Francisco
Department of Public Health
BEHAVIORAL HEALTH SERVICES

Drug and Supply Request Form

PHYSICIAN'S SUPPLY MEDICATIONS

Fax copies of Physician Medication Supplies Dispensing Logs for each requested medication.

PRESCRIBER	DRUG	STRGTH	QTY	ORDERED	REC'D
	Naloxone	2mg/2ml	2		
	Diphenhydramine	50mg/ml	1		
	Epipen	0.3mg	1		
	Tuberculin (Aplisol)		1ml		

MEDICATION ROOM SUPPLIES

SUPPLY	DESCRIPTION	PACKAGE SIZE	ORDER QTY/FILL QTY	REC'D
1. 7-day pill box	S, M, L			
2. Alcohol Prep Pads		200/box		
3. Applicator, Cotton Tipped Wood	3" Stick	100/pack		
4. Conforming Gauze Bandage, 1-ply	3" x 4yd Roll	1 roll		
5. Digital Oral Thermometer		1		
6. Refrigerator Thermometer*		1		
7. Face Mask, Blue		50/box		
8. Adhesive Bandage (Band-Aid)	¾" x 4"	50/100/box		
9. Adhesive Bandage (Band-Aid)	2" x 4"	12/box		
10. Gauze Sponge 2x2 8 ply		200/pk		
11. Hydrogen Peroxide 3%		16 oz/bottle		
12. Kerlix Bandage Wrap	4" x 4yd Roll	1 roll		
13. Latex Gloves (S, M, L) (Please circle)		100/200/box		
14. Medicine Cups, Graduated, Plastic	1oz	100/sleeve		
15. Medicine Cups, Souffle, Paper	1oz	250/sleeve		
16. Non-Stick Sterile Pad, 3x4	3" x 4"	100/box		
17. Paper bags (S, M, L)				
18. Paper Cups	5oz.	150/pk		
19. Porous Paper Tape, 1"	1" x 10yd Roll	1 roll		
20. Porous Paper Tape, 2"	2" x 10yd Roll	1 roll		
21. Rx Destroyer		1 gallon		
22. Sterile Gauze Pad, 2x2	2" x 2"	25/50/box		
23. Sterile Gauze Pad, 4x4	4" x 4"-	25/Box		
24. Surgical Betasept Soln., 4%	32oz/Bottle	1/bottle		
25. Syringe w/ needle TB 1cc 27g x ½"**		100/box		
26. Syringe w/ needle 3cc 21g x 1½"**		100/box		
27. Syringe w/ needle 3cc 22g x 1½"**		100/box		
28. Syringe w/ needle 3cc 23g x 1½"**		100/box		
29. Syringe w/ needle 3cc 25g x 1"**		100/box		
30. Syringe w/ needle 3cc 25g x 5/8"**		100/box		
31. Thermometer Sheaths, Disposable		100/box		
32. Tongue Depressor, Wood	6" Stick – Ea.	100/box		
33. Universal Precaution Kit		1		
34. Waste Container - Pharmaceuticals	2 gal, 3 gal	1 each		
35. Waste Container – Sharps	5qt, 1gal, 2gal, 3gal	1 each		

**Calibration certified (Traceable)*

***Syringes & Needles in compliance with DPH Occupational Bloodborne Pathogens Exposure Control Plan*

Drug and Supply Request forms must be retained for <u>three years.</u>

Attachment 5

City and County of San Francisco
Department of Public Health
BEHAVIORAL HEALTH SERVICES

Drug Name:_____
Strength:_____ **Form**:_____
Rx#:_____ Lot#:_____ Exp.:_____

Physician's Supply Medication Log

Medication Source (Pharmacy):_____ **Prescribing Physician:**_____

Date	Client	Qty. Dispensed	Qty. Remaining	Authorized Staff (Signature)
Quantity Supplied ➔				

Floor stock medication dispensing log must be retained for **three years**.

Attachment 6

City and County of San Francisco
Department of Public Health
BEHAVIORAL HEALTH SERVICES

Medication Destruction Log

Date	Name of Drug and Strength	Qty.	Rx # *Required for client medication*	Client Name *Required for client medication*	Authorized Staff (Name and Signature)	2nd Authorized Staff (Name and Signature) *Required for Controlled Substances*

Medication Destruction Log must be retained for **3 years**.

Attachment 4

CBHS Medication Room Compliance Checklist

Clinic Name_____

General

1. CBHS Medication Storage Policy & Procedure available Yes No

2. Medication room personnel licenses current and available for review Yes No

3. There are no medication "samples" in the facility Yes No

4. No expired, contaminated, deteriorated or recalled medications on premises (including physician's supply, patient meds, OTCs, supplies) Yes No

5. Medications are properly received from pharmacy deliver according to CBHS Medication Room Policy & Procedures Yes No

Medication Room

1. Locked; Access limited to authorized personal who are identified in writing and posted in medication room Yes No

2. Organized and clean appearance Yes No

3. Drugs are properly labeled according to federal and state laws; Labels altered only by persons legally authorized to do so Yes No

4. Faxed client medication requests are retained with date ordered/received Yes No

5. Separate logs for the following exist, are neat and are up to date:
   a. Physician's supply meds ordered/received from CBHS pharmacy Yes No
   b. Client medication requests by phone with dates ordered/received Yes No
   c. Meds dispensed from Physician's supply Yes No
   d. Room temperature (daily) Yes No
   e. Refrigerator temperature (daily) Yes No
   f. Medication destruction log Yes No
   g. Monthly expired medication review Yes No

6. No single dose parenteral container opened. Yes No

7. Multi-dose parenteral container dated when first opened. 28 day expiration Yes No

8. External drugs separated from internal drugs Yes No

Medication Room (continued)

9. No excessive amt of drugs present (more than 6-week supply) Yes No

10. Room temp within range (59-86°F) Yes No

Refrigerator (Skip if N/A)

1. Organized and clean appearance Yes No

2. Temp within range (36-46°F) Yes No

3. No food items or specimens present Yes No

4. Drugs requiring refrigeration properly stored & labeled. (Risperidone Consta, PPD) Yes No

5. Multi-dose parenteral container dated when first opened. 28 day expiration (except vaccines) Yes No

Controlled Substances (Skip if N/A)

1. Locked & separated from non-controlled drugs. Yes No

2. Log for dispensing/administering Physician's supply is separate from non-controlled Physician's supply log and is neat, completed and up to date Yes No

3. Log for daily inventory of Physician's supply Yes No

Disposal

1. Client identifiers are removed from prescription labels and leaflets before discarding/recycling Yes No

2. Sharps and hazardous waste disposal containers are stored in a secure location and disposed of properly Yes No

Comments_____
_____
_____
_____
_____

Date_____

Signature_____ Reviewed by: _____

5/16 (Medical Staff Member) (Medical Director)

Attachment 8 Retain Medication Room Compliance Checklist for **3 years**.

BHS Policies and Procedures	
City and County of San Francisco Department of Public Health San Francisco Health Network BEHAVIORAL HEALTH SERVICES	1380 Howard Street, 5th Floor San Francisco, CA 94103 (628) 754-9500 FAX (628) 754-9585
Policy or Procedure Title: DPH Clearinghouse Naloxone Distribution	
Issued By: DocuSigned by: Maximilian Rocha EB51A346C32641B... Maximilian Rocha, LCSW Director of Systems of Care Date: November 7, 2024	Manual Number: 3.01-08 References: California Civil Code Section 1714.22

Technical/Substantive Revision. Replaces 3.01-08 of December 8, 2021.

Equity Statement: The San Francisco Department of Public Health, Behavioral Health Services (BHS) is committed to leading with race and prioritizing Intersectionality, including sex, gender identity, sexual orientation, age, class, nationality, language, and ability. BHS strives to move forward on the continuum of becoming an anti-racist institution through dismantling racism, building solidarity among racial groups, and working towards becoming a Trauma-Informed/Trauma Healing Organization in partnership with staff, members, communities, and our contractors. We are committed to ensuring that every policy or procedure, developed and implemented, leads with an equity and anti-racist lens. Our policies will provide the highest quality of care for our diverse members. We are dedicated to ensuring that our providers are equipped to provide services that are responsive to our members' needs and lived experiences.

Purpose:
The purpose of the DPH Clearinghouse Naloxone Program is to address the opioid epidemic and allow a wide distribution of naloxone to permit individuals that receive naloxone to administer it. The purpose of this policy is to describe the procedures for safe storage and distribution of intranasal naloxone obtained through the DPH Clearinghouse.

Scope:
BHS Pharmacy serves as the focal point of the DPH Clearinghouse Naloxone Program from which DPH programs and DPH-affiliated programs obtain supplies of naloxone for distribution.

Policy:
The Naloxone Distribution Project (NDP) is funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and administered by the Department of Health Care Services (DHCS) to combat opioid overdose-related deaths throughout California. The NDP aims to reduce opioid overdose deaths through the provision of free naloxone nasal spray. Previously, a standing order was required to obtain nasal naloxone through the NDP. However, since the approval of over-the-counter (OTC) naloxone nasal spray, a standing order is now no longer required.

The standing order issued by the state Public Health Officer (authorized by California Civil Code Section 1714.22):

1) allows community organizations and other entities in California that are not currently working with a physician, to distribute naloxone to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist; and
2) allows for the administration of naloxone by a family member, friend, or other person to a person experiencing or reasonably suspected of experiencing an opioid overdose.

Through the NDP, qualified organizations and entities may request free naloxone from DHCS and have it directly shipped to their address. San Francisco Department of Public Health (SFDPH) has been designated a high-need entity by DHCS due to its high utilization. Thus, SFDPH may request a large quantity of recurring shipments. BHS Pharmacy will receive and store naloxone shipments from the NDP for distribution to SF programs serving high-risk patients in the City and County of San Francisco. Programs participating in the DPH Clearinghouse will have access to this naloxone supply and the programs' champions will be responsible for coordinating the obtaining of supplies and tracking staff training for their program.

The DPH Clearinghouse pharmacy and participating programs shall adhere to laws and regulations related to naloxone distribution.

Procedure:

BHS Pharmacy

1. DPH Clearinghouse naloxone supply acquisition
    a. Pharmacy will submit application(s) to NDP annually or as indicated by DHCS
    b. DHCS will deliver quarterly shipments of naloxone to BHS Pharmacy (1380 Howard Street)
2. Storage of DPH Clearinghouse supply
    a. Naloxone will be stored at 1380 Howard Street
    b. Naloxone will be stored separately from pharmacy medications in a safe and secure location
3. Program naloxone records
    a. Pharmacy will track the number of reversals as reported by programs
    b. For each naloxone order provided to programs, Pharmacy will log the program name, pickup date, quantity provided, expiration date, LOT number

Programs

1. DPH Clearinghouse program participation
    a. SFDPH and SFDPH-affiliated programs qualify to participate in the DPH Clearinghouse.
    b. Participating programs are required to exclusively receive naloxone for distribution through the DPH Clearinghouse.
    c. Each program shall have designated staff person(s) who will coordinate naloxone distribution including reordering and tracking of reversals.
2. Policies and Procedures
    a. Programs may utilize this policy and procedure, or may write their own site-specific policy and procedure (refer to Appendix A Model P& P Template)
3. Naloxone storage
    a. Stored naloxone will not be in immediate access to members.

   b. Naloxone is not required to be stored within a medication room. However, if stored in a medication room, they must be stored separately from other medications and shall follow any additional guidelines set out by the program
4. Obtaining Naloxone from BHS Pharmacy DPH Clearinghouse
   a. To request naloxone, the program will complete Microsoft Form:
      i. https://forms.office.com/g/atYLnaCW00
   b. Program will report total number of naloxone reversals with each reorder.
5. Naloxone distribution
   a. Naloxone will be distributed by clinic staff who have completed Naloxone Distribution training. Both clinical and non-clinical staff may participate.
   b. Eligibility for receiving naloxone includes the following:
      i. People who currently use opioids, have a history of opioid use, or are in frequent contact with people who use opioids, or
      ii. People at risk for overdose or in contact with someone at risk (including individuals who use stimulants or other agents which may be contaminated with or confused with opioids), or
      iii. Other persons in a position to assist during an opioid-related overdose
      iv. Naloxone should be given to any person who requests it, regardless of history
      v. Naloxone may be distributed to any person, and is not restricted to patients/members of the program
   c. Appropriate counseling on naloxone is required to be provided to individuals who receive naloxone through the program (i.e., verbal, QR code, written materials)
6. For naloxone administration within health facilities, follow the facility's guidelines for emergency response.
7. Documentation
   a. Each program will track the number of reversals the program is aware of, and report to the DPH Clearinghouse when reordering naloxone.
   b. Naloxone distribution will be documented in the naloxone log, including date of distribution, quantity given, staff or patient information as applicable, and documentation that overdose prevention education was provided to the patient.
   c. Labelling the naloxone is not required, however, programs may choose to do so.
8. Training
   a. Staff distributing naloxone are required to receive training on opioid overdose prevention and treatment.
   b. Minimum training requirements:
      i. The causes of an opiate overdose
      ii. Mouth to mouth resuscitation (but should only be given if using a mouth guard for Covid-19 safety)
      iii. How to contact appropriate emergency medical services (call 911)
      iv. How to administer the intranasal naloxone
   c. Each program will maintain records of all staff who have completed training. Refer to the example training log template in Appendix B.
   d. Approved training programs/resources:
      i. **DPH Overdose Recognition & Response training (Recommended)**
         1. **SFLearning**- for City & County staff

2. **learnsfdph**-for City & County staff AND Contractors
    1. https://learnsfdph.org/programs/sfdph-overdose-prevention/
3. Please see BHS Pharmacy Services Manual for detailed instructions

ii. Other trainings:

1. How to use nasal naloxone spray by SFDPH (6 min) https://www.youtube.com/watch?v=tIz79sDSR0E
2. How to Use Narcan with the DOPE Project (~10 min) https://www.youtube.com/watch?v=bUtYpbdUSus
3. Administering Naloxone- Training Video (~10 min) https://www.youtube.com/watch?v=nurz9qPGKws&feature=youtu.be

iii. Other training programs/resources recognized by medical director/designee

Definitions:
Throughout the document, references to "naloxone" will refer to the intranasal formulation of the opioid antagonist received by NDP used for the acute treatment of opioid overdose. The "pharmacy" will refer to BHS Pharmacy. The "program" will refer to participating programs.

Contact Person:

Director, BHS Pharmacy Services

Attachment(s):

Distribution:
BHS Policies and Procedure are distributed by the BHS Quality Management and Regulatory Affairs

Administrative Manual Holders
BHS Programs
SOC Program Managers
BOCC Program Managers
CDTA Program Managers

Policy & Procedure Title: [Program Name] Naloxone Program	
Category: Clinical	
Effective Date:	**Last Reissue/Revision Date**:
Management Team Sponsor/Author:	

I. Purpose
   a. Describe policy and procedure for safe storage and program distribution of intranasal naloxone obtained through the DPH Clearinghouse

II. Definitions
   a. Naloxone refers to the intranasal formulation of the opioid antagonist used for the acute treatment of opioid overdose

III. Policy and Procedure
   i. Ordering and replenishment
      1. Naloxone will be ordered centrally through coordination with the CBHS Pharmacy
      2. [Program Name] site
         a. Naloxone ordering and replenishment will be coordinated by [Program Name] (choose: [pharmacy] or [medication]) staff and will follow standard [Program Name] pharmacy protocols
         b. The [Program Name] (staff role; ex: pharmacy technician) will be responsible for regularly reviewing inventory of available naloxone and restocking supply as necessary
      3. Naloxone for distribution will be exclusively ordered through the DPH Clearinghouse as long as the state program continues
   ii. Storage and labeling
      1. Stored naloxone will not be in immediate access to clients
      2. Naloxone is not required to be stored within a medication room. However, if stored in a medication room, they will be stored separately from other medications and will follow any additional guidelines set out by the sponsoring program
   iii. Distribution
      1. Who will distribute:
         a. Naloxone will be distributed by designated clinic staff who have completed training in harm reduction and overdose prevention
         b. Both clinical and non-clinical staff may participate in Naloxone distribution following completion of training
      2. When will Naloxone be distributed?
         a. *Example: Individuals may drop in requesting Naloxone or may receive Naloxone during a clinic visit.*
      3. Who is eligible:

a. People who currently use opioids, have a history of opioid use, or are in frequent contact with people who use opioids, or
b. People at risk for overdose or in contact with someone at risk (including individuals who use stimulants or other agents which may be contaminated with or confused with opioids), or
c. Other persons in a position to assist during an opioid-related overdose
d. Naloxone should be given to any person who requests it, regardless of history
e. Naloxone may be distributed to any person, and is not restricted to patients/clients of the program

4. Staff are required to provide appropriate counseling and education on naloxone to individuals who receive naloxone through the program

iv. Naloxone Administration at Ambulatory Behavioral Health Facilities (For BHS Programs)
1. If a medical emergency occurs when medical staff are present (e.g. physicians, registered nurses, nurse practitioners, clinical pharmacists, or psychiatric technicians), a medical staff member will take the lead of the emergency situation and provide immediate assistance
2. If no medical staff are present, then the lead staff member on duty will take the lead of the emergency situation and provide immediate assistance
3. Personnel shall initiate a call to 911 and adhere to proper naloxone administration
4. Policy 3.02-21- Medical Emergencies in Ambulatory Behavioral Health Centers

v. Documentation
1. Each program will track the number of reversals the program is aware of, and report to the DPH Clearinghouse when reordering naloxone
2. Documentation of distributing to individuals and labelling the naloxone are not required however programs may choose to do so (add any program specific requirements)
3. For Mental Health Outpatient Avatar users (delete if not applicable):
a. Create a non-ISC order in OrderConnect for all BHS clients who receive the naloxone
b. Document in Avatar in the form of a progress note
c. In most cases naloxone will be provided in the context of another billable service, so it is recommended to include provision of naloxone as a line item to show that it was provided by a qualified provider
i. Suggested language: “Per protocol, naloxone was supplied directly to the patient to reduce the risk of fatal opioid overdose by a staff member who has completed training in

overdose prevention. Instructions for naloxone use were reviewed with the patient."

4. As a stand-alone service, provision of naloxone does NOT meet criteria for med support billable to Mental Health Medi-Cal. Therefore, if the service provided is primarily provision of naloxone it should be documented as targeted case management (T1017) if appropriate or ADM99 (non-billable)

vi. Quality assurance
   1. Unusual occurrences related to distribution of naloxone will be promptly reported and reviewed

IV. References
   a. *Insert relevant references here*
   b. Naloxone distribution standard work

Step	Details
1. Identify persons who would benefit from naloxone distribution *Identified by staff in the context of an appointment or patients may drop in requesting naloxone*	1. Offer naloxone routinely to patients with any history of substance use, history of overdose, or those prescribed opioids or benzodiazepines 2. Naloxone should also be given to any person who requests it, regardless of history 3. Distribution may be to patients/family/friends, any community member
2. Educate person on overdose response *Patient handout packaged with Naloxone kit*	1. Review steps of overdose response with person if needed.
3. Distribute naloxone	1. Give at least one box containing 2 vials of intranasal naloxone 2. Can give additional boxes if needed
4. Documentation (optional)	Program may choose to document naloxone distribution in log and/or health record 1. "*Per protocol, naloxone was supplied directly to the patient to reduce the risk of fatal opioid overdose by a staff member who has completed training in overdose prevention. Instructions for naloxone use were reviewed with the patient."*

ATTACHMENT B

Naloxone Staff Training Completion Tracker

Program Name: _____

Staff Name	Email	Method of Staff Training Completion	Date of Completion

VII. Medication Resources

The following Medication Resources, approved by the BHS Medication Use Improvement Committee in 2025, are included in this section and posted on the SFDPH website (sf.gov/resource/2024/medication-guidelines):

- Medications for Opioid Use Disorder
- Naloxone Guideline
- Direct to Inject Buprenorphine Guideline
- Safer Use of Psychotropic Medications in Children and Adolescents Guideline
- Safer Prescribing of Sedative-Hypnotics and Related Medications Guideline
- Medications for Nicotine Use Disorders Treatment Guidelines
- Approaches to Cannabis Use Disorder Treatment Guidelines

The following Medication Resources previously published in the 2025 CBHS Pharmacy Services Manual may still be accessed via the SFDPH website (sf.gov/resource/2024/medication-guidelines):

- Safer Prescribing of Mood Stabilizer Medications
- Safer Prescribing of Antipsychotic Medications Guideline
- Methadone for Treatment of Opioid Use Disorder in an Opioid Treatment Program (OTP): Recommendations for Management in the Fentanyl Era

Other guidelines approved in 2023 and 2024 may also be accessed via the SFDPH website (sf.gov/resource/2024/medication-guidelines).

Note that additional material regarding Opioid Use Disorder may be found on the SFDPH website under “Opioid Use Disorder Medication Prescribing Resources:”

- Opioid Use Disorder Background and Evaluation
- Opioid Use Disorder Clinical Considerations
- Opioid Use Disorder References and Further Reading
- Methadone for Treatment of OUD in Opioid Treatment Programs

Daniel Lurie
Mayor

San Francisco Health Network Behavioral Health Services
Medication Use Improvement Committee
1380 Howard St. 5th Floor
San Francisco, CA 94103

San Francisco Health Network
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

Medications for Opioid Use Disorder

SCOPE: This Medications for Opioid Use Disorder (MOUD) Guideline is intended to offer prescribing assistance for providers, patients and the interested general public to increase the effectiveness and safety of MOUD in the ambulatory care setting. It is not intended to be comprehensive in scope. These recommendations are not a substitute for clinical judgment, and decisions about care must carefully consider and incorporate the clinical characteristics and circumstances of each individual patient. References can be found in the OUD References and Further Reading.

MOUD PHARMACOTHERAPY SELECTION: Three medications, methadone, buprenorphine and naltrexone, are approved by the US Food and Drug Administration. The effect of each medication is through effects on the mu-opioid receptor and each agent has demonstrated health benefits including in reduction in unprescribed or cessation of opioid use. Beyond this, the agents differ in their mechanism of action and respective treatment outcomes.

The two major medications available for the treatment of OUD are buprenorphine and methadone, which have both demonstrated to reduce all-cause mortality by 50%. Choice between these agents is based on patient preference. Methadone and buprenorphine are available in Opioid Treatment Programs, while buprenorphine is available for office-based treatment and can be provided by any prescriber with a DEA license. Additional considerations include past treatment experience with MOUD, program structure and accessibility, patient medical and psychiatric co-morbidities and medications. For a list of contraindications and cautions for each agent, see Appendix 1. For buprenorphine induction methods see the section on Buprenorphine Initiation Methods

Buprenorphine and naltrexone are available as long-acting injections. Buprenorphine long-acting injectables must be obtained through a restricted distribution program and they should be dispensed directly to a member of the healthcare team.

For craving reduction and relapse prevention in a patient who is interested in a non-opioid agonist medication treatment, extended-release naltrexone injection may be an effective choice. It is important to note that oral naltrexone pills are not effective for OUD as evidence suggests they are no more effective than placebo. The main challenge to effective treatment with extended-release naltrexone injection is the long period of abstinence necessary to initiate the medication, limited effectiveness at retaining people in treatment and lack of demonstrated evidence for mortality reduction.

OPIOID OVERDOSE TREATMENT AND PREVENTION*:* Naloxone is a mu-opioid receptor antagonist that reverses the effects of opioids. In California, anyone who is at risk for experiencing or

witnessing an opioid overdose can be furnished take-home naloxone for bystander administration. Additionally, in March 2023, the US FDA approved naloxone nasal spray for purchase over-the-counter. More than one dose of naloxone may be necessary, as might rescue breathing and CPR for trained individuals or supplement oxygen if available, especially if the drug contains other central nervous system depressants.

People with OUD, both not in treatment and in treatment, should be offered a take-home naloxone kit and provided education on overdose recognition and reducing risk of opioid overdose. Non-prescribed and street drugs can contain opioids. Therefore, anyone that takes these should be offered a take-home naloxone kit and fentanyl test strips. The person's family and friends should be included in the education in order for them to be trained to identify and respond to an opioid overdose. For details on take-home naloxone, see the BHS Overdose Prevention and Naloxone guideline, BHS Recommendations for Take Home Naloxone, and the DPH Clearinghouse Naloxone Distribution Policy and Procedures. Providers may consider offering fentanyl test strips to patients who use drugs, now available via the DPH Naloxone Clearinghouse

OPIOID WITHDRAWAL AND MANAGEMENT: Opioid withdrawal typically does not include severe and life-threatening symptoms compared to withdrawal syndromes characteristic of other substances (e.g., alcohol and benzodiazepines). Although not life-threatening, opioid withdrawal can be uncomfortable and distressing. Patients experiencing opioid withdrawal symptoms must be treated humanely and their symptoms addressed to preserve their dignity. Failure to do so increases the chances of return to use, overdose, distrust of medical care, or abandonment of treatment.

The symptoms of opioid withdrawal are experienced as the opposite of the pharmacologic effects of opioids. The onset, duration, and intensity of withdrawal symptoms vary and are dependent upon the particular opioid used, the duration of use, and the degree of dependence and tolerance. Mood, anxiety, trauma, stress, and other factors can influence the experience of opioid withdrawal symptoms.

Opioid withdrawal management alone is not an effective treatment for OUD and should be part of a comprehensive treatment plan. When opioid withdrawal management is used alone, patients are at increased risk of return to use, overdose, and overall mortality. Patients withdrawing from opioids with severe and poorly managed co-occurring medical, psychiatric, and cognitive conditions may require close monitoring in a hospital or residential setting. Additionally, patients who are withdrawing from opioids and other substances (e.g., alcohol, benzodiazepines) may require close monitoring and additional interventions.

Medication treatment can and should be provided in all healthcare settings for interested individuals. For people who are interested in more recovery supports, linkage to appropriate services should occur as part of a patient's comprehensive treatment plan. While opioid withdrawal management alone is not considered adequate treatment, it may be included as the first of step-wise interventions that include evaluation, stabilization, and fostering readiness for and entry into treatment, as is the ASAM recommendation for all substance use disorders.

BUPRENORPHINE INITIATION METHODS: Buprenorphine can be initiated by multiple methods highlighted in the following section. In addition, Epic users can find these as an SmartSet under

"Buprenorphine - MOUD Order Set". The selection of buprenorphine initiation methods should be driven by patient choice. There are no randomized controlled trials currently to support one method over the other. Table 1 highlights some considerations when choosing buprenorphine initiation. This is not intended to replace clinical judgement.

Table 1. Buprenorphine Initiation Method Selection

See Appendix 4 for additional guidance

Method	Consider for	Potential Disadvantages
Sublingual traditional starts	- Using heroin or other short-acting opioids - People who do not have access to full-agonist opioids or wish to stop them immediately	- Patient must be able to stop opioids long enough to be in moderate withdrawal - Requires longer period of cessation for people using fentanyl
Sublingual overlap starts (also known as microdosing)	- Difficulty starting buprenorphine using traditional start - Currently on methadone - Transitioning from prescribed full opioid agonists for pain to buprenorphine - Using fentanyl daily - Not interested in stopping opioids before starting buprenorphine	- Off-label dosing - Patients need adjunctive medications to minimize opioid withdrawal - Requires following a scheduled dosing regimen which may be difficult for some
Sublingual macrodosing	- Patient understanding and preference to experience opioid withdrawal for one day which may be severe - Able to wait until they are in moderate opioid withdrawal to start	- Off-label dosing - Method with most limited evidence - High risk for precipitated withdrawal - recommend providing adjunctive medications - More tolerated with longer periods since last fentanyl use (~2 days)
Buprenorphine long-acting with sublingual to start	- Patient prefers injectable medication - Patient prefers to initiate with sublingual buprenorphine before initiating LAI	- Starting sublingual first may be a barrier for some patients
Buprenorphine long-acting by direct to inject	- Patient prefers injectable medication	- Off- label dosing - Risk of precipitated withdrawal – recommend

	- Patient prefers to initiate immediately with buprenorphine LAI - Patient has difficulty initiating with buprenorphine SL	providing adjunctive medications

SUBLINGUAL TRADITIONAL STARTS: These starts are well established in people switching from short-acting opioids such as heroin, oxycodone, morphine, etc. They require the person to be in mild to moderate opioid withdrawal prior to starting. Patients can be instructed to wait 12 hours from last opioid use and identify 3 symptoms or signs of opioid withdrawal prior to starting. Patients that are not physically dependent on opioids may benefit from lower starting doses of 2 mg.

Day 1: Buprenorphine 2 mg SL q2h prn opioid withdrawal (up to 8-16 mg)

OR

Day 1: Buprenorphine 4 mg SL q2h prn opioid withdrawal (up to 24 mg)

OR

Day 1: Buprenorphine 8 mg SL q2h prn opioid withdrawal (up to 24 mg)

AND

Day 2-7: Buprenorphine 8mg BID or TID

SUBLINGUAL OVERLAP INITIATIONS (aka MICRODOSING): Traditional protocols for buprenorphine initiation are well established and work for many individuals with OUD. However, there are various clinical circumstances when alternative, off-label, buprenorphine initiation strategies may be desired (see Table 1). Off-label methods for dosing buprenorphine has limited but growing evidence, although they are not universally accepted. These initiation strategies aim to use very small doses of buprenorphine that are gradually increased. Given the sub-therapeutic levels of buprenorphine, it is common patients will continue to use other full agonist opioids. This allows buprenorphine levels to build up slowly and minimizes the withdrawal patients experience. CBHS pharmacy has developed 2 protocols which are shown below and are accompanied by patient education,counseling points, and blister packs.

Prescribing/Dispensing Tips:

- All take home doses for overlap starts >1 day will be blister-packed for ease of use
- See table below for an example regimen → schedule. This should be adjusted depending on how patient tolerates the start or if they miss doses
- Buprenorphine mono-product is recommended when the tablets are being cut into quarters

Overlap Initiation 7-day Protocol (AKA The Howard Street Method)

Buprenorphine mono-product 2 mg tablets (NDC 50383-0924-93) Blister-pack days 1-3 and dispense #2 tablets	
Day 1	Dissolve ¼ of a 2 mg tablet (0.5 mg) under your tongue in the morning
Day 2	Dissolve ¼ of a 2 mg tablet (0.5 mg) under your tongue twice daily
Day 3	Dissolve ¼ of a 2 mg tablet (0.5 mg) under your tongue in the AM Then Dissolve ½ tablet (1 mg) in the afternoon and evening
Buprenorphine-Naloxone or Buprenorphine mono-product 2 mg Tablets Blister-pack days 4-6 and dispense #9 tablets	
Day 4	Dissolve 1 (2 mg) tablet under your tongue twice daily
Day 5	Dissolve 1 and ½ (3 mg) tablets under your tongue twice daily
Day 6	Dissolve 2 (4 mg) tablets under your tongue twice daily
Buprenorphine-Naloxone or Buprenorphine Mono-Product Provider can change to films based on patient preference	
Day 7	Custom (12-32 mg depending on clinical situation)

Overlap Initiation 4-day Protocol

Buprenorphine mono-product 2 mg tablets (NDC 50383-0924-93) Blister-pack and dispense #7 tablets	
Day 1	Dissolve ¼ of a 2 mg tablet (0.5 mg) under your tongue observed now, then every 6 hours for a total of 4 doses
Day 2	Dissolve ½ of a 2 mg tablet (1 mg) under your every 6 hours for a total of 4 doses
Day 3	Dissolve 1 (2 mg) tablet under your every 6 hours for a total of 4 doses

Patient Education:

- This is a gentle and gradual way for you to start buprenorphine that will not require you to stop using opioids until later.
- There is some discomfort during the overlap start. It is common that people feel mild anxiety, nausea, or restlessness. We will provide medications to take if you feel these symptoms. This can feel like early withdrawal, but it is rare that someone gets fully sick when they follow the blister pack.
- We blister-pack your medication to help you stay on your dosing schedule. It is important to follow the schedule to avoid severe withdrawal.
- If you miss doses of buprenorphine, please check in with your provider to avoid getting sick (also known as precipitated withdrawal).
- Commonly, people continue to use opioids given the smaller doses of buprenorphine are not enough. You can try to cut down on your opioid use gradually over the week. However, you do not have to. This can happen later when you're on a higher dose if that is your goal.
- Do not try to quantify how much opioid that you need to decrease per day – let your body naturally cut down. As the buprenorphine builds up in your body, you will notice that the same

amount of opioid does not cause the same effect, and you can begin to try less if you want at a rate that feels comfortable.
- You may not notice a decrease in opioid use or notice decreased effects from other opioids after the first few days as the buprenorphine slowly builds up.
- You may not feel 100% better right away. Your body is transitioning, and most people feel better and better with time.
- The goal of overlap starts is to avoid going through significant opioid withdrawal, though you may still notice some more mild opioid-withdrawal symptoms. Your provider may prescribe other medications to help treat these (ex. Restlessness, anxiety, trouble sleeping)
- After overlap starts, you may continue on buprenorphine at a higher total daily dose. Talk to your provider about what dose and duration is right for you.

SUBLINGUAL MACRODOSING: Macrodosing is a broad term used to describe starting buprenorphine at doses ≥16 mg. This method has limited evidence from patients in the Emergency Department and does not have substantial published evidence in the outpatient setting. Patients are less likely to experience precipitated withdrawal with longer periods of since last opioid use. For patients using fentanyl, it is often more well tolerated by waiting 48-72 hours since last fentanyl use. Therefore, the use should be limited to patient preference with adequate risk discussion.

Day 1: Buprenorphine 16 mg SL as needed for opioid withdrawal, then 8mg every 1-2 hours as needed for withdrawal up to 32 mg total

Days 2-7: Buprenorphine 8 mg TID

Patient Education:

- Severe opioid withdrawal may occur and adjunctive medications for opioid withdrawal management should be used
- Wait until you are in at least moderate opioid withdrawal prior to starting, waiting longer is associated with less precipitated withdrawal (closer to 2 days since last fentanyl use)

BUPRENORPHINE LONG-ACTING INJECTION WITH SUBLIGUAL TO START: There are two buprenorphine long-acting injectable (LAI) formulations. Sublocade is a monthly injection that has a long half-life which reduces the risk of overdose even after the patient misses an injection. Brixadi is available as a weekly and monthly product allowing for patients to have the choice in dosing frequencies. See Appendix 3 for a summary of buprenorphine LAI dosing. Any of the buprenorphine sublingual starting methods can be utilized to initiate buprenorphine prior to an injection. Each LAI has recommendations for how long a patient should be take buprenorphine prior to starting the LAI (see Appendix 3). CBHS Pharmacy supports off-label initiation of Sublocade) with some current amount of buprenorphine levels as demonstrated by one observed dose of buprenorphine SL that was tolerated or a current drug screen positive for buprenorphine.

BUPRENOPRHINE LONG-ACTING INJECTION WITH DIRECT TO INJECT: Direct to inject is a term used for initiating buprenorphine long-acting injectable in people who are not currently taking buprenorphine. This initiation method may be appropriate for some patients, in particular those who prefer this method. There is a small but growing amount evidence for initiating buprenorphine via direct to inject with Brixadi (weekly). Current evidence is from patients in the Emergency

Department and there was a lower risk of precipitated withdrawal when patients had a COWS ≥4. The pharmacokinetics of Sublocade and Brixadi (monthly) differ from Brixadi (weekly) in terms of time to peak levels. Therefore, direct to inject is only recommended with Brixadi (weekly). The following off-label dosing can be considered:

Product	**Buprenorphine Prior to Starting**	**Dosing**
Brixadi (weekly)	Not Required	24 mg or less

Some best practices we encourage include:

- Patients should be educated that this is off-label dosing with limited data in the outpatient setting
- Counsel patients that it is common to feel discomfort especially within the first 24 hours. We recommend prescribing adjunctive medications in case of withdrawal symptoms
- Documenting patient's consent for treatment with buprenorphine LAI in the medical record
- Screening for methadone prior to starting
- Using lower doses in patients with lower tolerance
- Initiating the medication in patients with higher COWS scores decreases the risk of precipitated withdrawal
- Provide ancillary opioid withdrawl medications as there may be discomfort particularly in the first day of initiation
- Sublingual buprenorphine should also be prescribed. The levels of buprenorphine with the first injection do not remain at therapeutic levels and therefore patients will need additional buprenorphine to be available until next visit (see Appendix 3 for additional details)

APPENDIX 1: MEDICATION TABLES

TABLE 2: MEDICATIONS FOR OPIOID Use Disorder

Medication	Mechanism of Action	Dose & Administration	Contra-indications	Adverse Effects	Comments
Buprenorphine **Buprenorphine long-acting injection**	Partial mu opioid agonist which reduces opioid withdrawal symptoms and cravings. The high binding affinity for the mu-opioid receptor blocks the effects of other opioids.	*Patients should be in mild to moderate opioid withdrawal (COWS >10) when initiating buprenorphine to prevent precipitated withdrawal* **Sublingual/buccal:** Induction 2-4 mg q2h prn opioid withdrawal symptoms up to 8 mg on Day 1. Then increase in 4-8 mg increments to a maintenance dose of 12-16 mg per day. Max 32 mg per day. To avoid precipitated withdrawal among people on fentanyl or methadone, clinicians offer low-dose buprenorphine inductions (with film	Use of opioid antagonists Known allergy to buprenorphine (rare)	Sedation, anxiety, constipation, nausea, vomiting, diaphoresis, headache	Buprenorphine was the first opioid agonist treatment available in an office-based setting. Buprenorphine can be prescribed for OUD treatment by any physician, nurse practitioner, pharmacist or physician assistant that has a DEA license. There are no regulations for treatment inclusion or exclusion or limits on number of patients one individual prescriber can treat. Partial mu opioid agonist leads to ceiling effect for respiratory depression and improved safety profile. However, when combined with additional CNS depressants the ceiling effect is mitigated although continues to be lower risk than other full agonist opioids. In addition to treating opioid withdrawal and cravings, maintenance treatment with buprenorphine is associated with increased treatment retention compared to detoxification. Buprenorphine binds with high affinity to the mu opioid receptor and can displace full opioid agonists leading to precipitated withdrawal. Therefore, an appropriate

		or patches) with overlap of full agonist opioid. A maintenance dose is established when a patient no longer experiences opioid cravings or opioid withdrawal. **Injection:** **Sublocade:** Recommended dose is 2 monthly initial doses of 300 mg followed by 100 mg monthly maintenance dose. Increasing the maintenance dose to 300 mg may be considered when benefits outweigh risks. Healthcare settings and pharmacies that dispense injection must be enrolled in REMS program. **Brixadi:**			initiation method should be discussed with patients. Buprenorphine can be prescribed in a co-formulated product with naloxone which was added due to block effects of buprenorphine if injected (which is exceedingly rare). Naloxone has minimal absorption when taken sublingually or buccally (see Hepatic Impairment for exceptions) but can result in side effects for some patients. All formulations of buprenorphine are safe and effective, regardless if they contain naloxone. The formulation should be based on patient preference and patients should not be required to use formulations co-formulated with naloxone. In January 2022, FDA issued a warning about the potential for dental problems in buprenorphine products that dissolve in the mouth. They recommend swishing with a large sip of water after the medication dissolved and recommend regular dental check-ups while on buprenorphine. Several professional societies called for FDA to retract this warning, stating that the FDA's findings are not based on solid research evidence and can lead to potentially harmful, stigmatizing effects that may further limit access to buprenorphine. BHS supports reducing barriers and stigma to buprenorphine access.

<table>
<tr>
<td></td>
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<td>For patients not currently taking buprenorphine, administer a test dose of 4 mg SL followed by an initial dose of 16 mg of Brixadi (weekly). Administer an additional dose of 8 mg within 3 days of first dose to achieve 24 mg.
Patients already taking SL buprenorphine may be converted to Brixadi (weekly) or Brixadi (monthly) at an equivalent dose. See above guidance for injection without prior SL administration.

Renal impairment: no adjustment

Hepatic impairment: Buprenorphine: decrease dose by</td>
<td></td>
<td></td>
<td>Injection:

Sublocade: Indicated for people who have initiated treatment with a buprenorphine containing product delivering the equivalent of 8-24mg of buprenorphine for a minimum of 7 days.

Brixadi: Indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. (1)

<table>
<tr><td>Daily dose of SL</td><td>Brixadi (Weekly)</td><td>Brixadi (Monthly)</td></tr>
<tr><td>≤ 6 mg</td><td>8 mg</td><td>N/A</td></tr>
<tr><td>8-10 mg</td><td>16 mg</td><td>64 mg</td></tr>
<tr><td>12-16 mg</td><td>24 mg</td><td>96 mg</td></tr>
<tr><td>18-24 mg</td><td>32 mg</td><td>128 mg</td></tr>
</table>
Drug Interactions: Metabolized by CYP3A4

Monitoring: Attend regular dental check ups.</td>
</tr>
</table>

		50% in severe impairment. Naloxone: avoid naloxone containing products in severe (and possibly moderate) impairment			
Methadone	Full m opioid agonist which reduces opioid withdrawal symptoms and cravings. The high binding affinity for the m opioid receptor blocks the effects of other opioids.	*Only available from a Opioid Treatment Program or as emergency treatment of withdrawal through "72 hour methadone" rules when treating OUD.* **Oral:** 10-50 mg PO daily titrated every 5 days to a maintenance dose of 0 – 120 mg daily or higher for people using fentanyl due to higher tolerance. A maintenance dose is established when a patient no longer experiences opioid cravings or opioid	Contraindications: Paralytic ileus, documented Torsade de pointes (Tdp) on methadone, use of opioids antagonists Caution: decompensated liver disease, severe apnea, severe asthma, severe COPD, sedative-hypnotic or CNS depressant abuse, familial QTc prolongation or QTc prolongation >450 msec, concomitant use	Sedation, constipation, nausea, vomiting, diaphoresis, QTc prolongation, Tdp, respiratory depression	The use of methadone for the treatment of OUD is restricted to licensed Opioid Treatment Programs (OTP). In addition to reducing withdrawal and cravings, methadone for OUD has the best evidence for treatment retention, in addition to reducing unprescribed opioid use, reduced seroconverstion of HIV and HCV, reduced mortality of OUD, reduced criminal behavior and improved birth outcomes. Methadone has a long half-life resulting in a steady-state serum levels 3-5 days after dose adjustments, therefore doses are titrated slowly to reduce toxicity. OTP's have additional confidentiality requirements under Code of Federal Regulations 42; therefore, methadone will not be present on CURES. ***Drug Interactions:*** Multiple drug interactions, primarily metabolized by

		withdrawal and is not experiencing side effects. Of note, higher doses are expected among people who use fentanyl. Further, women who are pregnant or those deemed to be rapid metabolizers may need split dosing. *Hepatic impairment:* no adjustments providers in package insert *Renal impairment:* CrCl ≥10mL/min: no dose adjustment. CrCL <10mL/min: use 50-75% of normal dose	of medications that prolong the QTc interval		CYP3A4, followed by CYP2B6 and CYP2C19 and, to a lesser degree by CYP2C9 and CYP2D6. Examples of medications increase methadone serum levels by CYP3A4 inhibition includes azole antifungals, macrolides, fluoroquinolones and some antidepressants Medications to avoid with methadone include efavirenz, ketoconazole, rifampin ***Monitoring:*** EKG monitoring practices are variable in terms of timing and dose. Expert consensus from the American Society of Addition Medicine (ASAM) recommends EKG in patients on methadone doses >120mg per day, patients with a history of QTc prolongation and in patients taking medications that prolong the QTc interval
Naltrexone long acting injection	mu opioid antagonist which may block the effects of opioids	**Injection:** 380 mg IM monthly Patients must not take opioids for 7-14 days before starting naltrexone, duration of opioid abstinence	Use with caution in patients with cirrhosis. Avoid use if acute liver injury or transaminitis. Likely safe in patients with	Nausea, headache, anxiety, sedation. Warnings of hepatotoxic effects are	Naltrexone that has no required certifications to prescribe or requirements for treatment setting. Does not treating opioid withdrawal.

		will depend on half-life of opioids used. Consider naloxone challenge to assess for opioid withdrawal.	Child's Pugh Class A or B cirrhosis. Typically not recommended for patients with Child's Pugh C or D unless benefits outweigh the risks of potential drug-induce liver injury and with shared patient decision making. , Pregnancy: Use is not recommended. May be considered if benefits are determined to outweigh the risks and with shared patient decision making.	derived from studies using oral dosages up to 300 mg/day for obesity and dementia. No reports of hepatotoxicity at FDA recommended dose.	A person must not have used opioids in 7-14 days prior to initiating naltrexone to avoid precipitated withdrawal. ***Monitoring:*** Check LFTs and INR prior to initiation if concern for liver disease. Labs are not required prior to initiating treatment. When possible, monitor LFTs periodically while on treatment (annually unless signs or symptoms of hepatitis develop).

TABLE 3: MEDICATIONS FOR MANAGING SYMPTOMS OF WITHDRAWAL

Medication	Target withdrawal symptom	Dose & Administration	Adverse Effects	Comments

Acetaminophen	Myalgias	**Oral**: 325-500 mg every 6 hours as needed	Nausea, loss of appetite	
Baclofen	Muscle cramps	**Oral:** 5-10 mg up to three times daily as needed	Drowsiness, nausea/vomiting, confusion, dizziness, hypotonia, asthenia	Use with caution with other CNS depressants as they may have additive effects with baclofen
Clonidine	Restlessness, sweating, anxiety	**Oral:** 0.1 to 0.2 mg (patients >90 kg may receive up to 0.3 mg); may repeat every 45 to 60 minutes if needed, up to a total of 4 doses until symptoms resolve, provided blood pressure and heart rate remain stable; maximum dose: 1.2 mg/day	Bradycardia, hypotension, dry mouth, dizziness, headache	Hypotension is uncommon at low doses. When possible, check blood pressure prior to starting. Use with caution if concern for hypotension or discuss symptoms to look our for with patients.
Hydroxyzine	Anxiety, insomnia	**Oral:** 25-50 mg every 6 hours as needed	Somnolence, dry mouth	
Ibuprofen	Myalgias	**Oral:** 400 mg every 6 hours as needed	Stomach upset	Take with food
Lofexidine	Restlessness, sweating, anxiety	**Oral:** 0.54-0.72 mg every 6 hours during the period of peak withdrawal symptoms (generally the first 5 to 7 days following last use of opioid) with dosing guided by symptoms and side effects. Max dose is 2.88mg/day. When discontinuing treatment, taper lofexidine by 1 tablet every 1-2 days. Adjust dose for renal and	Orthostatic hypotension, bradycardia, hypotension, dizziness, somnolence, sedation, dry mouth	Limited efficacy seen in clinical trials ***Drug Interactions:*** **Methadone**: Concern for QT prolongation. ECG monitoring is recommended when used concomitantly. **Oral naltrexone:** Concomitant use may reduce efficacy of oral naltrexone.

		hepatic impairment (see package insert).		**CYP2D6 Inhibitors:** Monitor for symptoms of orthostasis and bradycardia with concomitant use. ***Monitoring:*** Monitor vital signs before dosing and advise patients on how to minimize risk of hypotension, bradycardia and syncope. Monitor ECG in patients at risk for QT prolongation.
Loperamide	Diarrhea	**Oral:** 4 mg then 2 mg up to four times daily as needed	Dizziness, constipation, stomach upset	
Ondansetron	Nausea	**Oral:** 4-8 mg twice daily as needed for anticipated length of withdrawal	Constipation, fatigue, headache, malaise	Check QTc in individuals with risk factors for arrhythmias
Trazodone	Insomnia	**Oral**: 50-100 mg at bedtime as needed	Dry mouth, dizziness, fatigue, blurred vision, next-day somnolence	

APPENDIX 2: CBHS PHARMACY BUPRENORPHINE FAQ'S FOR CBHS PRESCRIBERS

What services does CBHS Pharmacy provide for buprenorphine patients?

CBHS Pharmacy provides specialty services for buprenorphine patients including the following:

Monitoring: Patients check in with a pharmacist every time they pick up buprenorphine. If the patient appears intoxicated with a CNS depressant, patients will be assessed by the pharmacist and possibly referred to onsite providers if available to re-evaluate for appropriateness for dosing. They will be assessed if they need urgent medical care. Patients may be instructed to return when they are more alert. Providers can also order onsite urine drug screening.

Observed dosing: Providers may request observed dosing for patients at the CBHS Pharmacy dispensing window.

Frequent dosing: Providers may request dosing schedules more frequent than every 28 days, including daily dosing (except holidays).

Alternative buprenorphine induction dosing support: Upon provider request, CBHS pharmacy provides prescriber consultation, medication bubble packing, in depth patient counseling and close monitoring for patients prescribed alternative initiation protocols (i.e. "micro-dosing").

Buprenorphine extended-release injection: The pharmacy processes and dispenses prescriptions for buprenorphine extended-release injections for providers that meet REMS requirements. The provider must pick up and administer the injection to the patient on the date it is due. This may be ordered in advance and delivered to the providers DEA registered address as long as the clinic meets the requirements for controlled substance storage.

Naloxone: Patients can be educated on the risks for opioid overdose and trained to respond to overdoses with naloxone. It can be furnished by a pharmacist, prescribed by a provider, or purchased over the counter.

Smoking cessation: Pharmacists can assess for tobacco use and furnish nicotine replacement therapy (patches, gum, or lozenges). Providers may also prescribe nicotine replacement therapy and pharmacists will provide thorough smoking cessation counseling.

Safer injection kits: CBHS pharmacy provides safe injection kits with syringes and sharps containers to our patients at no charge.

Fentanyl test Strips: CBHS pharmacy provides fentanyl test strips to patients at no charge. Programs can apply to stock a supply on site.

Medication and syringe disposal: Pre-paid postage medication take-away mailbags are available at the pharmacy, or medications may be dropped off at our medication take back receptacle. Used syringes can be disposed in receptacles provided in the building.

What is CBHS Pharmacy's policy on early or late buprenorphine pick-ups?

First early pick-up (e.g., lost meds, vacation): CBHS pharmacy does not allow patients to pick-up their medication before their assigned pick-up date without authorization by the prescriber. One early pick-up is allowed in a 365-day period. For example: Patient picks up a 7-day supply on a

Tuesday, making the following Tuesday their next assigned pick-up date. If the patient returns any day prior to their assigned pick-up date, authorization from the prescriber will be required.

Second or subsequent early pick-ups in a 365-day period: The patient is required to have consolidated daily observed dosing until their next pick-up date with prescriber authorization. For example: If patient is taking 8 mg TID, they will take 24 mg at once daily observed until next assigned due date. Prior to next pick-up, prescriber should identify reasons for frequent early pick-ups and adjust take-home supply accordingly.

Late pick-ups: Patients that are ≥30 days late picking up from their assigned pick-up dates will require authorization from the prescriber to dispense buprenorphine. Patients <30 days late picking up will be counseled on adherence and dispensed the prescription as written.

Does CBHS Pharmacy have any policies that may affect the buprenorphine prescription I write?

Dispense in 7-day increments: To keep patients assigned pick-up days the same day of the week, CBHS Pharmacy will dispense in increments of 7 days unless otherwise requested by the prescriber. Example: Prescription written for a 30-day supply will be dispensed for a 28-days' supply.

What are CBHS Pharmacy's hours of operation and location?

CBHS pharmacy is open 7 days per week. The window is open for pick-ups weekdays 9:00am-6:30pm and weekends 9:00am-4:00pm. On weekends, the pharmacy is closed for an hour lunch break 12:00pm-1:00pm. Pharmacy staff are available by phone weekdays 8:30am-8:00pm and weekends 9:00am-5:00pm for any questions. CBHS pharmacy is located at 1380 Howard Street.

What if my patient is due to pick-up on a holiday and CBHS Pharmacy is closed?

If a patient's scheduled pick-up date falls on a holiday when CBHS Pharmacy is closed, the patient will be allowed to pick-up their buprenorphine one business day before the holiday without counting as an early pick-up. CBHS Pharmacy posts signs reminding patients of holidays and this policy.

What is CBHS Pharmacy's vacation supply policy?

Approval from the prescriber is required. Other restrictions may apply, and a prior authorization may be required by the patient's insurance.

What is the record keeping requirements for prescribing buprenorphine?

The DEA has additional record keeping requirements for controlled substances prescribed for office-based opioid therapy, such as buprenorphine, beyond the usual for Schedule III substances. The following are the record keeping requirements:

Buprenorphine inventory log: Prescribers must keep an inventory of buprenorphine dispensed (21 CFR Section 1304.03[b]). This log is *required* even if the prescriber does not stock buprenorphine products. Because no BHS clinic stocks buprenorphine products, this is generally a log with a zero balance.

Who can I contact if I have further questions regarding buprenorphine at CBHS Pharmacy?

CBHS substance use disorder pharmacists can help! Call 628-754-9110 to request a phone consult. Or reach out by email at druginfo.bhs@sfdph.org.

APPENDIX 3: BUPRENORPHINE LONG-ACTING INJECTABLES (LAIS)

BUPRENORPHINE LONG-ACTING INJECTION (SUBLOCADE)

Dose: Patients not currently taking buprenorphine should receive an initial dose (e.g. 4mg) of transmucosal buprenorphine before administering the first injection. The starting dose is 300 mg IM. The second injection is 300mg and may be administered as early as 1 week and up to 1 month after the initial injection. After two injections, the maintenance dose is 100mg monthly. A monthly maintenance dose of 300mg may be considered in patients who tolerate 100mg but do not demonstrate a satisfactory clinical response.

Administration site: subcutaneous tissue of the abdomen, thigh, buttock, or back of the upper arm. Injection sites should be rotated between doses.

Dosing interval: monthly

Dosing window: minimum of 26 days between injections

Switching from established buprenorphine SL dose to buprenorphine LAI:

Buprenorphine Transmucosal Dose	Sublocade Dose		
	Dose 1	Dose 2	Dose 3
8-18 mg/day	300 mg	100 mg	100 mg
20-24 mg/day	300 mg	300 mg	100 mg

Overlap with sublingual medication: No overlap suggested in the package insert. Continual use of sublingual PRNs requires documentation of discussion with the patient around symptoms, duration of sublingual overlap, and plan to taper off if application. Due to likely subtherapeutic blood levels with initial dosing CBHS Pharmacy supports using supplemental sublingual buprenorphine for the first 3 months when the injections are the 300mg dose or patients on 100mg with ≤8mg/day sublingual ongoing. Beyond this duration for 300mg dose, a discussion should occur between pharmacist and prescriber to document clinical justification and plan.

Medication supply, storage and handling:

Supplied	Reconstitution	Refrigeration	Administration	Needle Size
Kit of prefilled syringe: 100 mg/0.5 mL 300 mg/1.5 mL	None	Yes, may be kept at room temperature for up to 12 weeks. Remove from refrigerator for at least 15 minutes prior to injection.	Do not remove from foil pouch until patient has arrived for injection. Do not attach needle until time of administration. Remove air bubble prior to injection. Pinch	19G 5/8 inch

			the skin and lift to avoid injecting into muscle and inject at a 45-90 degree angle to avoid dermal administration. Do not rub the injection site after.	

Pharmacokinetics:

Half-life	Time to maximum concentration	Time to steady state
43-60 days	24 hours after injection	4-6 months

REMS Program: The medication can only be purchased by a REMS certified pharmacy or healthcare setting. The REMS program is to mitigate risks of patients obtaining the medication and injecting it intravenously. A requirement of the REMS is that the medication is only provided to licensed healthcare providers and administered by healthcare providers. The medication can only be delivered to a healthcare providers location where their DEA license is registered. Certified programs can not distribute, transfer, loan, or sell the medication.

BUPRENORPHINE LONG-ACTING INJECTION (BRIXADI)

Dose: Target weekly dose is 24 mg and can go up to a maximum of 32 mg weekly. Doses for monthly injection range between 64-128 mg.

Dosing interval: weekly or monthly

Initiation:

1. **<u>If NOT currently receiving buprenorphine treatment (package insert guidance):</u>** Administer 4 mg of SL buprenorphine as test dose when there are signs of mild-moderate withdrawal. If no precipitated withdrawal after 1.5 hours, administer Brixadi 16 mg weekly. Administer an additional Brixadi 8 mg weekly dose within 3 days of 1st dose to achieve the recommended dose of 24 mg weekly. If needed, can administer an additional Brixadi 8 mg dose for a total weekly dose of 32 mg.

Off-label: Providers may consider initiating Brixadi at 24 mg weekly in cases for patients with higher tolerances or high buprenorphine doses in the past.

2. **<u>If on SL buprenorphine, can convert to either weekly or monthly injection:</u>** Transition to either weekly or monthly injection based on SL dose equivalent in table below.

Daily dose of SL buprenorphine	Brixadi (weekly)	Brixadi (monthly)
≤ 6 mg	8 mg	--
8-10 mg	16 mg	64 mg
12-16 mg	24 mg	96 mg
18-24 mg	32 mg	128 mg

3. **<u>Direct to Inject:</u>** See page 6 for rationale regarding this initiation method. In certain scenarios, Brixadi (weekly) can be initiated at 24 mg when patient is in mild-moderate withdrawal without a SL test dose.

Dose adjustments: An additional 8 mg injection may be administered based on clinical judgement during a dosing interval up to a maximum of 32 mg per week or 128 mg per month. Consider using sublingual supplemental as an alterative for ease of use and access.

Overlap with sublingual medication: No overlap suggested in the package insert. Continual use of sublingual PRNs requires documentation of discussion with the patient around symptoms, duration of sublingual overlap, and plan to taper off if application. Due to likely subtherapeutic blood levels with initial dosing CBHS Pharmacy supports using supplemental sublingual buprenorphine for the first four injections (weekly or monthly) and up to the equivalent of 32mg/day sublingual ongoing. Beyond this duration, a discussion should occur between pharmacist and prescriber to document clinical justification and plan.

Administration site: subcutaneous into tissue of buttock, thigh, abdomen, or upper arm. For those not currently on buprenorphine treatment, Brixadi (weekly) should not be injected into upper arm until steady state is reached (after 4 consecutive doses). Brixadi (monthly) does not require

injection site rotation. For Brixadi (weekly), the same site of injection should not be used for at least 8 weeks.

Dosing window: +/- 2 days for weekly injection and +/- 1 week for monthly injection to avoid misses doses, it should not be administered more frequently than weekly for the weekly or monthly for the monthly as an ongoing order.

Transitioning from Brixadi: Patient may be transition from weekly to monthly or from monthly to weekly dosing of Brixadi based on clinical judgement based on dose equivalencies. If patient continues to report opioid cravings and a dose escalation is needed, consider checking a buprenorphine plasma level or switching to Sublocade which can provide a higher plasma level.

Medication supply, storage and handling:

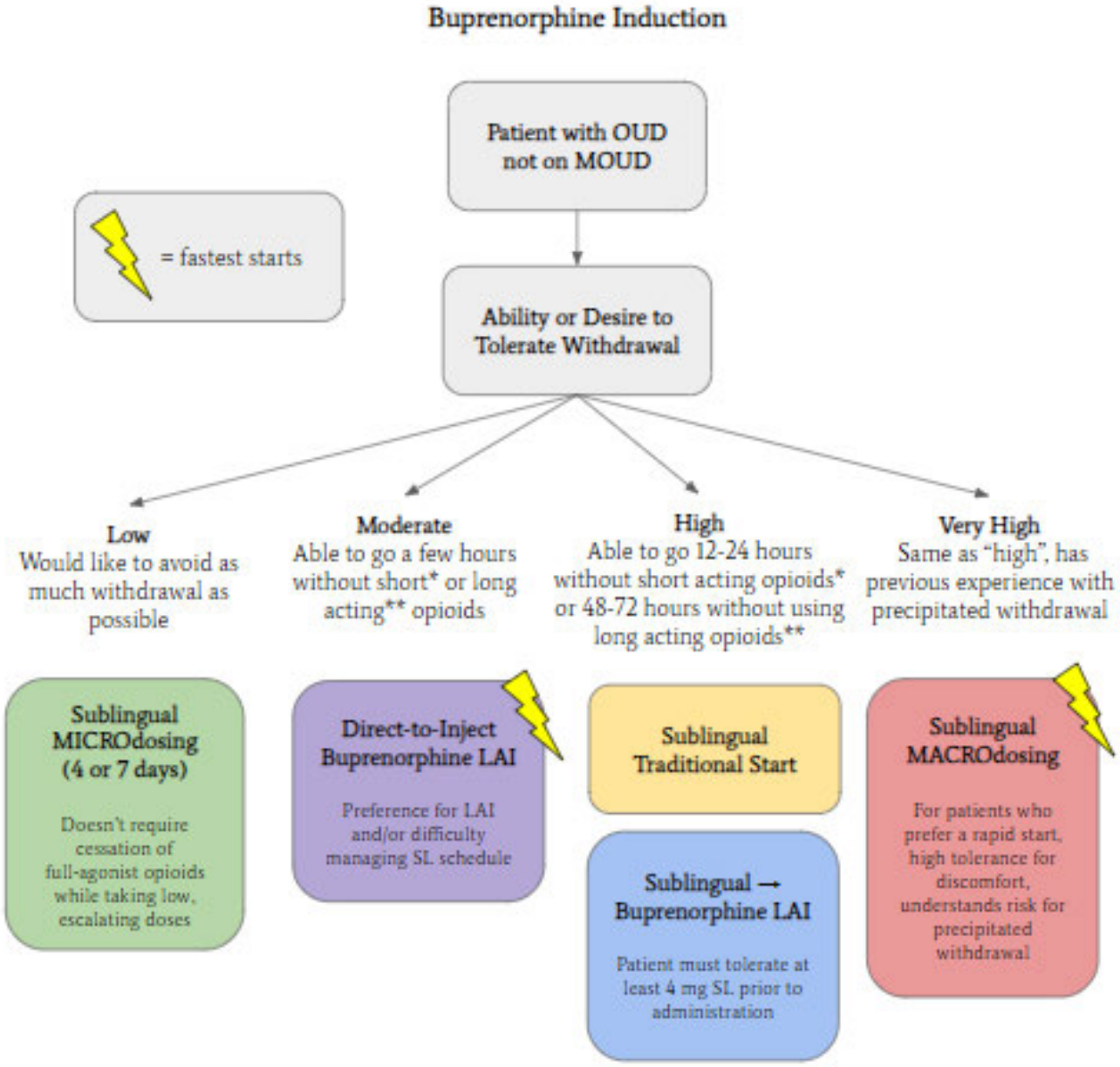
Supplied	Reconstitution	Refrigeration	Administration	Needle Size
Pre-filled syringes <u>Weekly:</u> 8 mg/0.16 mL 16 mg/0.32 mL 24 mg/0.48 mL 32 mg/0.64 mL <u>Monthly:</u> 64 mg/0.18 mL 96 mg/0.27 mL 128 mg/0.36 mL	None	Not required. Store at room temperate	Insert plunger into body of syringe and rotate clockwise until attached to stopper. Pinch skin at injection site and insert needle at 90° angle and inject medication until plunger pressed fully down. Hold for two seconds and then pull needle out of skin while keeping the plunger depressed. Once needle out of skin, slowly lift thumb off plunger and allow syringe guard to cover needle.	23G ½ inch needle

Pharmacokinetics:

	Half-life	Time to maximum concentration	Time to steady state
Weekly	3-5 days	24 hours	4 consecutive doses (4 weeks)
Monthly	19-26 days	6-10 hours	4 consecutive doses (4 months)

REMS Program: The medication can only be purchased by a REMS certified pharmacy or healthcare setting. The REMS program is to mitigate risks of patients obtaining the medication and injecting it intravenously. A requirement of the REMS is that the medication is only provided to healthcare providers and administered by healthcare providers. The medication can be delivered to a healthcare providers location where their DEA license is registered. Certified programs can not distribute, transfer, loan, or sell the medication.

APPENDIX 4: BUPRENORPHINE INDUCTION DECISION TREE



Always offer options to patients. If multiple unsuccessful attempts with buprenorphine, consider methadone clinic referral. Utilize SUD warm line for further guidance - (855) 300-3595

*Short acting opioids include heroin, oxycodone IR, hydrocodone, tramadol, codeine and morphine
**Long acting opioids include non-pharmaceutical fentanyl (due to lipophilic properties) and methadone.

Naloxone Guideline

SCOPE: This Naloxone Guideline is intended to offer prescribing assistance for providers, patients and the interested general public to increase the effectiveness and safety of naloxone in the ambulatory care setting. It is not intended to be comprehensive in scope. These recommendations are not a substitute for clinical judgment, and decisions about care must carefully consider and incorporate the clinical characteristics and circumstances of each individual patient. References can be found in the OUD References and Further Reading.

BACKGROUND: Naloxone is a mu opioid antagonist that reverses the effects of opioids. In the absence of opioids, it has no effect. When used for an opioid overdose, side effects can include opioid withdrawal symptoms, also known as precipitated withdrawal. These side effects are uncomfortable but are not life threatening.

Many community organizations and entities in California are in a position to help reduce deaths associated with opioid overdose by distributing naloxone but may find it difficult to obtain the required standing order from a physician. Therefore, in June 2018, California Department of Public Health (CDPH) issued a standing order for naloxone, authorized by California Civil Code Section 1714.22 This expanded access to naloxone for California residents and allowed organizations that cannot prescribe naloxone to distribute it to those who are at risk of experiencing an opioid-related overdose and those in a position to assist during an opioid-related overdose.[1] The standing order authorized the administration of naloxone to assist a person experiencing or suspected of experiencing an opioid overdose by a family member, friend, or other person who have been trained by an opioid overdose prevention and treatment training program.[1]

In October 1, 2018, the Department of Health Care Services (DHCS) created the Naloxone Distribution Project (NDP) to address the opioid crisis by reducing opioid overdose deaths through the provision of free naloxone.[2] Community organizations, such as county public health and behavioral health agencies like SFDPH and BHS, are eligible to apply to the NDP to receive naloxone. In October 2021, the SFDPH Naloxone Clearinghouse was created in response to San Francisco's opioid overdose epidemic and distributes free naloxone to DPH and DPH-affiliated programs within San Francisco. It has been in close collaboration with the DOPE Project in distributing naloxone to organizations in the city. Both organizations obtain free intranasal

naloxone through the NDP. The DPH Naloxone Clearinghouse aims to serve DPH and DPH affiliated programs, and the DOPE Project aims to serve community and grassroot organizations throughout San Francisco.

In March 2023, the US FDA approved naloxone nasal spray for purchase over-the-counter.[3] Therefore, a standing order is now no longer required for naloxone nasal spray. It is, however, still a requirement for intramuscular naloxone.
See Appendix 1 for more specific training requirements under the standing order.

See Appendix 3 for specific information about naloxone access, prescribing, use and client education.

Naloxone Law AB-714 Effective September 5, 2019: Guidance for Prescribers

OVERVIEW: Assembly Bill 714 (AB-714) replaces existing naloxone law AB 2760. The intent of the law is to require prescribers to educate clients about the risks of opioid-induced respiratory depression, opioid overdose, opioid use disorder, and opioid overdose prevention; and to provide prescriptions of naloxone or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid-induced respiratory depression when certain conditions are met.

The law focuses on clients receiving opioid or benzodiazepine prescriptions; and clients with an increased risk of opioid overdose, including those with opioid use disorder.

Section 741.a.1.B addresses the combination of opioids and benzodiazepines. BHS recommends providing education and offering naloxone or another FDA approved medication to any client prescribed a sedative-hypnotic (including benzodiazepines and non-benzodiazepine hypnotics) who is also taking an opioid, has a history of opioid overdose, has opioid use disorder or who may be at risk for opioid-induced respiratory depression. See BHS Safer Prescribing of Sedative-Hypnotics Guideline for more information.

BHS clients who themselves are not at risk for opioid-induced respiratory depression may have friends, family, or acquaintances who are at risk for this. Though not required by law, prescribers should use their clinical judgement to determine if prescribing naloxone to these individuals is appropriate.

See Appendix 2 for more specific requirements for prescribers.

DOCUMENTATION: BHS recommends that prescribers document both offering naloxone and educating on overdose prevention in a progress note. If a client accepts a prescription for

naloxone, the prescriber may either provide the prescription and complete an informed consent, or refer the client to CBHS pharmacy to pick up the medication (no prescription or signed consent required). If a client declines a prescription for naloxone, or already has a supply from a different prescriber or pharmacy, the prescriber should document this in the progress note.

See Appendix 3 for specific information about naloxone prescribing, access, use and client education.

APPENDIX 1

The following text from the law explains the specific training requirements under the standing order:

California Code, Civil Code - CIV § 1714.22

(2) "Opioid overdose prevention and treatment training program" means any program operated by a local health jurisdiction or that is registered by a local health jurisdiction to train individuals to prevent, recognize, and respond to an opiate overdose, and that provides, at a minimum, training in all of the following:

(A) The causes of an opiate overdose.

(B) Mouth to mouth resuscitation.

(C) How to contact appropriate emergency medical services.

(D) How to administer an opioid antagonist.

APPENDIX 2

The following text from the law explains the specific requirements for prescribers:

741. (a) Notwithstanding any other law, when prescribing an opioid or benzodiazepine medication to a patient, a prescriber shall do the following:

(1) Offer the patient a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid-induced respiratory depression when one or more of the following conditions are present:

(A) The prescription dosage for the patient is 90 or more morphine milligram equivalents of an opioid medication per day.

(B) An opioid medication is prescribed within a year from the date a prescription for benzodiazepine has been dispensed to the patient.

(C) The patient presents with an increased risk for opioid overdose, including a patient with a history of opioid overdose, a patient with a history of opioid use disorder, or a patient at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.

(2) Consistent with the existing standard of care, provide education to the patient on opioid overdose prevention and the use of naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid-induced respiratory depression.

(3) Consistent with the existing standard of care, provide education on opioid overdose prevention and the use of naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid-induced respiratory depression to one or more persons designated by the patient, or, for a patient who is a minor, to the minor's parent or guardian.

(b) A prescriber is not required to provide the education specified in paragraphs (2) or (3) of subdivision (a) if the patient receiving the prescription declines the education or has received the education within the past 24 months.

(c) This section does not apply to a prescriber under any of the following circumstances:

(1) When prescribing to an inmate or a youth under the jurisdiction of the Department of Corrections and Rehabilitation or the Division of Juvenile Justice within the Department of Corrections and Rehabilitation.

(2) When ordering medications to be administered to a patient while the patient is in either an inpatient or outpatient setting.

(3) When prescribing medications to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2 of the Health and Safety Code.

APPENDIX 3

How to Obtain Naloxone

1. DPH Naloxone Clearinghouse (SF DPH or DPH Affiliated Organizations)
    a. How to Apply: Email the following to DPH-Naloxone_Clearinghouse@sfdph.org
        i. Email subject: "New Application – [Program Name]"
        ii. Quantity requested per quarter
        iii. Contact person name and email
        iv. Program details blurb
        v. Example: "The goal of Project FRIEND is to increase naloxone utilization in San Francisco by effectively training first responders and EMS personnel in naloxone administration and distribution in the community. Staff (paramedics) are trained and reversals are attempting to be tracked via an online logging system and QR code on the kits themselves."
2. Prescribed by provider
    a. Documentation:
    BHS recommends that prescribers document both offering naloxone and educating on overdose prevention in a progress note. If a client accepts a prescription for naloxone, the prescriber may either provide the prescription and complete an informed consent or refer the client to CBHS pharmacy to pick up the medication (no prescription or signed consent required). If a client declines a prescription for naloxone, or already has a supply from a different prescriber or pharmacy, the prescriber should document this in the progress note.
3. Community pharmacy
    a. California law allows for trained pharmacists to furnish naloxone without a prescription
    b. CBHS Pharmacy will furnish naloxone to BHS and non-BHS clients.
    1380 Howard St, 1st Floor Pharmacy
    Monday-Friday, 9:00am-6:30pm
    Saturday-Sunday, 9:00am-4:00pm
4. Distribution programs
    a. Available at all Needle Exchange sites. Schedule available at: http://sfaf.org/client-services/syringe-access/site-schedule.html

Naloxone Product Information

Naloxone nasal spray is covered by most insurance plans. It is convenient to use. For information on other available naloxone products, please contact CBHS pharmacy.

Table Naloxone

	Naloxone 4mg/0.4ml Intranasal Spray
Dosing	Spray entire contents of device into one nostril upon signs of opioid overdose. Call 911. May repeat x1

Quantity	1 twin pack
Required supplies	None
Comments	Does not require assembly or additional supplies

Client Education

Education should include:

- How to identify a potential opioid overdose: person not responsive when shaken, breathing slowly, stopped or labored breathing, blue/gray lips and fingernails, pale/clammy skin
- Call 911
- Proper administration of naloxone. If not responsive in 3 minutes, give second dose
- Follow the instructions from the 911 dispatcher. This may include rescue breathing and/or chest compressions
- Remaining with the person until help arrives

Education materials on naloxone and how to respond to an opioid overdose are available in multiple languages at: http://www.pharmacy.ca.gov/licensees/naloxone_info.shtml under "Fact Sheets" and https://www.sf.gov/substance-use-and-overdose-prevention-services

Videos on overdose prevention and how to use several naloxone products are available at the following website: https://prescribetoprevent.org/

Education on how to use naloxone nasal spray including an instructional video are available at the manufacturer's website at: https://www.narcan.com/patients/how-to-use-narcan

APPENDIX 4

DPH Clearinghouse Naloxone Distribution FAQ's

What is the Naloxone Distribution Project?

The state Naloxone Distribution Project (NDP) is funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and administered by the Department of Health Care Services (DHCS) to combat opioid overdose-related deaths throughout California. The NDP aims to reduce opioid overdose deaths by providing free intranasal naloxone spray to the public.

What is the DPH Naloxone Clearinghouse?

The DPH Naloxone Clearinghouse is a DPH program that distributes naloxone to San Francisco-based community and medical programs, including SFDPH and DPH-affiliated programs. It is funded by various sources including the DHCS NDP, grants, and opioid settlement funds.

What is Naloxone?

Naloxone is a life-saving medication that reverses an opioid overdose. It has few known adverse effects and no potential for abuse. Naloxone is not a controlled medication. It can be prescribed or purchased over-the-counter

How does naloxone work?

Naloxone reverses an opioid overdose by blocking the opioid receptors in the brain from opioids like heroin, fentanyl, and opioid pain medications. The reversal effects are temporary and last between 30 to 90 minutes. It takes a few minutes for naloxone to start working. If an individual does not respond after approximately three minutes, the second dose of naloxone is given.

Is naloxone safe?

Yes, naloxone is a safe medication that reverses an opioid overdose. Naloxone should be used even if you're unsure what kind of drugs someone took and they are suspected of an opioid overdose.

Are there any major contraindications to naloxone?

There are no contraindications to naloxone unless there is a known allergy to naloxone or components of the intranasal naloxone spray.

What is NARCAN (naloxone HCl) Nasal Spray?

NARCAN Nasal Spray is the commercial name of the intranasal formulation of naloxone.

Can naloxone be used for a fentanyl overdose?

Yes. Fentanyl is a potent opioid, and naloxone can be used in a fentanyl-related overdose. Since fentanyl is a powerful opioid, additional doses of naloxone may be required to reverse the overdose.

How much does it cost to obtain naloxone through the NDP?
The medication is free through the NDP.

Is training required to distribute naloxone?
Yes. The staff of community clinics, organizations, and other entities distributing naloxone under the NDP and a standing order must receive opioid overdose prevention training and instruct individuals on using naloxone.

Do minors need parental consent to receive naloxone and education?
If possible, the minor and their parents or guardians should be involved in the education and distribution of naloxone. There could be situations where naloxone is distributed to a minor, but the involvement of parents or guardians is not possible or advisable. The minor's risk factors for experiencing or witnessing an opioid overdose and their maturity should be considered when determining whether they would benefit from naloxone. The distribution of naloxone under the standing order is not a prescription per se and, therefore, would not need parental consent. The standing order for the distribution of naloxone did not restrict the age of individuals who may receive naloxone and education.

In terms of prescriptions, CAL. FAM. CODE § 6929(b) states that "A minor who is 12 years of age or older may consent to medical care and counseling relating to the diagnosis and treatment of a drug- or alcohol-related problem." It would be reasonable to prescribe and dispense naloxone to a minor 12 years and older under this California law. All attempts to involve parents, guardians, and support systems should be attempted unless when it's not possible or advisable. Additionally, under current California naloxone access laws, a person who gives out naloxone under a prescription or standing order is not subject to civil action, criminal prosecution, or professional review for distribution (CA Civ Code § 1714.22 (2020)).

Does California have a Good Samaritan Law?
Yes. Individuals administering naloxone according to the law and in good faith will not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for this administration, except in cases of gross negligence or willful & wanton misconduct.

Do minors have the right to confidentiality about their substance use?
Yes. While it is required to involve parents or guardians in the minor's mental health treatment, a minor has the right to confidentiality about their substance use. The minor's consent is required to disclose their substance use. The exceptions that permit the communication of relevant facts to the parents or guardian involve: a.) the minor lacking capacity to make a rational decision on whether to consent to the disclosure to parents or guardian and b.) if there is a substantial threat to the minor's life or physical wellbeing such that the disclosure of relevant facts to the parents

or guardian may reduce that threat. The confidentiality policies are more restrictive for clinics that meet specific criteria under 42 CFR Federal policies.

Can we distribute naloxone to our clients only?
Naloxone can be distributed to a person at risk of an opioid-related overdose or to a family member, friend, or other people in a position to assist. Staff members can receive naloxone under this program.

Are there any NDP documentation requirements for naloxone distribution?
The NDP requires tracking the number of known opioid reversals with naloxone. However, there are no requirements to document the distribution of naloxone kits to individuals in the community. The DPH Clearinghouse requires programs to document the training of their staff.

Daniel Lurie
Mayor

San Francisco Health Network Behavioral Health Services
Medication Use Improvement Committee
1380 Howard St. 5th Floor
San Francisco, CA 94103

San Francisco Health Network
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

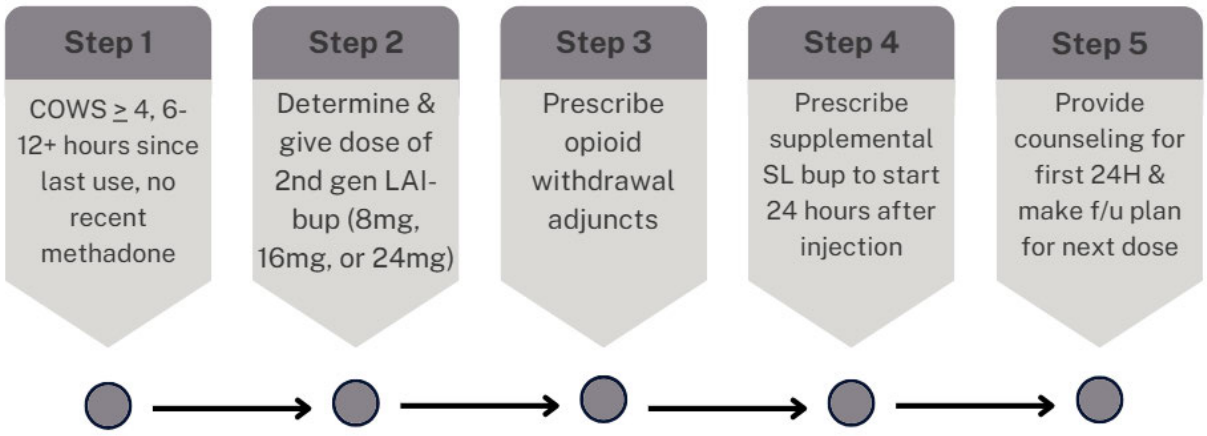
Direct to Inject Buprenorphine Guideline

SCOPE: This Direct to Inject Buprenorphine Guideline is intended to offer prescribing assistance for providers, patients and the interested general public to increase the effectiveness and safety of medication for opioid use disorder (MOUD) in the ambulatory care setting. It is not intended to be comprehensive in scope. These recommendations are not a substitute for clinical judgment, and decisions about care must carefully consider and incorporate the clinical characteristics and circumstances of each individual patient. References can be found in the Opioid Use Disorder References and Further Reading.

BACKGROUND: San Francisco Department of Public Health does not recommend the use of brand names when describing medications, however to reduce the risk of medication errors this protocol will refer to brand names of buprenorphine long-acting injectables as they have the same generic names. Buprenorphine long-acting injection is available as monthly Sublocade, weekly Brixadi and monthly Brixadi.

Direct to inject (DTI) is a term used for initiating buprenorphine long-acting injectable in people who are not currently taking buprenorphine. Given fentanyl's dominance of the drug market and ongoing overdose epidemic, DTI initiation using weekly Brixadi is gaining interest. The evidence for DTI is based on preliminary data coming from Emergency Department settings where patients with moderate-severe opioid use disorder (OUD) were offered DTI Brixadi 24mg for Clinical Opiate Withdrawal Scale (COWS) score ≥4 without a sublingual test dose (D'Onofrio, 2023). DTI is feasible because weekly Brixadi serum levels peak at 24 hours post-injection (Braeburn, 2023). This slow increase in buprenorphine serum levels facilitates a gradual build-up of buprenorphine while minimizing the risk of precipitated withdrawal that is seen with the quick serum peak (1-2 hours) of sublingual buprenorphine. A case series of SFDPH patients initiated on buprenorphine via DTI in outpatient settings in 2024 demonstrated that DTI was generally well-tolerated, with most patients experiencing mild to moderate withdrawal and approximately 75% retained on buprenorphine at 30 days (Rosenwohl-Mack, 2025).

DIRECT TO INJECT (DTI) PROTOCOL:



COUNSELING FOR THE FIRST 24 HOURS:

- Mild to moderate withdrawal may continue to worsen after the injection, as time since last opioid use increases and before buprenorphine has reached adequate serum levels. For most people it is not as severe as precipitated withdrawal and self-resolves.
- It is recommended that patients avoid using any opioids after injection and rely on withdrawal adjunct medicines as much as possible. However, if a patient is going to use, we recommend waiting at least 6 hours after injection. See Appendix 2 for patient-facing handout
- WAIT to take supplemental sublingual buprenorphine for 24 hours after injection to minimize risk of precipitating withdrawal.
- If the patient doesn't start sublingual buprenorphine or receive another injection within 7 days, they will have to start the buprenorphine initiation process over again from the beginning – recommend booking follow up appt for patient within 1-2 days of injection and emphasizing importance of follow up

FOLLOW-UP

- 24 hours after the injection, start taking additional sublingual buprenorphine, 8-32mg/day. Start with smaller doses (e.g., 2mg) at first and increase as tolerated.
- Clinicians should follow up within 24-48 hours to assess patient experience and determine next dose of buprenorphine. Internal data suggests that patients can tolerate a monthly Brixadi or Sublocade as soon as 24 hours after DTI.
- The first dose of weekly Brixadi lasts for 5-9 days. If the patient is planning to continue on buprenorphine, they should receive their next dose of buprenorphine (whether sublingual or long-acting injectable) between 1-8 days after their first injection.

INITIAL VISIT WORKFLOW

Document Initial Visit Assessment:

Time since last use:

Opioid(s) patient uses:

Any other substances used in past week:

COWS score:

Has patient been on buprenorphine before:

Has patient tried DTI before?

Assess Patient Withdrawal and Time Since Last Opioid Use

- Assess patient COWS score and time since last opioid use

Clinical Opiate Withdrawal Scale (COWS)	
Sign / Symptom	**Score**
Resting Pulse Rate (beats per minute) *Measure pulse rate after patient is sitting or lying down for 1 minute*	≤80: 0 81-100: +1 101-120: +2 >120: +4
Sweating *Not accounted for by room temperature or patient activity over the last 0.5 hours*	No report of chills or flushing: 0 Subjective report of chills or flushing: +1 Flushed or observable moistness on face: +2 Beads of sweat on brow or face: +3 Sweat streaming off face: +4
Restlessness observation during assessment	Able to sit still: 0 Reports difficulty sitting still, but is able to do so: +1 Frequent shifting or extraneous movements of legs/arms: +3 Unable to sit still for more than a few seconds: +5
Pupil size	Pupils pinned or normal size for room light: 0 Pupils possibly larger than normal for room light: +1 Pupils moderately dilated: +2 Pupils so dilated that only the rim of the iris is visible: +5
Bone or joint aches *If patient was having pain previously, only the additional component attributed to opiate withdrawal is scored*	Not present: 0 Mild diffuse discomfort: +1 Patient reports severe diffuse aching of joints/ muscles: +2 Patient is rubbing joints or muscles and is unable to sit still because of discomfort: +4
Runny nose or tearing *Not accounted for by cold symptoms or allergies*	Not present: 0 Nasal stuffiness or unusually moist eyes: +1 Nose running or tearing: +2

	Nose constantly running or tears streaming down cheeks: +4
GI Upset *Over last 0.5 hours*	No GI symptoms: 0 Stomach Cramps: +1 Nausea or loose stool: +2 Vomiting or diarrhea: +3 Multiple episodes of vomiting or diarrhea: +5
Tremor *Observation of outstretched hands*	No tremor: 0 Tremor can be felt, but not observed: +1 Slight tremor observable: +2 Gross tremor or muscle twitching: +4
Yawning *Observation during assessment*	No yawning: 0 Yawning once or twice during assessment: +1 Yawning three or more times during assessment: +2 Yawning several times/minute: +4
Anxiety or irritability	None: 0 Patient reports increasing irritability or anxiousness: +1 Patient obviously irritable/anxious: +2 Patient so irritable or anxious that participation in the assessment is difficult:+4
Gooseflesh skin	Skin is smooth: 0 Piloerection of skin can be felt or hairs standing up on arms: +3 Prominent piloerection: +5
Total Score: 5-12=mild withdrawal; 13-24 = moderate withdrawal; 25-36=moderately severe withdrawal; more than 36 = severe withdrawal	

  - Ideally patient would wait until COWS ≥ 4 **and** at least 6-12 hours since last opioid (eg., fentanyl, heroin) use
  - Recent methadone: Methadone has a long half-life, especially when at steady state (e.g., given in regular daily doses). If a patient has taken a single dose of methadone a few days prior to DTI, the risk of withdrawal is much lower than if the patient has been on regularly daily methadone within the past week. To err on the side of caution, it may be advisable to postpone DTI if a patient has taken methadone in the past 72 hours or been on regularly daily methadone dosing within the past week, though this should be a risk/benefit discussion with the patient.

- If patient's COWS < 4 or last use was <6 hours ago, can decide to:
  - *Give injection after conversation and consent from patient t*he injection may be reasonable and be given at the clinician's discretion and after a risk/benefit discussion with the patient
  - *Ask patient to return to clinic a few hours later or the next day*: In some cases, it may be possible for the patient to return to clinic a few hours later. Alternatively, if the patient can return the next day, advise them to stop using at least 6-12 hours before visit. Consider offering buprenorphine 0.5mg SL tablets q12 hours until the appointment, as there is some preliminary evidence that small amounts of buprenorphine prior to injection may potentially ease injection experience (Rosenwohl-Mack, 2025).

Determine Injection Dose

- Clinicians can choose between 8, 16, and 24mg doses of weekly Brixadi
- Most patients receive 16mg or 24mg, with 8mg more often for those with suspected low opioid tolerance or significant worry of worsening withdrawal
- Higher doses are likely associated with increased withdrawal with DTI but may be needed for patients using fentanyl with higher opioid tolerance (see Table 1 for dosing equivalents).
- It is recommended to weigh the risks and benefits of worsening withdrawal vs subtherapeutic dosing in determining which dose to give.
- See Appendix 1 for administration instructions

TABLE 1: CONVERSION FROM SUBLINGUAL BUPRENORPHINE TO WEEKLY BRIXADI

Daily Dose of Sublingual Buprenorphine	Brixadi Weekly Dose Equivalent	Brixadi Monthly Dose Equivalent
<6mg	8mg	--
8-10mg	16mg	64mg
12-16mg	24mg	96mg
18-24mg	32mg	128mg

Prescribe Opioid Withdrawal Adjuncts

We recommend the following opioid adjunct orders (if using SFDPH Epic, can use 'Opioid Withdrawal Adjunctive' orderset):

- Clonidine 0.1mg q6h prn withdrawal and restlessness, #12
- Ondansetron 4mg q8h prn nausea or vomiting, #9
- Hydroxyzine 50mg q6h prn anxiety, #12
- Loperamide 2mg q6h prn diarrhea; #12
- Trazodone 100mg qhs prn insomnia, #3 (if appropriate)
- Ibuprofen or acetaminophen (if no contraindications)

Prescribe Supplemental Sublingual Buprenorphine

Patients should not start supplemental sublingual buprenorphine until 24 hours after their injection (though they should ideally pick up the prescription on the day of the injection, along with the opioid withdrawal adjuncts). As a general rule, most patients need a maximum of 32mg sublingual

buprenorphine equivalent per day, and the following suggested PRN total daily doses are based on providing patients a total of 32mg sublingual buprenorphine equivalence per day x 1 week. At the time of the injection, we recommend booking a follow up appointment in 1-2 days, as well as informing patient that if they miss this appointment they can return any time in the next 7 days, so we recommend sending a 1 week supply of sublingual buprenorphine.

TABLE 2. SUBLINGUAL BUPRENORPHINE OVERLAP AFTER DTI

DTI Brixadi Weekly Dose	Goal Total Daily Dose of Sublingual Buprenorphine	Example SIG
8mg	28mg/day	8mg q6h prn withdrawal or cravings #28, do not take first dose until 24h since injection
16mg	22-24mg/day	8mg q8h prn withdrawal or cravings #21, do not take first dose until 24h since injection
24mg	16-20mg/day	4mg q6h prn withdrawal or cravings #28, do not take first dose until 24h since injection

Counseling and Follow-up for Ongoing Buprenorphine

- The patient should abstain from using any opioids for as long as possible after injection (and for at least 6 hours); rely on withdrawal adjunct meds as much as possible. See Appendix 2 for patient-facing handout.
- WAIT to take supplemental sublingual buprenorphine for 24 hours after injection to minimize risk of precipitating withdrawal.
- Clinician should follow-up with in 24-48 hours after injection. Clinicians should counsel patients at the follow up visit they will give additional sublingual or injectable buprenorphine, depending on the patient's preference
- Patient can safely receive monthly Brixadi or Sublocade starting 24 hours after DTI (see 'Follow Up Visits')

FOLLOW-UP VISITS

Deciding on Subsequent Buprenorphine at Follow-up Visits:

At 24 hours after weekly Brixadi injection, the dose is at its peak, and it is safe to give more buprenorphine without concern about precipitating withdrawal. At that time, sublingual buprenorphine, a second weekly injectable, or a monthly injectable buprenorphine can be given. Factors to consider in determining dose and timing of subsequent buprenorphine:

- Patient preference for sublingual vs. weekly vs. monthly injection

- If there is uncertainty about the dose of buprenorphine a patient is likely to need, starting with a few days of sublingual dosing gives patients the ability to titrate to the dose they need
- If concern for low tolerance, waiting 2+ days between injections can minimize concern for dose stacking

Documentation for Follow-up Visits:

24-48-hour f/u documentation:

Any withdrawal in 24 hours after injection (yes/no):

- If yes, how many hours after injection?
- If yes, mild/moderate/severe?

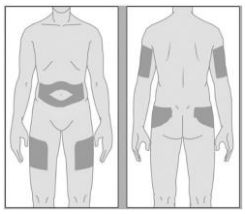
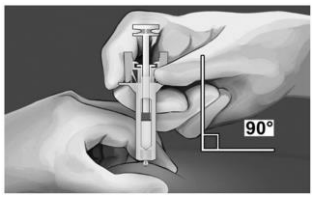
Opioid use since injection (fentanyl/heroin/other), if so how long after & did they feel effects:

Any sublingual buprenorphine since last injection, if so how long after & did it help withdrawal:

How does this compare to prior buprenorphine experiences:

Plan for next steps (note and confirm w patient plan for next buprenorphine injection):

APPENDIX 1: ADMINISTRATION INSTRUCTIONS

Steps for injection	
1	Provide patient education and anticipatory guidance: • Pain usually lasts 1-3 min after injection; ice packs are typically sufficient for analgesia • Advise the patient that they will NOT have a lump, in contrast to Sublocade
2	Prepare the syringe: Take the plunger and while holding the syringe, **twist clockwise** until the plunger is in place.
3	Select the injection site: for first 4 injections, do NOT offer the upper arms (plasma levels are 10% lower after injection here). Options include the buttock, thighs, and abdomen. 
4	Clean the injection site with 1-4 alcohol swabs in circular motion moving outward from site.
5	Grasp the syringe and remove the needle cap. There may be a small amount of liquid at the tip of the needle.
6	Pinch skin between your thumb and index finger.
7	Insert needle fully into the subcutaneous tissue at a 90-degree angle. Insert fully (hub the needle). 
8	After the needle is inserted, release the skin you are grasping. Slowly push down the plunger until it latches in the safety device 'wings.' This will ensure all of the medicine has been injected.
9	Keep the plunger pressed fully down while you hold the safety syringe in place for an additional 2 seconds. 

10	Gently pull the needle out. Once removed, you can take your thumb off of the plunger (this will retract the needle tip). 
11	Dispose of the needle in a sharps container.

APPENDIX 2: PATIENT HANDOUT

Direct-to-Inject Buprenorphine: Is it for me?

What is it?

- Buprenorphine is a medication for people who use opioids (for example, fentanyl or heroin)
- Being on buprenorphine can help you stay well and avoid cravings and withdrawal. It can help you cut down or stop using opioids, if that is your goal. It can also protect you from overdose.
- There is a new long-acting buprenorphine injection that you can start directly (without taking buprenorphine pills or strips first)

How does it work?

- When you are in mild opioid withdrawal, ideally at least 6 hours after the last time you used fentanyl or heroin, you can get an injection
- The injection reaches its full dose 24 hours after you get it
- You may feel a little rough for the first 24 hours until the medicine takes full effect, but precipitated withdrawal is very unlikely
- After 24 hours from the injection, the buprenorphine is at a good level in your body and most people feel much better

How should I expect to feel?

- Some people feel better as soon as they get the injection
- Some people don't notice anything at all
- Some people feel a little rough for 24 hours

What should I do if I feel worse after the injection?

- Tell someone! There are many options to help.
- You can get medications for anxiety, nausea, diarrhea, difficulty sleeping, or pain
- You should try to avoid using heroin or fentanyl, but if you do decide to use, it is best to wait at least 6 hours after the injection (to decrease your risk of worsening withdrawal)

What next?

- Once it's been 24 hours since the injection, the buprenorphine is at a stable level in your body and you should feel pretty good
- If your first dose wasn't high enough, you can take additional buprenorphine (pills or films) or get another injection
- The first injection only lasts 1 week, so it's important to return to see your provider within a week for more bup, so you don't have to start the process over again

What do people who get it say?

- "I felt a little under the weather overnight, but I feel fine now"
- "I thought I might have to go out and use, but I tried to just sleep through it and I felt good in the morning"
- "I never thought this could work for me! Everyone should try this."

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SAFER PRESCRIBING OF SEDATIVE-HYPNOTICS AND RELATED MEDICATIONS GUIDELINE

SCOPE: This Safer Prescribing of Sedative-hypnotic Medication Guideline is intended to offer prescribing guidance for providers, patients and the interested general public to increase the effectiveness and safety of sedative-hypnotic use. It is not intended to be comprehensive in scope. These recommendations are not a substitute for clinical judgment. Decisions about care must carefully consider and incorporate the clinical characteristics and circumstances of each individual.

INTRODUCTION: Sedative-hypnotics are prescribed for multiple conditions in mental health, most often for acute anxiety and insomnia. See treatment guidelines in the references and further reading section at the end of this document for suggested treatment algorithms for the use of these medications.

Unlike most other medications commonly prescribed in mental health settings, sedative-hypnotics have a high incidence of misuse, abuse and diversion. These medications are associated with memory impairment, can affect the ability to safely operate motor vehicles, and can increase the risk of falls. They have significant risks for respiratory depression and even death in combination with other CNS depressants including opioids and/or alcohol. Because of these safety concerns BHS recommends using alternatives to sedative-hypnotic medication as first line therapy. If sedative-hypnotic medication is prescribed, then short-term use is preferred (less than two weeks). For more chronic use, there are specific treatment recommendations in the next section.

Of note, insomnia and anxiety (and associated treatment medications) are also associated with an increased risk of falls and fractures in older adults. Accordingly, the selection of a specific sedative-hypnotic medication, form of administration, dose and duration of treatment is a complex decision-making process involving multiple factors. These factors often include individualized treatment goal(s), patient choice, history of past medication trials, family history, side effect profile and others.

TREATMENT RECOMMENDATIONS FOR SEDATIVE-HYPNOTIC USE: Sedative-hypnotics are most often prescribed for anxiety and/or insomnia in mental health settings. There are numerous effective and safer non-medication and non-sedative-hypnotic medication therapies for these conditions. All patients should first be offered these treatments, in combination with non-pharmacological interventions. See Appendix 2 for more information on

the treatment of insomnia and Appendix 3 for information on the treatment of anxiety, trauma and obsessive-compulsive disorders. Appendix 4 contains information about herbal supplements.

All patients being considered for a sedative-hypnotic medication should have a complete evaluation, including a CURES report (California's prescription drug monitoring program) to identify any prescribed scheduled substances. Note that CURES does not include methadone from methadone treatment facilities. Specific risk factors that could lead to poor outcomes should be identified and documented. Risk factors include:

- Current or previous alcohol or substance use disorder
- History of overdose
- Fall risk
- Traumatic brain injury
- Memory problems
- Sleep apnea
- Age >60
- Chronic obstructive pulmonary disease

CURES reports and risk factors should be reviewed every 6 months during treatment with sedative-hypnotics. Patients with significant risk factors should be offered alternative non-sedative-hypnotic therapies. If patients with significant risk factors are currently taking sedative-hypnotics, they should be tapered off them unless there is a documented justification for continuing treatment.

When starting sedative-hypnotics, initial prescriptions should be limited in quantity and dose. Patients should be informed that these medications are high risk for adverse events in chronic use. If use greater than two weeks is indicated, providers should document a justification. Providers should consistently document attempts to change to non-medication or non-sedative-hypnotic medication therapies.

Special attention should be paid to patients receiving opioid medication therapy as well as sedative-hypnotic therapy. In combination, there is a significantly increased risk of respiratory depression, over-sedation, and accidental overdose death. Providers should clearly document the justification for such combination therapy and an evaluation of risk. Prescribers should consult with their colleagues about these cases. Patients should be offered naloxone rescue kits with instructions and training on their use. Providers should coordinate care with the opioid prescriber. If patients request that their providers do not communicate, the prescribing of sedative-hypnotics is not recommended.

BENZODIAZEPINES

Introduction: Benzodiazepines are used for various indications including anxiety, panic disorder, alcohol withdrawal, seizures, catatonia, mania, agitation, muscle spasms, and insomnia. This guideline refers to the use of benzodiazepines for anxiety, panic disorder, and insomnia. The use of benzodiazepines for other indications is beyond the scope of this guideline. Please

refer to "SFHN BHS Medications for Alcohol Use Disorder Guideline" for details on how to use benzodiazepines in the management of alcohol withdrawal. Please refer to "SFHN BHS Safer Use of Mood Stabilizers Guideline" for information on the use of benzodiazepines for agitation in acute mania.

Benzodiazepines work by binding to the γ subunit of the GABA-A receptor, thereby causing an allosteric modification of the receptor which increases the receptor activity. By doing so, benzodiazepines increase the frequency of channel opening events, increasing chloride ion conductance and inhibiting the action potential.

Due to the delayed onset of therapeutic action for antidepressant medications, benzodiazepines can be used for rapid, symptomatic treatment of anxiety and panic disorder. They are also used for insomnia due to their sedating effect. Benzodiazepines differ in their onset of action, duration of action and relative potency. See Table 1 below for details on specific benzodiazepines.

TABLE 1: BENZODIAZEPINE DOSAGE FORMS AND PHARMACOKINETICS

Generic name	Dosage forms	Onset of Action[1]	Relative Potency (mg)[2]	Duration (hours)[2]
Alprazolam	IR Tab: 0.25, 0.5, 1, 2mg Oral solution: 1mg/mL ODT tab: 0.25, 0.5, 1, 2mg XR tab: 0.5, 1, 2, 3mg	Intermediate	0.5	IR: 5 XR: 11
Chlordiazepoxide	Cap: 5, 10, 25mg	Intermediate	10	
Clonazepam	Tab: 0.5, 1, 2mg ODT tab: 0.125, 0.25, 0.5, 1, 2mg	Intermediate	0.25-0.5	12
Diazepam	Tab: 2, 5, 10mg Oral solution: 5mg/mL Injection: 5mg/mL Rectal gel: 5mg/mL	Rapid	5	Variable (dose and frequency dependent)
Flurazepam	Capsule: 15, 30mg	Rapid	15	7-8
Lorazepam	Tab: 0.5, 1, 2mg Oral solution: 2mg/mL Injection: 2mg/mL, 4mg/mL	Intermediate (PO tab) Rapid (Soln, Inj)	1	6-8
Midazolam	Oral syrup: 2mg/mL Injection: 1mg/mL, 5mg/mL	Rapid	5 (PO) 2 (IV)	2
Oxazepam	Cap: 10, 15, 30mg	Slow	15-30	
Temazepam	Cap: 7.5, 15, 22.5, 30mg	Slow	10	
Triazolam	Tab: 0.125, 0.25mg	Intermediate	0.25	6-7

1. Rapid onset= within 15 minutes, Intermediate= 15-30 minutes, Slow= 30-60 minutes
2. Approximate. Duration of action is determined by redistribution rather than by metabolism, therefore half-life is not a good determination of duration of action (LexiComp Drug Information Handbook).

Benzodiazepines with faster onsets of action and shorter half-lives tend to have higher abuse potential and increased risk and severity of withdrawal syndromes. Common adverse effects of benzodiazepines include confusion, dizziness, sedation, short-term memory loss, disinhibition,

ataxia, blurred vision, slurred speech, and muscle weakness. Benzodiazepines are associated with an increased risk of hip fractures when used short-term in older adults. Benzodiazepines can impair the ability to drive a vehicle or operate heavy machinery.

Long-term use of benzodiazepines is associated with depression, cognitive impairment, increased rates of motor vehicle crashes, increased rates of falls and hip fractures, and increased rates of mortality. Chronic exposure to benzodiazepines alters the regulation of GABA-A receptor subunits and can lead to tolerance, physical dependence, and withdrawal. Investigations of the association between use of benzodiazepines and cognitive decline have yielded mixed results. However, there is a body of evidence suggesting chronic benzodiazepine use is associated with cognitive decline and dementia. Chronic use of benzodiazepines is not recommended.

Benzodiazepines are not recommended for use in Post-Traumatic Stress Disorder as they are associated with lack of efficacy, worse overall severity, worse psychotherapy outcomes, aggression, depression, and substance use. They may interfere with the extinction of fear conditioning and/or potentiate the acquisition of fear responses and worsen recovery from trauma.

Drug Interactions: See Appendix 1 (Table 5) for information about drug interactions.

Discontinuation after Chronic Use: Discontinuing benzodiazepines after chronic daily administration is associated with withdrawal symptoms including sleep disturbances, irritability, panic attacks, hand tremor, sweating, difficulty concentrating, nausea, dry retching, headaches, palpitations, muscular pain/stiffness, and perceptual changes. Very serious withdrawal may include seizures or psychotic symptoms. Withdrawal phenomena tend to be more severe following withdrawal from high doses or short-acting benzodiazepines. Benzodiazepines should always be tapered rather than ceased abruptly, unless a very severe adverse effect requires rapid discontinuation.

The EMPOWER trial mailed 148 chronic benzodiazepine consumers aged 65-95 an 8-page education brochure on the risks of taking sedative-hypnotics along with a picture of a 20-week tapering protocol. After 6 months, 27% of individuals who received this intervention had discontinued their benzodiazepines and an additional 11% had reduced their dose. This handout can be given to patients as an educational tool to support patients during a taper of a sedative-hypnotic: https://media.api.sf.gov/documents/EmpowerPatientHandout_B4mNLBK.pdf

Pregnancy: It is important to remember that every pregnancy has at least a 3-5% change of a birth defect ("background risk"), and the use of medication during pregnancy should involve an individualized risk-risk-benefit discussion of the risk (to both mother and baby) of untreated or undertreated mental illness, the risk of medication, and the potential benefit of the medication treatment.

While some studies indicated that the use of benzodiazepines during the first trimester is associated with an increased risk of congenital malformations such as cleft lip or palate, particularly at higher medication doses, other studies, including recent data from the Massachusetts General Hospital National Pregnancy Registry for Psychiatric Medications, have

not found this association. Maternal use in the third trimester is also associated with infant withdrawal syndromes that may persist for several months after delivery. If use of a benzodiazepine is needed during pregnancy, lorazepam may be relatively favorable due to its lack of active metabolites and short half-life. Intermittent use of benzodiazepines is less likely to induce withdrawal symptoms in the infant.

Lactation: The American College of Obstetrics and Gynecology (ACOG) rates benzodiazepines as L3, moderately safe, and generally views benzodiazepines as compatible with breastfeeding. Shorter acting benzodiazepines are preferred in order to minimize any effect on the breastfed infant. Benzodiazepines are generally found in low levels in breastmilk. Reports of sedation, poor feeding, and respiratory distress have been published and are mostly associated with longer acting benzodiazepines such as diazepam and clonazepam. Pre-term infants and newborns may have reduced ability to metabolize benzodiazepines, and there is concern about medication accumulation in those infants. Adverse effects in infants are rare with lorazepam, midazolam, and oxazepam, so these are the preferred benzodiazepines in breastfeeding women.

Pediatrics: Benzodiazepines have not been well studied in children and adolescents. Due to the associated adverse effects, risk of dependence, and the possibility of a "paradoxical response", their use should be limited in this population. Long-term use is not recommended. There is not consistently good clinical trial data supporting the long-term use of benzodiazepines for insomnia or other disorders in pediatric patients. Other agents such as antihistamines and alpha-adrenergic receptor agonists have been used in pediatric populations to target both insomnia and anxiety; however, the clinical trial data is lacking for the long-term use of these agents in pediatric populations as well.

Older Adults: Older adults are more sensitive to potential side effects of benzodiazepines due to altered pharmacokinetics and pharmacodynamics. Some benzodiazepines undergo Phase I metabolism, which include hepatic oxidation and reduction reactions, while others undergo Phase II metabolism, which include glucuronidation reactions. Phase I metabolism is reduced in older adults while Phase II remains relatively preserved. Benzodiazepines with oxidative pathways and longer half-lives, such as diazepam and flurazepam, are more likely to accumulate in the body and cause prolonged effects. Lorazepam, oxazepam, and temazepam undergo Phase II glucuronidation and are preferred over other benzodiazepines in older adults. Adverse effects in older adults, including sedation, ataxia, falls, delirium, short and long-term cognitive impairment, and disinhibition contribute to increased mortality and higher rates of hospitalization. The risk of dependence in older adults increases with age and is more likely among those with multiple medical conditions, depression, and alcohol use disorder.

The American Geriatrics Society (AGS) publishes a list of potentially inappropriate medications for older adults. The current AGS recommendation is to avoid all benzodiazepines in most adults age 65 years of age or older. When the use of these agents is unavoidable they should be initiated at lower doses, monitored carefully, and used short-term only. Consider reducing the use of other CNS active medications that increase the risk of falls if the patient has a history of falls and a safer agent is not available.

Renal and Hepatic Impairment: See Appendix 1 (Table 4) for information on the use of benzodiazepines in individuals with renal and hepatic impairment. Practice caution if using benzodiazepines in renal or hepatic impairment.

NON-BENZODIAZEPINE RECEPTOR AGONISTS [NBRAs, "z-drugs"]

Introduction: NBRAs (often referred to as z-drugs) include zolpidem, zaleplon, and eszopiclone. While they are not chemically related to benzodiazepines based on their molecular structures, they are also GABA-A positive allosteric modulators. They are approved for use in treating sleep-onset insomnia due to their capacity to decrease sleep latency. Eszopiclone and extended-release zolpidem may be used for sleep maintenance.

Considerations when Initiating Treatment: Table 2 below lists recommended dosage ranges for NBRAs. Current labeling for zolpidem recommends that lower doses be used in women because of reported greater increases in serum concentrations compared with men that could impair the ability to drive or other activities that require mental alertness. Prolonged elevated levels into the following day may also be seen after taking extended-release zolpidem. The FDA also recommends that the starting dose of eszopiclone for all individuals be reduced to 1 mg because of reports of impaired driving skills, memory, and coordination for almost 12 hours after taking an evening dose.

TABLE 2: NBRA DOSAGES AND PHARMACOKINETICS

Generic name	Dosage forms	Onset of Action	Duration	Usual Dose (mg)
Eszopiclone	Tablet: 1, 2, 3 mg	<30 minutes	~8 hours	1-3
Zaleplon	Capsule: 5, 10 mg	<30 minutes	~4 hours	10-20
Zolpidem (immediate-release)	Tablet: 5, 10 mg	<30 minutes	~8 hours	Men: 5-10 Women: 5
Zolpidem (extended-release)	ER tablet: 6.25, 12.5 mg	<30 minutes	~8 hours	Men: 6.25-12.5 Women: 6.25
Zolpidem (sublingual)	Tablet (*Edular*): 5, 10 mg	<30 minutes	~8 hours	Men: 5-10 Women: 5
	Tablet (*Intermezzo*): 1.75, 3.5 mg	20 minutes	~4 hours	Men: 3.5 Women: 1.75
Zolpidem (oral spray)	Spray: 5 mg/100 µL spray	20 minutes	~8 hours	Men: 5-10 Women: 5

Adverse Effects: Psychological dependence is common with NBRAs. Additional common adverse effects of NBRAs include drowsiness, dizziness, and headache. NBRAs can potentially impair next-day cognitive performance and driving ability. Other complex sleep-related behaviors that have been reported with NBRAs include sleep-walking, sleep-eating, and sleep-driving; emergence of these adverse events warrant discontinuation of the medication. NBRA's

are associated with an increased risk of hip fractures when used short-term. NBRAs are controlled substances (Schedule IV) that carry risks of withdrawal, dependence, and abuse.

Drug Interactions: See Appendix 1 (Table 5) for information about NBRA drug interactions.

Pregnancy: Based on limited data, a clear association between NBRAs and teratogenicity has not been identified; the risk of other neonatal outcomes has not been clearly established. There is limited retrospective study data on increased risk of preterm birth or decreased birth weight associated with zolpidem exposure during pregnancy.

Lactation: Based on limited data, zolpidem and zaleplon are known to be excreted in human milk; similar information is not known for eszopiclone. Caution should be exercised when administering NBRAs to a nursing woman.

Pediatrics: The safety and effectiveness of NBRAs have not been established in pediatric patients, so their use cannot be recommended. Controlled clinical studies of their use in pediatric patients with insomnia due to Attention-Deficit Hyperactivity Disorder failed to demonstrate efficacy and there were some reports of hallucinations in children during the studies.

Older Adults: Lower doses of NBRAs in older adults are recommended to minimize adverse events associated with impaired motor and/or cognitive performance, potential for falls, and unusual sensitivity to sedative-hypnotic medications.

Renal and Hepatic Impairment: See Appendix 1 (Table 4) for information on the use of NBRAs in individuals with renal and hepatic impairment.

OREXIN ANTAGONISTS

Introduction: Orexin antagonists are a class of sedative-hypnotics which includes lemborexant, suvorexant, and daridorexant. Their mechanism of action involves blocking the orexin receptors OX_{1R} and OX_{2R}. The orexin signaling system is a central promoter of wakefulness; by blocking this signal orexin antagonists are thought to suppress the wake drive. They are indicated for the treatment of insomnia, with more robust effects on sleep maintenance than on sleep onset. These medications are thought to have fewer cognitive and motor effects than benzodiazepines or NBRAs. They are contraindicated in individuals with narcolepsy. See Table 3 for dosing information.

TABLE 3: OREXIN ANTAGONISTS DOSING AND PHARMACOKINETICS

Generic name	Dose range	Time to peak	Duration (hours)	Comments
Lemborexant	5-10mg	1-3 hours	7+	Time to effect delayed by ~2 hours if taken with a meal
Suvorexant	5-20mg	2 hours	7+	Time to effect delayed by ~1.5 hours if taken with a meal

Daridorexant	25-50 mg	1-2 hours	8+	Time to effect delayed by ~1.3 hours if taken with a meal

Adverse Effects/Warnings: The most common side effects of orexin antagonists include somnolence, headache, and abnormal dreams. Women and obese individuals tend to have higher blood levels of suvorexant compared to men and non-obese individuals at similar doses. This was not observed with the use of lemborexant or daridorexant. Prescribers should carefully assess for dose-related side effects prior to increasing the dose of suvorexant in women and obese individuals.

There are several warnings associated with the use of orexin antagonists. As they are central nervous system (CNS) depressants, individuals should be monitored for daytime somnolence. They can impair driving and increase the risk of falling asleep while driving. Individuals should be monitored for worsening of depression or suicidal ideation while on these medications. Prescribing the lowest feasible number of tablets is advisable in individuals at risk for suicidal behavior. Complex behaviors such as sleep-driving, sleep-eating, amnesia, and hallucinations have been reported with these medications. If any of these behaviors occur, orexin antagonists should be discontinued. Sleep paralysis and hypnagogic/hypnopompic hallucinations may occur. Prescribers should counsel individuals about the possibility and nature of these events.

Drug Interactions: The major metabolic pathway for orexin antagonists is via CYP3A4. See Appendix 1 (Table 5) for information about drug interactions.

Pregnancy: No human data has been published regarding teratogenic risk. Consider enrolling in pregnancy registry if using medication during pregnancy.

Lactation: Amounts of orexin antagonists in milk appear to be low. If they are required by the mother, it is not a reason to discontinue breastfeeding. However, until more data become available, monitor the infant for sedation, especially while nursing a newborn or preterm infant.

Pediatrics: Suvorexant, lemborexant, and daridorexant have not been studied in pediatric patients and their use is not recommended.

Older Adults: No meaningful differences in safety or effectiveness were seen for older adults treated with suvorexant in clinical trials. No dose adjustments are recommended at this time. Adults >65 years experienced more somnolence on the 10mg dose of lemborexant compared to adults <65 years. Caution should be used for doses >5mg in adults >65 years.

Renal and Hepatic Impairment: See Appendix 1 (Table 4) for information on the use of orexin antagonists in individuals with renal and hepatic impairment.

APPENDIX 1: SEDATIVE-HYPNOTIC DOSING REFERENCE TABLES

TABLE 4: SEDATIVE-HYPNOTIC USE IN RENAL AND HEPATIC IMPAIRMENT

Generic Name	Renal Impairment	Hepatic Impairment
BENZODIAZEPINES		
Alprazolam	No dose adjustments	No dose adjustments
Chlordiazepoxide	CrCl ≥ 10ml/min: No dose adjustment CrCl≤ 10ml/min: Reduce dose by 50% Dialysis: Reduce dose by 50%	Undergoes hepatic metabolism. No dose adjustment recommendation provided
Clonazepam	Metabolites may accumulate No dose adjustment recommendation provided	Undergoes hepatic metabolism Contraindicated in significant hepatic impairment.
Diazepam	No dose adjustments	Mild-to-moderate: Reduce dose by 50% Severe: use is contraindicated
Flurazepam	No dose adjustments	No dose adjustments
Lorazepam	No dose adjustments Use is not recommended in severe renal impairment.	No dose adjustments for mild-to-moderate impairment Lower doses may be required for severe impairment.
Midazolam	No dose adjustments Half-life of drug and metabolites may be prolonged.	Duration of action may be prolonged Consider reducing dose if using multiple doses.
Oxazepam	No dose adjustments	No dose adjustments Hepatic dysfunction not expected to decrease drug clearance
Temazepam	No dose adjustments	No dose adjustments
Triazolam	No dose adjustments	No dose adjustments
NBRAs (“Z-DRUGS”)		
Eszopiclone	No dose adjustments in mild to moderate impairment (not studied in severe impairment)	No dose adjustments
Zaleplon	No dose adjustments in mild to moderate impairment (not studied in severe impairment)	Dose reduced in mild to moderate impairment
Zolpidem	No dose adjustments in mild to moderate impairment (not studied in severe impairment)	Dose reduced in mild to moderate impairment
OREXIN ANTAGONISTS		
Daridorexant	No dose adjustments	No dose adjustments for mild to moderate impairment (not

		recommended for severe impairment)
Lemborexant	No dose adjustments	No dose adjustments for mild to moderate impairment (not recommended for severe impairment)
Suvorexant	No dose adjustments	No dose adjustments for mild to moderate impairment (not recommended for severe impairment)

TABLE 5: SEDATIVE-HYPNOTIC DRUG INTERACTIONS

Interaction	Clinical Concern/Comments/Recommendation
BENZODIAZEPINES	
CNS depressants (e.g., opioids, alcohol)	Increased risk of overdose and death. Avoid concomitant use.
CYP3A4 inducers (e.g., carbamazepine, phenytoin)	Decreases levels of alprazolam, clonazepam and diazepam which are metabolized by CYP3A4.
CYP3A4 inhibitors (e.g., fluconazole, diltiazem, grapefruit juice)	Increases levels of alprazolam, clonazepam and diazepam which are metabolized by CYP3A4.
Omeprazole	Increases the concentration of diazepam and prolongs its half-life.
Estrogen containing contraceptives	Increases the concentration of alprazolam. Decreases the concentration of lorazepam, oxazepam and temazepam which are metabolized via glucuronidation.
NBRAs ("Z-DRUGS")	
Alcohol, opioids, other CNS depressants	Additive CNS depressant effects. Avoid combination to reduce risk
CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin)	Decreases in NBRA metabolism may lead to their accumulation with increased risk of toxicity. Use of lower doses may be warranted
CYP3A4 inducers (e.g., rifampin)	Increases in NBRA metabolism may lead to decreased levels and reduced effectiveness. Use of higher doses may be warranted
OREXIN ANTAGONISTS	
CNS depressants (e.g., opioids, alcohol)	Additive CNS depressant effects. Avoid concomitant use due to increased risk of CNS depression
Weak CYP3A4 inhibitors (e.g., ranitidine, cimetidine)	Decreases in orexin antagonist metabolism may lead to their accumulation with increased risk of toxicity Lemborexant: Maximum dose is 5mg Suvorexant: No adjustment needed
Moderate CYP3A4 inhibitors (e.g., atazanavir, ciprofloxacin,	Decreases in orexin antagonist metabolism may lead to their accumulation with increased risk of toxicity Lemborexant: Avoid concomitant use

fluconazole, diltiazem, grapefruit juice)	Suvorexant: Decrease dose to 5mg Daridorexant: Maximum dose is 25mg
Strong CYP3A4 inhibitors (e.g., ketoconazole, ritonavir, nefazodone)	Decreases in orexin antagonist metabolism may lead to their accumulation with increased risk of toxicity. Avoid concomitant use with orexin antagonists
Strong and moderate CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, modafinil, St. John's wort)	Increases in orexin antagonist metabolism may lead to decreased levels and reduced effectiveness. Lemborexant: Avoid concomitant use Suvorexant: Efficacy may be reduced

APPENDIX 2: NON-SEDATIVE-HYPNOTIC TREATMENT OF INSOMNIA

Insomnia is often a symptom of a comorbid condition. Left untreated over time, patients may develop numerous psychological and behavioral issues that exacerbate insomnia, worrying about inability to sleep or daytime consequences of poor sleep, having distorted beliefs about the origin or meaning of insomnia, making schedule changes to accommodate the insomnia, and spending excessive time in bed. Treatment of insomnia should begin by treating comorbidities (such as major depression, pain, and movement disorders) or by eliminating activating medications. Psychologic and behavioral treatment should restructure maladaptive cognitions and establish healthy sleep habits/environments. Short term pharmacological treatment may be used to supplement these therapies. See References section for more information.

PATIENT RESOURCES:
SLEEP DIARY: This can be used by patients to track their sleep patterns.
https://media.api.sf.gov/documents/SleepDiary_Px3IMCI.pdf

SLEEP HABITS DO'S AND DON'TS**:** The American Academy of Sleep Medicine recommends that patients practice good sleep hygiene techniques in combination with other treatments for insomnia. This is an easy-to-read handout that reviews healthy sleep habits that can be given directly to patients.
English: https://media.api.sf.gov/documents/Sleep-Habits-ENGLISH_lwl4Vtl.pdf
Spanish: https://sf.gov/sites/default/files/2024-03/SleepHabits-SPANISH.pdf
Chinese: https://sf.gov/sites/default/files/2024-03/SleepHabits-CHINESE.pdf
Vietnamese: https://sf.gov/sites/default/files/2024-03/SleepHabits-VIETNAMESE.pdf
Tagalog: https://sf.gov/sites/default/files/2024-03/SleepHabits-TAGALOG.pdf
Russian: https://sf.gov/sites/default/files/2024-03/SleepHabits-RUSSIAN.pdf

PROVIDER RESOURCES:
CBT: CBT geared specifically for insomnia (CBT-I) has been found to improve sleep quality, reduce use of sedative-hypnotic medications and improve quality of life in a cost-effective manner. These handouts are outlines of CBT-I sessions and can be used by providers as a guide for nonpharmacological management of insomnia:
https://media.api.sf.gov/documents/CBTforInsomniaHandout_z1AjPuZ.pdf

SLEEP CLINIC REFERRAL: Sleep studies can be beneficial for ruling out medical causes of insomnia such as sleep apnea.

For patients receiving primary care in San Francisco Health Network, e.g., a SFDPH primary care clinic, prescribers using Epic can submit E-Consult to Sleep Study via Add Order function. E-Consult will be routed to sleep study coordinator in the Division of Pulmonary and Critical Care Medicine at Zuckerberg San Francisco General Hospital for scheduling as appropriate.

UCSF Sleep Disorders Center | UCSF Health
(415) 885-7886
Refer by medical provider: Any physician, regardless of specialty, can refer patients
Download referral form and FAX from this link:
https://www.ucsfhealth.org/clinics/sleep-disorders-center

Insurance accepted:

- •Medi-Cal (San Francisco residents only)
- •Medicare (referred by UCSF, SF hospital, or SF clinic)

Urgent consults: Take 72 hours
Non-urgent consults: Take more than 72 hours depending on the volume of patients; will be performed as soon as possible
Visit with sleep specialist required after receipt of referral (sleep specialist will decide need for inpatient overnight study or outpatient monitoring)

NON-SEDATIVE-HYPNOTIC MEDICATIONS:

Non-sedative-hypnotic medications are preferred to sedative-hypnotic medications as the first line pharmacological treatment of insomnia. Table 6 below provides recommendations for non sedative-hypnotic medication therapy for insomnia.

TABLE 6: NON-SEDATIVE-HYPNOTIC MEDICATIONS FOR INSOMNIA:

Name	Dosage Range	Mechanism	Comments
Doxepin*	3-10mg	Tricyclic antidepressant	At 3-6mg, selectivity for H1-R. Doses >10mg will have anticholinergic effects. More pronounced effect on sleep maintenance than onset.
Gabapentin	100-1200mg	Structurally related to GABA, may modulate the release of excitatory neurotransmitters	May also be helpful for neuropathic pain
Hydroxyzine	25-100mg	H1 receptor antihistamine	May be helpful in the short term (see Table 8)
Mirtazapine*	Up to 7.5mg specifically for sleep (7.5mg-45mg for comorbid conditions)	Central presynaptic alpha-2 antagonist	At lowest doses, more selectivity for H1-R. May increase appetite and triglycerides; may cause weight gain
Melatonin	0.5mg-20mg	Melatonin receptor agonist. Low doses intended to aid in circadian shift. Higher doses have more sedative effect.	Consider starting at 0.5-1mg dose in early evening (several hours before bedtime). Lower doses (up to 0.5mg) may be more effective.Works best if combined with exposure to sunlight during the day. Best evidence for sleep cycle disturbances, e.g., due to jet lag.
Ramelteon	8mg	Melatonin receptor agonist	Only for sleep-onset insomnia. Mild therapeutic

			effect, may take several days to experience benefit, very different subjective experience than benzodiazepines. Not covered by many insurance companies
Trazodone*	12.5-300mg	Histamine and alpha-1 antagonism, serotonergic potentiation	Start at low doses, may cause "hangover" feeling in the morning

*See related SFHN BHS Safer Prescribing of Antidepressant Medication Guideline for more information on these medications

APPENDIX 3: NON-SEDATIVE-HYPNOTIC TREATMENT OF ANXIETY, TRAUMA AND OBSESSIVE-COMPULSIVE DISORDERS

GENERAL CONSIDERATIONS: Anxiety, trauma, and obsessive-compulsive disorders encompass a group of conditions including but not limited to Generalized Anxiety Disorder (GAD), Panic Disorder (PD), Social Anxiety Disorder (SAD), Post-Traumatic Stress Disorder (PTSD), and Obsessive-Compulsive Disorder (OCD). These disorders may present alone or co-occur with other psychiatric conditions such as Depression, Bipolar Disorder, Schizophrenia, and Substance Use Disorders.

Proper diagnosis and treatment of other psychiatric conditions may alleviate anxiety, such as antipsychotics for schizophrenia or mood stabilizers for mania. Anxiety may manifest as a symptom of an underlying medical problem or as a side-effect of medications.

Treatment of these disorders should begin by evaluating for and treating any underlying medical problems and by targeting any contributory medications. These disorders may be treated with non-pharmacological interventions, such as psychotherapy and behavioral treatments, as well as with medications. Selective serotonin reuptake inhibitors (SSRIs) are recommended as first line pharmacologic treatment for anxiety, trauma and obsessive-compulsive disorders.

PSYCHOTHERAPY AND BEHAVIORAL TREATMENT: Psychotherapy can help uncover underlying causes of fears, teach patients how to relax and decrease anxiety responses, look at situations in new ways and develop better coping and problem-solving skills. Many people find relief from acute symptoms in 8-10 weeks of focused therapy, with ongoing treatment helpful in maintaining and supporting change. In general, the types of psychotherapy most studied and found to be effective focus on cognitive and behavioral change. Evidence-basedpsychotherapeutic techniques include:

- Cognitive Behavioral Therapy (CBT)
- Behavioral Techniques
- Acceptance and Commitment Therapy (ACT)
- Prolonged Exposure Therapy (PE)
- Cognitive Processing Therapy (CPT)
- Relaxation Techniques
- Breathing Exercises
- Stress Reduction
- Lifestyle changes including diet and physical exercise

MEDICATIONS: Selective Serotonin Reuptake Inhibitors are the medication class with the most evidence to support their use in anxiety, trauma and obsessive-compulsive disorders. See Table 7 below for information on other medications with some evidence for their use in the various disorders. Tables 8 and 9 provide more details about the use of these medications.

TABLE 7: MEDICATION GUIDE FOR ANXIETY, TRAUMA, AND OBSESSIVE-COMPULSIVE DISORDERS

	Generalized Anxiety Disorder	Panic Disorder	Social Anxiety Disorder	Post-Traumatic Stress Disorder	Obsessive-Compulsive Disorder
***Selective Serotonin Reuptake Inhibitors**	√	√	√	√	√
***Serotonin Norepinephrine Reuptake Inhibitors**	√	√	√	√	√
***Mirtazapine**	√	√	√	√	
***Tricyclic Antidepressants**	√	√		√	√
***Monoamine Oxidase Inhibitors**		√	√	√	
Buspirone	√				
Hydroxyzine	√				
Pregabalin	√		√		
Gabapentin	√		√		
Propranolol			√ (performance anxiety)		
Prazosin				√ (nightmares)	
Clonidine/guanfacine				√	
Nefazodone				√	

√ Evidence exists for the use of this medication or medication class for this indication
*See related SFHN BHS Safer Prescribing of Antidepressant Medication Guideline for more information on these medications

TABLE 8: DOSING INFORMATION

Medication	Daily Dose Range	Renal Adjustment	Hepatic Adjustment	Comments
Buspirone	10-60mg	No	No	Works best when used in conjunction with SSRIs/SNRIs. Onset of effect is delayed by 2 weeks, so best if doses daily rather than PRN.
Hydroxyzine	25-400mg in divided doses (limit 100mg in Europe)	Yes	Yes, in cirrhosis	May be helpful for symptomatic use in the short term and as potential alternative to a benzodiazepine PRN. Minimally anticholinergic, but use with caution with higher doses (potential for QT prolongation) and consider additive

				effects of multiple sedating medications.
Pregabalin	150-600mg	Yes	No	May be helpful for discontinuing long term benzodiazepines for those with GAD. Upon discontinuation, dose should be tapered over a week.
Gabapentin	100-1200mg up to TID	Yes	No	Limited evidence for anxiety, but at very low doses, may be helpful in elderly patients. To discontinue steady dose, taper over a week.
Propranolol	10-240mg in divided doses	No	No	Consider if patient's anxiety has strong component of autonomic arousal. **Avoid in patients with asthma or other airway disease**. Monitor blood pressure and heart rate.
Prazosin	1-15mg	Titrate cautiously	No	Helpful for trauma-related nightmares. Start with 1mg and titrate carefully, monitoring blood pressure. Watch out for first dose effect
Clonidine	0.1-0.6mg	Use lower initial doses and monitor closely	No	Decreases sympathetic outflow from the CNS. May be helpful for agitation and hyperarousal not adequately treated by SSRIs. Monitor blood pressure and pulse.
Guanfacine	1-4mg	Use lower doses	Use caution	Decrease sympathetic outflow from the CNS. May be helpful for agitation and hyperarousal not adequately treated by SSRIs. Monitor blood pressure and pulse.
Nefazodone	100-600mg in divided doses	No	Use caution	Take on an empty stomach. **Risk of hepatotoxicity; do not use with known liver disease.** Monitor LFTs every 3-6 months and discontinue therapy if AST/ALT reach 3x or greater the upper limit of normal.

TABLE 9: INFORMATION ABOUT PREGNANCY AND LACTATION

Untreated or undertreated moderate-to-severe psychiatric symptoms during pregnancy have a known and significant risk to both mother and baby. Additionally, every pregnancy has at baseline a 3-5% chance ("background risk") of a birth defect, as well as the possibility of other adverse outcomes such as spontaneous abortion, preterm delivery, decreased birth weight, or neonatal withdrawal symptoms. The use of medication during pregnancy should involve an individualized risk-risk-benefit discussion of the risk (to both mother and baby) of untreated or undertreated mental illness, the risk of medication (such as teratogenesis or neonatal toxicity), and the potential benefit of the medication treatment.

Recommended references for prescribers: Micromedex ("Pregnancy and Lactation" section), Reprotox, LactMed, MotherToBaby.

MotherToBaby also has information sheets for patients for a wide variety of exposures during pregnancy and breastfeeding, including medications: https://mothertobaby.org/fact-sheets/

Consider referring pregnant patients who are taking psychotropic medications for participation in the National Pregnancy Registry for Psychiatric Medications: https://womensmentalhealth.org/research/pregnancyregistry/

Considerations for select medications:

Medication	Pregnancy Considerations	Lactation
Buspirone	Animal studies have failed to demonstrate a risk to the fetus. Human study data is minimal, and risk or safety has not yet been established.	Limited data. Likely low levels in breast milk. Safety has not been established.
Hydroxyzine	Animal studies have demonstrated fetal abnormalities associated with doses substantially above human therapeutic range. In human studies, data varies; thus far, H1 antihistamine exposure during pregnancy has not been clearly associated with teratogenicity or other neonatal adverse outcomes, but some studies conflict. Potential benefits may warrant use in pregnant women despite potential risks, particularly if doses are low and intermittent.	Small occasional doses are most likely compatible with breastfeeding. Larger or more prolonged doses may cause drowsiness or other effects such as decreased milk supply. Monitor infants for drowsiness, adequate weight gain, and developmental milestones.
Pregabalin	Animal studies have demonstrated fetal abnormalities associated with doses substantially above human therapeutic range. In human studies	Limited data. Likely low levels in breast milk. Safety has not been established.

	thus far, there are inconsistent findings regarding teratogenicity or other neonatal risks of pregabalin exposure during pregnancy. If taking anticonvulsant medication throughout pregnancy, folic acid supplementation is recommended.	
Gabapentin	Animal reproduction studies have shown an adverse effect on the fetus at doses similar to or lower than human therapeutic range. However, in human studies thus far, gabapentin exposure during pregnancy is not clearly associated with teratogenicity. Other neonatal risks, including risk of withdrawal, are not well-established. Potential benefits may warrant use despite potential risks. See above re: folic acid supplementation.	Relatively compatible with breastfeeding; monitor infants for drowsiness, adequate weight gain, and developmental milestones. Acceptable for refractory restless leg syndrome during lactation.
Propranolol	Animal reproduction studies have conflicting data regarding adverse effects on the fetus. In human studies thus far, beta blocker exposure is not clearly associated with teratogenicity or other neonatal risks. Potential benefits may warrant use of the drug in pregnant women despite potential risks. Infants should be monitored at birth for bradycardia,	Low levels in breast milk. Considered relatively compatible with breastfeeding at usual doses; monitor infants for drowsiness or feeding difficulty.

	hypoglycemia, and respiratory depression.	
Prazosin	Limited case series of pregnant women have not demonstrated any fetal abnormalities or other adverse effects, but risk or safety have not yet been established.	Limited data. Safety has not been established.
Clonidine	Animal reproduction studies have not shown teratogenicity. Human study data is limited and thus far does not indicate clear association between clonidine exposure during pregnancy and teratogenicity. Risks of other neonatal adverse outcomes have not yet been established.	Limited data. Levels in breast milk may vary. Safety has not been established. Possible association with decreased milk supply. Avoid using when nursing infants born <34 weeks gestation
Guanfacine	Animal studies have not demonstrated fetal abnormalities at doses above human therapeutic range, some increase in rat pup mortality and decrease in pup weight was observed. Human study data is limited and thus far does not show an increase in teratogenicity, but risk or safety have not yet been established.	Limited data. Levels in breast milk are likely low, but may vary. Safety has not been established.
Nefazodone	Animal studies have not demonstrated fetal abnormalities at doses above human therapeutic range, some increase in rat pup mortality and decrease in pup weight was observed. Human study data is limited and thus far does not show an increased risk of teratogenicity, but risk or	Levels in breast milk are likely low. Monitor infants for drowsiness, lethargy, and poor feeding. Adverse effects have been reported in a breastfed preterm infant.

	safety have not yet been established.	

APPENDIX 4: HERBAL SUPPLEMENTS

In the US, herbal supplements are not regulated by the FDA. Purity and potency of available products are unknown. The regulations surrounding herbal supplements do not guarantee that they are effective or safe for anyone to use. Supplements should be reviewed for possible adverse effects and drug interactions before being cleared for patient use. Most insurance plans do not cover herbal supplements, so patients may have to pay out-of-pocket if they wish to try them. Table 10 below describes some supplements used for insomnia, GAD, PD and OCD.

TABLE 10: HERBAL SUPPLEMENTS FOR INSOMNIA, GAD, PD AND OCD

Insomnia			
Supplement	**Dose Range**	**Efficacy**	**Comments**
Valerian Root	400-900mg	Frequently studied with conflicting results	Daytime sleepiness; vivid dreams; may have BZD-like withdrawal symptoms with chronic use
L-tryptophan	1-4 gm	Two out of three published studies showed positive outcomes for sleep	Stomach upset
Magnesium	200-800mg	Evidence is low and variable	Can cause diarrhea (may be less likely with Mg glycinate formulation). If patient with chronic constipation, consider Mg citrate or oxide.
Generalized Anxiety Disorder			
Supplement	**Dose range**	**Efficacy**	**Comments**
Chamomile	1100mg/day	One small randomized trial showed modest efficacy (p =0.047) in mild to moderate GAD.	Well tolerated, though allergies and anaphylaxis reported
Kava	125-250 mg/day	Number of studies found in favor of kava over placebo in anxiety, but results are not consistent.	**Hepatotoxicity,** sedation, tremors, ataxia, visual disturbance, mild euphoria, urinary retention, scaly skin rash with heavy use
L-theanine	200-400mg/day	May provide relief of anxiety symptoms in psychotic disorders, but no evidence to support use in GAD.	Well tolerated
Ashwagandha	250-500mg/day	Has been shown to reduce cortisol levels and anxiety symptoms in some studies. More research is needed.	Rare hepatotoxicity. Check drug interactions.
Silexan (lavender oil preparation)	80-160mg/day	Meta-analysis of five randomized placebo-controlled trials showed superiority (at 80mg/day dose) to placebo for reducing HAM-A scores and self-rated anxiety. (Caveat: trial researchers received honoraria from the Silexan manufacturers)	Available OTC as Nature's Way "CalmAid." Prescription medication in Germany for treatment of anxiety. Generally well-tolerated, minimal drug interactions. Most common side effect is herbal burps. Rare nausea.
Panic Disorder			

Supplement	Dose range	Efficacy	Comments
Inositol	12-20gm/day	Limited evidence from 2 small studies.	Flatulence, mania
Obsessive-Compulsive Disorder			
Supplement	**Dose range**	**Efficacy**	**Comments**
Inositol	18gm/day	Limited evidence as monotherapy; No evidence for additional benefit as augmentation to SSRI treatment.	Flatulence, mania
N-acetyl cysteine	1200-2400mg/day	Limited evidence from small randomized controlled trial suggest tolerability and efficacy for adjunct treatment.	Well tolerated
Valerian Root	765mg/day	Superior to placebo as monotherapy in one small study.	Somnolence, vivid dreams; may have BZD-like withdrawal symptoms with chronic use

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Safer Use of Psychotropic Medications in Children and Adolescents Guideline

SCOPE: This Safer Use of Psychotropic Medications in Children and Adolescents Guideline is intended to offer psychotropic medication prescribing guidance and resources for providers, clients, their parents, guardians, and the interested general public to increase the safety of psychotropic medication use in children and adolescents. It is not intended to be comprehensive in scope. These recommendations are not a substitute for clinical judgment. Decisions about care must carefully consider and incorporate the clinical characteristics and circumstances of each individual client.

STANDARDS: This document, and our daily practices, are guided by multiple well-accepted guidelines in our field, such as: American Academy Child and Adolescent Psychiatry (AACAP) Practice Parameters Regarding Psychotropic Medications, and the California Department of Social Services and Department of Health Care Services (DHCS) Foster Care Quality Improvement Project California Guidelines for the Use of Psychotropic Medication with Children and Youth in Foster Care with an understanding that research findings and consensus regarding best practices in the field change over time.

RECOMMENDATIONS: Prior to consideration of psychotropic medications for a child or adolescent, a full psychiatric assessment (see relevant AACAP parameters) should be completed. As part of assessment and treatment, the prescriber will consider a multidisciplinary plan of treatment and interventions, and work to ensure these treatments are in place as indicated to address the client's overall behavioral health needs.

Prescribers endeavor to collaborate with the client's primary care and relevant specialty care medical providers as appropriate to the client's needs. Considerations for use of pharmacologic management and medication selection in child and adolescent populations, and medication-specific monitoring, may be found in Medication Resources at the SFDPH website: https://www.sf.gov/resource--2024--medication-guidelines. In addition to baseline height, weight, blood pressure and heart rate done annually on all clients followed by a prescriber, additional, physical and/or laboratory examinations should be considered at baseline and ongoing when indicated. Significant findings should be communicated to the client's other medical provider(s).

Respect of client and family preferences and resource limitations is important. In cases of client/family refusal or non-adherence with minimally acceptable standards for health monitoring, prescribers should document efforts made toward such adherence and the reasons given by clients, parents and guardians for non-adherence.

The evidence-based treatments of substance use disorders among youth are primarily psychosocial and behavioral interventions. These interventions include family-based therapy, cognitive-behavioral therapy, motivational interviewing, contingency management, and harm reduction. The evidence for pharmacological interventions among youth is sparse compared to adults. Despite the lack of robust evidence-based data, pharmacological treatments do have the potential to supplement and potentiate psychosocial interventions and enhance outcomes. While the FDA has approved several medications for treating adult substance use disorders, the only FDA-approved medication for youth (16 years and older) is buprenorphine/naloxone for opioid use disorder.

Several initial and feasibility studies on using medications to treat substance use disorder in adolescents and young adults show positive results and tolerability. The common limitations of these studies include small sample sizes, studies needing replication, and generalizability. Medications showing encouraging results and tolerability in treating substance use disorders in youth are mentioned in Table 1 below. The current available studies suggest that there are no major safety or tolerability issues with the medications listed. Providers are encouraged to consult resources or with providers experienced in treating youth substance use disorders as needed. Any pharmacological treatment must be in combination with psychosocial and behavioral therapies.

MEDICATION CONSENT: Psychiatric medication consent for a minor must be obtained from a parent or legal guardian, per BHS Policy & Procedure for Psychiatric/Psychotropic Medication Consent in Ambulatory Care and per California WIC 369.5(d) and 739.5(d); however, obtaining consent is different for minors in foster care or who are court-dependent (e.g, juvenile court). For a minor in foster care or who is a court-dependent, the consent for psychotropic medication will come from the judicial officer through the JV220 process unless the court has ordered that the parent or legal guardian has retained the authority to approve or deny such medication, as noted in WIC §369.5. Please refer to BHS JV220-223 Policy and Procedure for additional information about the JV220 process.

Substance use disorder treatments are addressed in the California Family Code 6929: "A minor who is 12 years or older may consent to medical care and counseling related to the diagnosis and treatment of a drug- or alcohol-related problem." This Family Code does not allow a minor to receive "narcotic replacement therapy" without the consent of the minor's parent or guardian. While the Family Code 6929 allows a minor 12 or older to consent to SUD treatment, the involvement of parents or legal guardians is strongly recommended. Unless there is a compelling reason not to contact parents and legal guardians, there should be attempts to contact them and these attempts should be recorded in treatment records. There could be situations where disclosing substance use or treatment may compromise the safety of a minor and this clinical decision should be documented in the minor's treatment records. Table 2 contains the required medication consent for minors and recommendations.

TABLE 1: Description of Medication Consent Requirements for Psychiatric and Substance Use Disorder Medications in Minors

	Custody of parent or guardian	**Court dependent**
Psychiatric Medications	**Parent or guardian**	**JV220**
Medications for SUD, except "Narcotic replacement therapy"	**Parent or guardian recommended** or 12–17-year-old minor	**JV220 recommended** or 12–17-year-old minor
"Narcotic replacement therapy" (e.g., methadone, buprenorphine products)	**Parent or guardian**	**JV220**

See Appendices for worksheets that may be used to facilitate the medication assent process for different age groups.

APPENDICES:

1. List of FDA Approved Medications for Children and Adolescents
2. Health Choices Worksheet which are designed to include children and adolescents in the medication assent process.
   2A Very Young Child Medication Assent Form
   2B Middle Child Medication Assent Form
   2C Adolescent Medication Assent Form

REFERENCES/RESOURCES:

San Francisco Health Network Behavioral Health Services Medication guidelines. Available at: https://www.sf.gov/resource--2024--medication-guidelines

American Academy of Child & Adolescent Psychiatry Practice Parameters. Available at: https://www.aacap.org/AACAP/Resources_for_Primary_Care/Practice_Parameters_and_Resource_Centers/Practice_Parameters.aspx

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Appendix 1: Psychiatric Medications with FDA Approval in Children and Adolescents

Antidepressants and Anxiolytics		
Medication	**Indication**	**Age Range**
Amitriptyline	Depressive disorders	12+
Clomipramine	Obsessive-compulsive disorder	10+
Duloxetine	Generalized Anxiety Disorder	7-17
Escitalopram	Major Depression Generalized Anxiety Disorder	12+ 7+
Fluoxetine	Depression Obsessive-compulsive disorder	8-18 7-17
Fluvoxamine	Obsessive-compulsive disorder	8-17
Imipramine	Depression Enuresis	12+ 6+
Sertraline	Obsessive-compulsive disorder	6-17
Antipsychotics and Mood Stabilizers		
Medication	**Indication**	**Age Range**
Aripiprazole	Bipolar disorder Irritability associated with autistic disorder Schizophrenia	10+ 6+ 13+
Asenapine	Bipolar manic and mixed episodes	10-17
Brexpiprazole	Schizophrenia	13+
Chlorpromazine	Schizophrenia/psychosis	6 months+
Haloperidol	Psychotic disorders Tourette's disorder	3-12 3-12
Lithium	Bipolar Disorder	7+
Lurasidone	Bipolar depression Schizophrenia	10-17 13-17
Olanzapine	Schizophrenia Bipolar disorder	13+ 13+
Paliperidone	Schizophrenia	12-17
Pimozide	Tourette's disorder	12+
Quetiapine	Bipolar disorder Schizophrenia	10+ 13+
Risperidone	Irritability associated with autistic disorder Bipolar mania Schizophrenia	5+ 10-17 13-17
ADHD Medications		
Medication	**Indication**	**Age Range**
Amphetamine/ dextroamphetamine	ADHD	3+ (IR); 6+ (XR)
Atomoxetine	ADHD	6+
Clonidine ER	ADHD	6+
Dexmethylphenidate	ADHD	6+
Dextroamphetamine	ADHD	3+
Guanfacine ER	ADHD	6+
Lisdexamfetamine	ADHD	6+
Methamphetamine	ADHD	6+
Methylphenidate	ADHD	6+
Serdexmethylphenidate/ dexmethylphenidate	ADHD	6+
Viloxazine	ADHD	6-17

Narcolepsy Medications		
Medication	**Indication**	**Age Range**
Sodium oxybate	Narcolepsy (excessive daytime sleepiness/cateplexy)	7+
Oxybate salts (Calcium, magnesium, potassium, and sodium)	Narcolepsy (excessive daytime sleepiness/cataplexy)	7+

Appendix 2: Medications for Adolescent Substance Use Disorders

	Medication	FDA Age	Trial Ages	SUD Outcomes
Alcohol use disorder	Naltrexone	Off Label	15+	Mixed - Mostly positive
Cannabis use disorder	N-acetylcysteine	Off Label	13+	Positive
Tobacco use disorder	Nicotine replacement therapy	Off Label	12+	Mixed - mostly positive for patches, negative for nasal spray
	Bupropion SR	Off Label	12+	Positive at 300 mg
	Varenicline	Off Label	17+	Efficacy not established for ages ≤16
Opioid use disorder	Buprenorphine (Buprenorphine / Naloxone)	16+	13+	Positive
	Extended-release naltrexone	Off Label	16+	Positive
	Methadone	Off Label	14+	Positive

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MEDICATIONS FOR NICOTINE USE DISORDERS TREATMENT GUIDELINE

SCOPE: This Medications for Nicotine Use Disorders (MNUD) Treatment Guideline is intended to offer information for providers, clients and the interested public to increase the utilization and effectiveness of MNUD. It is not intended to be comprehensive in scope. These recommendations are not a substitute for clinical judgment, and decisions about care must carefully consider and incorporate the clinical characteristics and circumstances of each individual client.

INTRODUCTION: NUD are chronic, remitting and relapsing diseases characterized by the compulsive use of tobacco and/or other nicotine products despite known negative health and psychosocial consequences. As with many substances with misuse potential, the DSM-5-TR details diagnostic criteria for Tobacco Use Disorder (TUD; specifiers: in early remission, in sustained remission, on maintenance therapy, in a controlled environment, mild, moderate, severe) in addition to Tobacco Withdrawal, and Unspecified Tobacco-Related Disorder. To meet criteria for TUD, clients must exhibit at least 2 out of 11 DSM-5-TR criteria over a 12-month period leading to clinically significant impairment and/or distress. The severity of the use disorder is based on the number of criteria met with mild use disorder associated with 2-3, moderate use disorder associated with 4-5, and severe use disorder associated with 6 or more criteria met. Frequency of nicotine use as well as earlier age of use onset are associated with higher severity NUD. While the broader term NUD is not used in the DSM5-TR, we are employing it here to acknowledge the increasing importance of also treating non-tobacco-related nicotine use (e.g. electronic cigarettes [e-cigarettes]).

The disease burden from nicotine products can arguably be conceptualized on a relative risk scale. Combustible tobacco products (e.g. cigarettes, cut tobacco, bidis, cigarillos, water pipe tobacco, western pipe tobacco, smokeless tobacco, and cigars) occupy the highest risk category. Orally delivered tobacco products (e.g. chewing tobacco, dip tobacco, snus) are in a moderately lower risk category. E-cigarettes and heat-not-burn devices occupy a mildly lower risk category. Finally, traditional NRT (e.g. nicotine gums, lozenges, patches) is the second lowest risk category next to not using nicotine at all. From a harm reduction perspective, one goal may be to help those with NUD move from higher risk category use to lower risk category use and ideally abstinence. Clinical professional organizations' expert opinions, recommendations, and guidelines will likely be changing in the face of increasing publications of randomized control trials (RTCs) on non-combustible NUD treatments.

In the past 60 years smoking rates have significantly declined from approximately 40% prevalence in 1965 to 11.6% in 2022. The use of e-cigarettes and other electronic nicotine delivery systems has remained somewhat stable in adults over the last 20 years with a recent increase from 4.5% in 2021 to 6% in 2022. Rates of e-cigarette use in middle and high schoolers increased steadily from 2011 to a peak in 2019 of 27.5% and decreased to 5.9% in 2024. Smoking rates have also decreased in people with mental health (MH) and/or substance use disorders (SUD) and these populations still experience double the rates of NUD. Nearly half of all deaths occurring in those being treated for SUD and/or severe MH disorders are due to tobacco-related illnesses and tobacco-related deaths occur decades earlier than in the general population. Most people with SUD and MH disorders want to quit using nicotine products and want

information and resources to aid in so doing and are in many cases willing and ready to attempt to quit using nicotine products.

Challenges to NUD treatment in the SUD and MH populations include a history of tobacco used as a therapeutic tool in treatment facility settings, lack of adequate staff training, lack of knowledge about treatment resources, and time constraints. Providers and clients alike may share concerns about MH or SUD symptom relapse/exacerbation. On the contrary, persons who abstain from tobacco use during SUD treatment are less likely to relapse to other drugs or alcohol. Although it is not uncommon for people to believe that nicotine helps improve or control MH symptoms, research suggests that nicotine use is associated with greater depressive symptoms, anxiety and an increase in suicidal behavior. People with depression, schizophrenia and post-traumatic stress disorder can quit without impairing their mental health recovery. Having a psychiatric disorder can make this population more susceptible to relapses related to stress and other emotional drivers. In fact, a psychiatric diagnosis is a risk factor for relapse even for those who have not smoked in more than one year. Clients and providers may expect failure to quit as the rule, not the exception. Despite this misconception, this population can stop smoking at rates comparable to those in the general population. Nicotine use should be routinely and aggressively treated within behavioral health systems. To this end, DHCS and SFDPH BHS Pharmacy reimburse for and cover MNUD. Treatment should include both counseling and medication interventions as well as relapse support offered well past the point of cessation.

ASSESSMENT AND INTERVENTION PLANNING: A comprehensive approach to addressing quitting is summarized in Table 1. See Appendix 1 for resources available to clients and providers.

Table 1: "5 A's" Algorithm

ASK	
Ask about nicotine use at every encounter	Identify all nicotine users and determine nicotine product used, quantity and current tobacco use status **Suggested Dialogue:** "Lisinopril is used to treat hypertension which is often made worse by nicotine products. Do you, or does someone in your household smoke or use nicotine?" "Anxiety is made worse by nicotine. Do you, or does someone in your household smoke or use nicotine?"
ADVISE	
In a clear, personalized, non-judgmental message advise every nicotine user to quit	**Suggested Dialogue:** "As your medical provider I want to encourage you to consider cutting down or quitting smoking/nicotine use." "I'm concerned about your smoking/nicotine use and how that is affecting your goal to stop drinking alcohol. Did you know that some research has shown when you stop drinking and using nicotine products at the same time you can improve your chances of successfully quitting both?"
ASSESS	
Assess willingness to make a quit attempt in the next month Discuss client specific benefits Identify client's position on readiness to change model	**Preparation**: Ready to make a quit attempt in the next 30 days → Proceed to Assist **Pre-Contemplative:** Not ready to quit in the next 6 months → Offer empathy and autonomy support. Offer to set a date in the future to check-in and provide motivational intervention.

	Contemplative: Ready to quit in the next 6 months → Schedule a follow up "what is getting in the way of you quitting now?" **Maintenance:** Quit for longer than 6 months → Relapse prevention
ASSIST	
Aid client in quitting	See Appendix 2 Nicotine Cessation Client Interview 1) Assess nicotine use history 2) Set a quit date "have you thought about a quit date?" a. Alternative: recommended practicing not smoking for 24 hours and seeing how it goes→ then setting a quit date 3) Develop a quit plan which may include: a. Referral to resources (see Appendix 1) b. Identifying social support/resources c. Identifying pattern of use/triggers d. Planning coping skills and routine changes e. Exploring past attempts and identifying what worked well and what didn't work well f. Determining preferred method of cessation (medication-assisted, cold turkey, reduction)
ARRANGE	
Schedule follow-up contact	The highest risk of drop-out is within the first 7 days. Some evidence suggests more contact with mental health clients leads to more success. Actions during follow-up: 1) Congratulate any successes 2) Review wins and challenges 3) Assess pharmacotherapy Minimum follow-up frequency: 1) First contact within the first week after the quit date 2) Second contact within the first month after quit date 3) Further contact as needed

NICOTINE WITHDRAWAL: Nicotine causes physical dependence and tolerance to the user. When quitting, nicotine withdrawal symptoms can peak in the first three days. Symptoms typically subside over the next three weeks but may continue for months. Symptoms include negative mood, urges to use, difficulty concentrating, increased appetite/weight gain, insomnia, irritability, anxiety, and restlessness. About half of nicotine users experience at least four of these symptoms when they quit. Any of the first-line pharmacologic agents described below are efficacious in reducing withdrawal symptoms. Clients that report prolonged cravings and withdrawal may be candidates for extended treatment or a combination of pharmacotherapy agents to target symptoms. See Appendix I for client resources regarding nicotine withdrawal and behavioral strategies to treat nicotine withdrawal symptoms and cravings.

NICOTINE USE DISORDER PHARMACOTHERAPY: The use of pharmacotherapy doubles the rate of abstinence from smoking compared to "cold-turkey" approaches. Three pharmacologic modalities are approved by the US Food and Drug Administration (FDA) for the treatment of tobacco-related NUD and include: nicotine replacement therapy (NRT), varenicline, and bupropion. These agents have different mechanisms of action and should be used with the consideration of client specific factors and preferences.

The goal of treatment is complete abstinence from smoking. Clients who fail to quit, but reduce the number of cigarettes per day, still incur the negative health risks associated with smoking. The health benefits of smoking reduction are not well studied, however clients that are able to reduce their smoking are more likely to quit in the future. Pharmacotherapy can even increase quit rates in light smokers (<5 cigarettes/day). Best outcomes are obtained when pharmacotherapy is used with behavioral counseling. See Appendix 3 for a summary of pharmacotherapy options available, common side effects, and dosing recommendations.

Recent RTCs and meta-analytic reviews suggest that e-cigarettes can help smokers quit at rates equivalent or higher than FDA approved MNUD. This option may be a viable harm reduction approach for some clients who can completely stop smoking with the use of e-cigarettes. Given the known short-term risks and the unknown long-term effects of e-cigarette use, no professional organizations currently endorse encouraging clients to adopt this approach to smoking cessation.

MNUD for e-cigarette use is an active area of research. RTCs and meta-analytic reviews indicate that varenicline may help people quit e-cigarettes while combination NRT or bupropion for this indication are inconclusive currently. Depending on the amount of nicotine consumed, some e-cigarette users may require higher than usual doses of NRT given some e-cigarettes can contain very high concentrations of nicotine and this is an active area of research. Please see this link for an example of an e-cigarette cessation MNUD guideline for adults:
https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH%20Document%20Library/Community/CessationServicesandResources/VapingCessationGuideforPharmacists2019TRC.pdf

NRT: NRT relieves nicotine withdrawal symptoms and is used to treat nicotine cravings. The combination NRT, using long-acting nicotine (transdermal patch) plus short-acting nicotine as needed (e.g. gum or lozenge) is more effective than either alone, however the choice is based largely on client preference. Additionally, NRT can safely be added to varenicline or bupropion to improve abstinence rates.

Side effects: Treatment side effects differ depending on route of administration. Thorough education of how to use each product is necessary to maximize benefit and limit side effects. For clients that experience vivid dreams with the nicotine transdermal patch, it is suggested to remove the patch at bedtime. Clients that complain of gastrointestinal symptoms with nicotine gum products should be educated on proper gum chewing technique to minimize oral ingestion of nicotine. Those with temporomandibular joint disease, poor dentition, or dental appliances may find nicotine lozenges easier to use compared to the gum.

Drug interactions: There are no clinically meaningful drug interactions with nicotine in any of the routes of administration described. Some clients may experience increased side effects (i.e. nausea, headache, indigestion) to NRT when used in combination with varenicline, however the mechanism to this interaction is unknown.

VARENICLINE: Varenicline is an oral, partial agonist of the nicotinic acetylcholine receptor reducing withdrawal symptoms including cravings and decreasing nicotine's reinforcing properties. Randomized controlled trials with varenicline suggest a more robust quit rate in the general population when compared to other monotherapy treatment modalities. When compared to combination NRT, varenicline did not show superior efficacy and produced similar quit rates. Varenicline allows for an alternative gradual approach to quitting for clients who are not able or willing to quit completely. The American Thoracic Society 2020 Guidelines for Initiating Pharmacologic Treatment in Tobacco-Dependent Adults strongly recommend varenicline over nicotine patches alone or bupropion alone for initiating treatment in adults with tobacco dependence. Those guidelines also strongly recommend starting varenicline for adults who are not ready to discontinue tobacco use rather than waiting until they are ready to stop tobacco use.

Side effects: Varenicline carried a boxed warning regarding potential neuropsychiatric side effects (e.g. behavioral changes, hostility, agitation, depressed mood, and suicidal thoughts and attempts) that was removed in 2016 after more subsequent studies demonstrated no difference in neuropsychiatric side effects compared with NRT or bupropion in people with NUD with or without psychiatric comorbidities.

Drug interactions: There are no clinically meaningful pharmacokinetic drug interactions with varenicline. Some clients may experience increased side effects (i.e. nausea, headache, indigestion) to NRT when used in combination with varenicline, however the mechanism to this interaction is unknown.

BUPROPION: Bupropion is an oral antidepressant medication that enhances norepinephrine and dopamine release in the brain. Its exact mechanism to aid in smoking cessation is not known. It can be considered for those with underlying depression but is also effective in those that are not diagnosed with depression. Bupropion can potentially reduce the amount of weight gain associated with smoking cessation and can be considered in clients for which this would be a concern. When used as monotherapy for the treatment of NUD, bupropion demonstrates slightly lower abstinence rates than other first-line therapies.

Side effects: Bupropion reduces the seizure threshold in a dose-dependent manner and should be avoided in clients with a known seizure disorder or predisposition to seizure (e.g. alcohol withdrawal, bulimia nervosa).

Drug Interactions: The major metabolic pathway for bupropion is via CYP2B6 and acts as a moderate inhibitor of CYP2D6. See Table 2 for more information about drug interactions.

Table 2: Bupropion Drug Interactions

Interaction	Clinical Concern
CYP2D6 substrates (ex: fluoxetine, tamoxifen, risperidone, beta-blockers, tramadol)	Increased concentrations of 2D6 substrates when co-administered with bupropion.
CYP2B6 inducers (ex: phenytoin, carbamazepine, rifampin)	Decrease in bupropion exposure when co-administered. Efficacy may be reduced.
MAO inhibitors in preceding 14 days or concurrent use of reversible MAO inhibitors	Increased risk of hypertensive reaction. Combination is contraindicated.

DURATION OF TREATMENT WITH NUD MAT: All clients who initiate pharmacotherapy should have initial follow-up via an office visit or phone call within one to two weeks to assess for positive responses, side effects, and medication optimization. The optimal duration of MNUD has not been established, even for longer-studied TUD interventions.

NRT manufacturers recommend treatment for two to three months, however BHS recommends continuing NRT until the client feels they are no longer at risk for relapse as continued pharmacotherapy can help prevent relapse. When treated with NRT for two months relapse rates are up to 80% during the first year following NRT cessation. It is estimated that approximately 50% of relapses could be averted with extended NRT use past the recommended guidelines. Long-term treatment with NRT (> 6 months) has not been associated with additional major health risks or adverse effects and is preferable in clients who are at high risk of relapsing to cigarette use. Clients with prolonged use may be at higher risk of nicotine withdrawal when stopping their NRT and should be tapered using a lower dose patch, gum, or lozenge. Insurance companies may not cover smoking cessation medications beyond three months and may require additional authorizations for continued use.

Clients may benefit from continuing varenicline after the recommended 12 weeks to prevent relapse. Safety and efficacy have been established up to 6 months of continued use.

The duration of treatment with bupropion may be influenced by other indications outside of NUD (i.e. depression, ADHD) that would require longer term treatment. The recommended duration of treatment with bupropion for TUD is 7-12 weeks, however safety and efficacy has been established up to 12 months of continued use.

SELECTION OF MNUD: Appendix 4 provides decision guidance in selecting pharmacologic therapy. Recommendations are based on RCTs, availability, and other practical considerations. Client preference and co-morbid conditions should be considered when choosing an initial agent as the three different treatment modalities have relatively comparable abstinence rates ranging from 20-35%. Clients with no response to the initial agent at four weeks should have a re-assessment of their treatment to determine if a change in medication is indicated. Medication dosing and administration should be reviewed to ensure adherence and proper use. Those with a partial response to the initial treatment may benefit from the addition of a second agent based residual symptoms such as ongoing withdrawal or cravings. For clients who successfully quit then relapse, the medication that previously worked should be considered again.

OFF-LABEL AGENTS WITH INSUFFICIENT EVIDENCE TO RECOMMEND AS FIRST-LINE THERAPY

Nortriptyline: Nortriptyline is a tricyclic antidepressant medication with modest evidence for use in TUD. It can be considered for clients who require adjunctive treatment to a first-line therapy. It may be poorly tolerated in many clients due to sedation, dry mouth, constipation, and dizziness. Nortriptyline should be avoided in clients at risk of arrhythmias, bipolar disorder, and those at risk of overdose.

Clonidine: Clonidine has limited evidence to support its use in smoking cessation with conflicting efficacy study results. Side effects such as drowsiness, fatigue, and dry mouth may further limit its use. A drawback to clonidine is its risk of withdrawal symptoms, including rebound hypertension, diaphoresis, insomnia, headache and anxiety/agitation. Immediate release oral clonidine products should be slowly dose reduced over 6-10 days. Use of clonidine oral tablets should be considered carefully with regards to clients' ability to tolerate a BID or TID regimen and ability to taper off once treatment is complete

CO-OCCURING DISORDERS AND SPECIAL POPULATIONS

Cardiovascular disease: In those with stable cardiovascular disease (CVD) the same treatments can safely be used as the general population. Caution should be used with NRT in the first two weeks immediately following a myocardial infarction because of its potential to increase cardiac demand.

Pregnancy: Smoking during pregnancy is the most important modifiable risk factor associated with adverse pregnancy outcomes. Smoking cessation before pregnancy is most beneficial or early in pregnancy is more beneficial for the mother and fetus, however quitting at any time in pregnancy can provide benefit. The U.S. Clinical Practice Guideline and American College of Obstetrics and Gynecology state that pregnant smokers or nicotine users should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. It is reasonable to consider pharmacotherapy in women who are unable to quit and are at high risk for continued smoking throughout pregnancy. In pregnancy, NRT should be used with the clear goal of the client to quit smoking and with close supervision after discussing the risks of continued smoking against possible risks of NRT. There is no strong evidence that pregnant smokers who use NRT are at higher risk of adverse events than pregnant smokers not using NRT. Bupropion can also be considered in this population after discussing the risks and benefits of treatment. Bupropion is known to cross the placenta and is associated with a low risk of teratogenicity. Varenicline is not recommended for use in pregnancy due to limited safety information.

Lactation: The Committee on Drugs of the American Academy of Pediatrics recommends NRT as the preferred pharmacotherapy in breastfeeding women. Although nicotine passes into breast milk, the risks associated with smoking are deemed to be of greater harm. Nicotine may have adverse effects on the infant, such as interfering with lung development and increasing the risk of sudden infant death syndrome. Bupropion and its active metabolites are present at low concentrations in breast milk. It may be used in breastfeeding women after discussion of the potential risks of exposure that include vomiting, jitteriness, sedation, and potential seizures. Data on varenicline in humans is not available and thus should be avoided in breastfeeding women.

Co-occurring mental illness: Those with mental illness are often more nicotine dependent than the general population and may need higher doses, longer duration of treatment, and combined medications to optimize therapy. Clients on medications for the treatment of their mental illness may incur changes in medication blood levels depending on their smoking status. This drug interaction is due to the induction of CYP 1A2 secondary to the hydrocarbons found in smoke that are inhaled from cigarettes; therefore, nicotine replacement therapy would not have the same effect. See Appendix 5 for a summary of psychotropic medications susceptible to this interaction. Monitoring medication side effects and symptoms of illness are necessary as a client quits smoking or relapses to determine if a dose change is required.

Depression: Consider using bupropion for clients with a diagnosis of depression although bupropion's efficacy has been shown independent of depressive symptoms. The largest smoking cessation study in adults did not demonstrate differences in neuropsychiatric adverse events in those with or without depression between those treated with varenicline or bupropion or NRT plus placebo and varenicline demonstrated higher efficacy compared to bupropion or NRT.

Schizophrenia: For individuals with NUD and comorbid schizophrenia, varenicline or bupropion, with or without NRT, are recommended first line agents. Bupropion should be used with caution and close monitoring in these situations since it can worsen positive psychotic symptoms.

Bipolar disorder: For individuals with bipolar disorders and NUD, NRT, bupropion, and varenicline are effective and well tolerated pharmacotherapies when paired with behavioral support. Caution with the use of bupropion in this population may be warranted given the theoretical potential of switching to manic/hypomanic episodes although this has not been found in larger studies.

Anxiety disorders: Varenicline showed higher efficacy with greater abstinence rates compared to bupropion or NRT, although each was also effective, and did not increase anxiety.

Substance use disorders: Clients with a co-occurring substance use disorder have the highest prevalence of smoking among people with mental illness reaching as high as 98%. Some evidence supports treating NUD improves treatment of other substance use disorders. Clients with comorbid substance use disorders have a lower abstinence rate than the general population and may benefit from more intensive behavioral interventions. Active substance abuse precludes clients from enrollment into most prospective studies, therefore other patient factors, like comorbidities, should be considered in treatment selection.

Adolescents: Initially, the focus in this group had been primary prevention strategies through public health education and regulatory legislative actions. However, psychosocial and pharmacological interventions are also used to treat NUD in adolescents. The American Academy of Pediatrics (AAP) recommends NRT for NUD in youth despite a lack of FDA approvals citing the effectiveness of NRT in adults and the severe negative health consequences of tobacco and e-cigarette use as the rationale for advocating NRT for minors. In limited studies, the effectiveness of NRT in youth is more modest than in adults and there is no evidence of serious harm from NRT in adolescents. As with adults, the only absolute contraindication for NRT in youth is hypersensitivity. Other relative contraindications like

cardiovascular disease, diabetes, and hyperthyroidism should be considered in minors as well but in general the risks of continued tobacco or e-cigarette use far outweigh the potential risks of NRT. Lower doses of nicotine patches and gum should be used in those with body weight less than 45 kilograms. Youth require a prescription from a healthcare provider to access all forms of NRT since OTC NRT is only available to those 18 years and older. Varenicline and bupropion should be used at the discretion of the clinician in collaboration with the minor and guardian(s) as evidence in this age group is limited. Prescribed MNUD for minors is covered by Medi-Cal. Minors 12-17 years old can consent to MNUD treatment and parental consent is also encouraged. Given known short-term and unknown long-term risks of e-cigarette use, their use in harm reduction approaches to minor tobacco smokers is not advisable. Furthermore, e-cigarettes are not legal to purchase for those under 21 years old and there are no prescribable e-cigarettes, their use in this population is not possible. The AAP strongly advises against the use of e-cigarettes in smoking cessation for minors.

Although adolescents' use of e-cigarettes is very likely less harmful than combustible tobacco, clear evidence exists that this use is associated with medical and mental health symptoms including anxiety, depression, and suicidal ideation and behavior. No current consensus on MNUD for e-cigarette-using youth is available but the AAP position advocates NRT for this population since it is less risky than continued e-cigarette use. Depending on the amount of nicotine consumed, some e-cigarette users may require higher than usual doses of NRT given some e-cigarettes can contain very high concentrations of nicotine and this is an active area of research. Varenicline also helped adolescents quit using e-cigarettes in a recent RCT. Please see this link for an example of an e-cigarette cessation guideline for adults that may assist in treating e-cigarette use in adolescents:
https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH%20Document%20Library/Community/CessationServicesandResources/VapingCessationGuideforPharmacists2019TRC.pdf

Older adults: There are no meaningful differences in safety or efficacy in older adults.

Hepatic impairment: NRT can safely be used in hepatic impairment although clearance may be reduced. Bupropion should be used with caution in clients with hepatic impairment and dose reductions are recommended for those with moderate-severe impairment. No dosage adjustment is necessary for varenicline.

Renal impairment: No dosage adjustment is necessary for NRT. Bupropion side effects should be monitored in those with reduced renal clearance. Varenicline requires dose reduction for clients with creatinine clearance less than 30 ml/min. See Appendix 3 for recommendations.

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APPENDIX 1: LOCAL RESOURCES

Program Name	Overview
Free Smoking Cessation Groups	
San Francisco Tobacco Free –Project (TFP) https://www.sf.gov/san-francisco-tobacco-free-project 25 Van Ness, Avenue, 5th floor San Francisco, CA 94102 Phone: (628) 206-7668 Email: tfp-chep@sfdph.org	This program provides free cessation support through quit-smoking classes, coaching, and "SF Quit! Kits" with helpful tools and resources. TFP also leads public health advocacy, including successful efforts to ban flavored tobacco and limit retail sales near schools.
We Breathe https://californialgbtqhealth.org/about-us/we-breathe/ 1127 11th Street, Suite 925 Sacramento, CA 95814 Email: info@californialgbtqhealth.local Phone: 916-497-0923	We Breathe provides expertise on working with LGBTQ communities, preventing and reducing tobacco use among LGBTQ Californians, and addressing tobacco-related health disparities within LGBTQ communities by fostering culturally competent strategies and policies.
Northern California Intergroup of Nicotine Anonymous https://www.nica-norcal.org/ 2261 Market Street, #229-A San Francisco, CA 94114	A 12-step help program.
Free Phone and Online Programs	
Kick It California (KIC) https://kickitca.org/ English: 1-800-300-8086 Spanish: 1-800-600-8191 Mandarin & Cantonese: 1-800-838-8917 Vietnamese: 1-800-778-8440 Korean: 1-800-556-5564 Deaf/Hearing Impaired: 1-800-933-4TDD **Text Program:** **"quit smoking" to 66819** **"quit vaping" to 668919**	KIC offers free quit support via multiple channels such as phone, text messaging, mobile apps, and online chat plus self-help materials. Online help is available in six languages to help clients quit smoking.
quitSTART smartphone app https://www.cdc.gov/tobacco/campaign/tips/quit-smoking/quitstart-app/	A free smartphone app is a product of Smokefree.gov, a smoking cessation resource created by the Tobacco Control Research Branch at the National Cancer Institute in collaboration with the FDA. The app takes personal information about a person's smoking history and gives tips, inspiration, and challenges to assist in becoming smokefree.
Smokefree.gov https://smokefree.gov/ **Text Program:** **"quit" to 47848**	An online website created by the Tobacco Control Research Branch at the National Cancer Institute that provides free, accurate, evidence-based information and professional assistance to help support the immediate and long-term needs of people trying to quit smoking. Smokefree.gov offers free text messaging 6-8 weeks program that give 24/7 encouragement, advice, and tips for becoming smokefree. It also provides specialized resources for women, veterans, and teens.
Resources for Providers	

Rx for Change http://rxforchange.ucsf.edu/	Clinician-Assisted Tobacco Cessation is a comprehensive tobacco cessation training program that equips health professional students and practicing clinicians, of all disciplines, with evidence-based knowledge and skills for assisting clients with quitting. UCSF and the Purdue University College of Pharmacy openly shares the Rx for Change materials with others at no cost; however, all persons who receive any component of the Rx for Change program must complete an online registration process. Rx for Change can be used only for non-commercial teaching and research purposes and cannot be used for profit.
Smoking Cessation Leadership Center https://smokingcessationleadership.ucsf.edu/	A national program office of the Robert Wood Johnson Foundation at the University of California, San Francisco reduces disparities in tobacco use and increases cessation through community partnership. Their goal is to drive health systems change by eliminating barriers to access to tobacco treatment, promoting tobacco policy that supports cessation, and providing education and training.
Kick It California (KIC) **1800-300-8086** https://kickitca.org/education-training e-Referral link: https://kickitca.org/patient-referral	Kick It California (KIC) provides training for the California Smokers' Helpline. KIC helps organizations with professional training, structure and provides the following free services: • Providers can refer tobacco users to KIC to get a free, personal quit plan from trained coaches via the e-referral link. • Free training and technical assistance such as webinars, continuing education opportunities, and training for integrating cessation services into practice. • Provider Toolkits complete with webinars and client educational materials (digital and print materials).

APPENDIX 2:

NICOTINE CESSATION CLIENT INTERVIEW FORM

Date: Time: Provider's name:

Section 1: Patient information

Name (Last, First): Date of birth: Gender:

Primary phone number: Home address:

Insurance provider:

BIN	PCN	Cardholder ID	Group number

PCP name: PCP phone number:

Section 2: Medical conditions

Current medical conditions:	Past medical conditions:
1	1
2	2
3	3
4	4
5	5

Section 3: High-risk screening

1	Pregnant or planning to become pregnant in the next 6 months?	No	Yes	IF YES to any, consult with or refer patient to PCP.
2	Heart attack in past 2 weeks?	No	Yes	
3	History of arrhythmias or irregular heartbeat?	No	Yes	
4	Unstable angina or chest pain with strenuous activity?	No	Yes	

Section 4: Other history

1 Family history of nicotine use or nicotine-related diseases?

2 Other medical conditions? (e.g. Do you have serious dental problems or have you been diagnosed with TMJ [pain or popping of the jaw]? If yes, avoid gum. Do you have a history of severe acid reflux or stomach upset? If yes, monitor for exacerbation from gum or lozenges.)

Section 5: Medications and allergies/hypersensitivities

Current medications:

Allergies/Hypersensitivities:

Section 6: Assess Tobacco Use History

ASK: What types of nicotine do you use?

Type	How much and how often (e.g. # cigarettes, # mg nicotine per day)?	How long used?
Cigarettes		
E-cigarettes/JUUL/vaping		
Smokeless tobacco (dip, chew)		
Cigars or cigarillos		
Other:		

ASK: How many minutes after you wake up do you have your first cigarette/tobacco/nicotine?

ASK: Any recent changes in your tobacco/nicotine use?

ASK: Have you tried to quit before? **Y N**

- **If YES:** How many times? When was last quit attempt? Longest quit attempt?

  ASK: Did you call the tobacco quit line or participate in any other form of counseling? **Y N**

  - **If YES:** What did you like, or not like, about it?

  ASK: What quitting medicines have you tried in the past? Discuss effectiveness, withdrawal symptoms, how med was taken (daily and duration), overall experience (does it make sense to try it again?).

  ASK: Main reasons for returning smoking/tobacco/nicotine use? Anticipated challenges this/next time?

- What would you say are the good things about nicotine? What do you like about nicotine?

- What are the not so good things about nicotine? What are your main reasons to quit?

ASK: Are you ready to set a quit date? Y N (if yes, record quit date below under "Documentation")

- On a scale from 0 – 10, (where "0" is not ready to quit smoking and "10" is ready to quit smoking), what score would you give yourself right now?
- If not 0, you gave yourself a score of ___. Why do you think ___ and not a lower number?
- If 0, is there anything that would help raise your score to a 1 or 2?

DOCUMENTATION

IF READY TO SET QUIT DATE, complete the following and initial to the left of each requirement.

___ Discuss medication options and select treatment
___ Ask patient to choose a quit date (if using bupropion SR or varenicline, consider medication start date)

Patient's planned quit date is:

___ Refer patient to Tobacco Quitline (1-800-QUIT NOW) or other program:
___ Document treatment plan
___ Schedule follow-up appointment within 2 weeks of quit date:

Date and time:

Circle one: In-person or Telephone ASK: Confirm preferred contact #

___ Advise patient to follow-up with PCP
___ Contact patient's PCP within 3 business days

APPENDIX 3: FDA-APPROVED MEDICATIONS FOR TOBACCO USE DISORDER

Product	Dosage^	Common Side Effects	Availability	Counseling Points	Advantages	Disadvantages
Short-Acting Products						
Nicotine Gum 2 mg, 4 mg	For the following weeks, use gum as needed for cravings or urges to smoke: Wks 1-6 every 1-2 hrs Wks 7-9 every 2-4 hrs Wks 10-21 every 4-8 hrs *If 1st cig within 30 min of waking: use 4mg* *If 1st cig after 30 min of waking: use 2mg* Use at least 9/day for first 6 weeks if using as monotherapy NTE: 24 pcs/day *for combination NRT, start with 2 mg dose	Mouth/jaw soreness, indigestion, hiccups Dizziness/ lightheadedness N/V, with incorrect technique	Prescription and OTC	• Chew each piece slowly • Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) • Resume chewing when tingle fades • Repeat chew/park steps until most of the nicotine is gone (tingle does not return, generally 30 min) • Park in different areas of mouth No food or beverages 15 minutes before or during use	• Might serve as an oral substitute for tobacco • Can be titrated to manage withdrawal symptoms • Can be used in combination with other agents to manage situational urges • Relatively inexpensive	• Frequent dosing can be problematic with significant dental work • Proper chewing technique is required for effectiveness PRECAUTIONS • Avoid use with TMJ • Recent (</= 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious worsening angina pectoris

^NRT dosing is based on recommendations from package inserts. Clients can safely smoke and continue to use NRT beyond package instructions. We recommend using NRT until the client feels ready to step down therapy or stop treatment with minimal risk for relapse.

Product	Dosage^	Common Side Effects	Availability	Counseling Points	Advantages	Disadvantages
Nicotine Lozenge 2 mg, 4 mg	For the following weeks, take one lozenge* as needed for cravings or urges to smoke: Wks 1-6 every 1-2 hrs Wks 7-9 every 2-4 hrs Wks 10-21 every 4-8 hrs NTE: 20 pcs/day *If 1st cig within 30 mins of waking:* use 4 mg *If 1st cig after 30 mins of waking:* use 2 mg *for combination NRT, start with 2 mg dose Use at least 9/day for first 6 weeks if using as monotherapy	Mouth and throat soreness, indigestion, hiccups	Prescription and OTC	• Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini lozenge) • Nicotine release may cause a warm, tingling sensation • Do not chew or swallow • Occasionally rotate to different areas of the mouth • No food or beverages 15 minutes before or during use	• Might serve as an oral substitute for tobacco • Can be titrated to manage withdrawal symptoms • Can be used in combination with other agents to manage situational urges • Relatively inexpensive	• Frequent dosing • Gastrointestinal side effects can compromise use of lozenge PRECAUTIONS • Recent (</= 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious worsening angina pectoris • Avoid in soy allergy
Short Acting Products						
Nicotine Nasal Spray 10 mg/ml metered spray	Spray 1-2 sprays in each nostril every hour as needed for nicotine cravings. *One dose= 1 spray in each nostril, each spray delivers 0.5 mg.* NTE: 5 doses/hr or 40 doses/day Use at least 8 doses for 6-8 weeks (for monotherapy)	Nasal irritation, change in sense of smell/taste, cough, tearing, headache	Prescription Only	• Avoid with underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) or severe reactive airway disease • Do not sniff or inhale the spray when administering	• Can be titrated to rapidly manage withdrawal • Can be used in combination with other agents to manage situational urges • Shown to be more efficacious than other short-acting NRT	• Frequent dosing • Nasal irritation can be problematic • Relatively expensive PRECAUTIONS • Avoid with underlying chronic nasal disorders • Recent (</= 2 weeks)

^NRT dosing is based on recommendations from package inserts. Clients can safely smoke and continue to use NRT beyond package instructions. We recommend using NRT until the client feels ready to step down therapy or stop treatment with minimal risk for relapse.

Product	Dosage^	Common Side Effects	Availability	Counseling Points	Advantages	Disadvantages
						myocardial infarction • Serious underlying arrhythmias Serious of worsening angina pectoris
Long-Acting Products						
Nicotine Transdermal Patch 7 mg, 14 mg, 21 mg (24-hr release) patches	Place one patch on dry skin every 24 hours as directed*: 21 mg/24 hrs x 4 wks, 14 mg/24 hrs x 2 wks, 7 mg/24 hrs x 2 wks Start with 21 mg patch if smoking > 10 cigs/day and 14 mg patch is ≤ 10 cigs NTE: 21 mg/day (Higher doses may be considered on an individual basis for those that smoke >20 cigs or continue to smoke while using the patch)	Local skin reaction, insomnia, vivid dreams	Prescription and OTC	• Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week • May wear patch for 16 hours if client experiences sleep disturbances (remove at bedtime) • Not recommended for use by clients with dermatologic conditions (i.e. psoriasis, eczema, atopic dermatitis)	• Once-daily dosing • Discreet appearance • Can be used in combination with other agents • Delivers consistent nicotine levels over 24 hours • Relatively inexpensive	• When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms PRECAUTIONS • Avoid with chronic dermatologic conditions (psoriasis, Eczema, atopic dermatitis) • Recent (</= 2 weeks) myocardial infarction • Serious underlying arrhytmias Serious of

^NRT dosing is based on recommendations from package inserts. Clients can safely smoke and continue to use NRT beyond package instructions. We recommend using NRT until the client feels ready to step down therapy or stop treatment with minimal risk for relapse.

Product	Dosage^	Common Side Effects	Availability	Counseling Points	Advantages	Disadvantages
						worsening angina pectoris
Oral Medications						
Bupropion Sustained Release (SR) 150 mg tablet	Begin therapy 1–2 weeks prior to quit date: Take 150 mg PO qAM x 3 days, then 150 mg PO BID **Contraindications:** • Seizure disorder • Current or prior diagnosis of bulimia or anorexia nervosa • Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines • MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors	Insomnia, dry mouth, nervousness/difficulty concentrating, nausea, dizziness, constipation, seizures	Prescription Only	• Allow at least 8 hours between doses • Avoid bedtime dosing to minimize insomnia • Use with caution in clients with concomitant therapy with medications/conditions known to lower the seizure threshold	• May reduce weight gain associated with quitting • May be beneficial in clients with co-morbid depression • Once daily bupropion extended-release (XL) may be used in place of the SR formulation to enhance adherence • Can be used in combination with NRT • Dose tapering is not necessary	• Seizure risk is increased • Several contraindication and precautions preclude use in some clients (see below) • No emergent relief
Varenicline 0.5 mg, 1 mg tablets	Start 1 week before quit date: On days 1-3, take 0.5 mg PO qAM On days 4-7, take 0.5 mg PO BID On weeks 2-12, take 1 mg PO BID Dosing adjustment is necessary for clients with severe renal impairment (< 30 ml/min) to a maximum of 0.5 mg BID	Nausea, vomiting, sleep disturbances (insomnia, abnormal/vivid dreams), constipation, flatulence, taste alteration	Prescription Only	• Take dose after eating and with a full glass of water • Clients that incur sleep disturbances can be instructed to take the evening dose earlier in the day or may require skipping the evening dose • Avoid alcohol while taking • Gradual approach with no defined quit date or if clients continue to smoke	• Offers a different mechanism of action for clients who failed other agents • Dose tapering is not necessary • May provide greater efficacy in the general population compared to other monotherapy • Can be used in combination with NRT	• Cost of treatment • No emergent relief • Clients should be monitored for potential neuropsychiatric symptoms

^NRT dosing is based on recommendations from package inserts. Clients can safely smoke and continue to use NRT beyond package instructions. We recommend using NRT until the client feels ready to step down therapy or stop treatment with minimal risk for relapse.

Product	Dosage^	Common Side Effects	Availability	Counseling Points	Advantages	Disadvantages
				past quit date: Titrate dose as above to 1 mg PO BID. Clients should reduce smoking by 50% in first 4 weeks, then additional 50% in following 4 weeks, continued until abstinence in 12-24 weeks	agents	
Off-Label Agents						
Nortriptyline 10 mg, 25 mg, 50 mg, 75 mg capsules	Take 25 mg PO at bedtime. Increase dose as tolerated by 25 mg/week up to 75-125 mg **Contraindications** MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors	Dry mouth, orthostatic hypotension, cardiac arrhythmia, constipation, urinary retention, sexual dysfunction, sedation	Prescription Only	• Begin therapy 4 weeks prior to quit date • Take at bedtime to avoid daytime sedation • Should be used with caution in clients with a history of cardiovascular disease • Should be tapered off	• May be beneficial in clients with co-morbid depression, anxiety, insomnia, or chronic pain • Relatively inexpensive • Can be used in combination with NRT	• High side effect burden • Dangerous in overdose • May require blood level monitoring
Clonidine 0.1 mg, 0.2 mg, 0.3 mg tablets 0.1 mg/24hr, 0.2 mg/24 hr, 0.3 mg/24 hr patches	**Oral**: Can be started at 0.1 mg PO BID and titrated to 0.4 mg divided TID **Patch**: Apply 0.1 mg/24 hr patch to dry skin every 7 days. Can be titrate based on effect and tolerability.	Decreased heart rate, sedation, orthostatic hypotension, dizziness, dry mouth, constipation	Prescription Only	• Begin therapy 48-72 hours before quit attempt • Do not discontinue abruptly, dose must be gradually reduced • Start medication at bedtime as it can cause drowsiness and dizziness	• May be beneficial in clients with co-morbid ADHD or insomnia • Weekly patch may improve adherence • Relatively expensive	• Can be poorly tolerated due to side effects • Drug interaction and disease states may limit use

^NRT dosing is based on recommendations from package inserts. Clients can safely smoke and continue to use NRT beyond package instructions. We recommend using NRT until the client feels ready to step down therapy or stop treatment with minimal risk for relapse.

APPENDIX 4: TOBACCO USE DISORDER MEDICATION PHARMACOTHERAPY SELECTION

Level of Recommendation	Medication(s)	Pertinent Treatment Considerations (Not exhaustive, see Appendix 3 for additional details)
Strongest	Varenicline	1) Shown to be most efficacious in general and MH populations compared to other monotherapy pharmacologic treatments
	NRT combination: nicotine patch + gum or lozenge	2) Cost-effective 3) Has history of demonstrating superior efficacy over other monotherapy pharmacologic treatments 4) Produces relatively constant levels of nicotine and allows for acute dose titration as needed
Moderate	NRT monotherapy: nicotine patch, gum, or lozenge	5) NRT monotherapy results in significantly lower quit rates than combination NRT 6) If a single NRT agent is preferred, the patch has been shown to be most efficacious.
	Bupropion	7) Least robust effects compared to other pharmacologic treatments 8) Treatment for co-morbid depression 9) Drug interactions, precautions, and contraindications may preclude use in clients with mental health disorders
Lowest	Nortriptyline	10) Moderate efficacy in clients who cannot use a first-line agent or who need an adjunct to first-line therapy 11) Treatment of co-morbid depression, chronic pain, insomnia, and anxiety 12) High side effect burden 13) Dangerous in overdose
	Clonidine	14) Treatment of comorbid ADHD 15) Limited evidence of benefit over placebo

APPENDIX 5: NOTABLE DRUG INTERACTIONS OF PSYCHIATRIC MEDICATIONS WITH HYDROCARBONS FROM TOBACCO SMOKE

Drug/Class	Mechanism of interaction and effects
Alprazolam	Conflicting data on significance, but possible ↓ plasma concentrations (up to 50%); ↓ half-life (35%).
Caffeine	Metabolism (induction of CYP1A2); ↑ clearance (56%). Caffeine levels likely ↑ after cessation
Chlorpromazine	↓ AUC (36%) and serum concentrations (24%). ↓ Sedation and hypotension possible in smokers; smokers may require ↑ dosages.
Clozapine	↑ Metabolism (induction of CYP1A2); ↓ plasma concentrations (by 18%). ↑ Levels upon cessation may occur; closely monitor drug levels and reduce dose as required to avoid toxicity.
Fluvoxamine	↑ Metabolism (induction of CYP1A2); ↑ clearance (24%); ↓ AUC (31%); ↓ Cmax (32%) and Css (39%). Dosage modifications not routinely recommended but smokers may need ↑ dosages.
Haloperidol	↑ Clearance (44%); ↓ serum concentrations (70%); data are inconsistent therefore clinical significance is not established
Methadone	Possible ↑ metabolism (induction of CYP1A2, a minor pathway for methadone). Carefully monitor response upon cessation.
Olanzapine	↑ Metabolism (induction of CYP1A2); ↑ clearance (98%); ↓ serum concentrations (2%). Dosage modifications not routinely recommended but smokers may need ↑ dosages.
Propranolol	↑ Clearance (77%; via side-chain oxidation and glucuronidation).
Ropinirole	↓ Cmax (30%) and AUC (38%) in study with clients with restless legs syndrome. Smokers may need ↑ dosages.
Tizanidine	↓ AUC (30–40%) and ↓ half-life (10%) observed in male smokers.
Tricyclic antidepressants (e.g. imipramine, nortriptyline)	Possible interaction with tricyclic antidepressants in the direction of ↓ blood levels, but the clinical significance is not established.

Not a comprehensive list, for additional interactions see:
https://smokingcessationleadership.ucsf.edu/sites/smokingcessationleadership.ucsf.edu/files/A4%20DI%20TABLE.pdf

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APPROACHES TO CANNABIS USE DISORDER TREATMENT GUIDELINE

SCOPE: This Approach to Cannabis Use Disorder Treatment Guideline is intended to offer prescribing assistance for providers, clients, and the interested general public to increase the effectiveness and utilization of CUD treatment in the ambulatory care setting. It is not intended to be comprehensive in scope. These recommendations are not a substitute for clinical judgment, and decisions about care must carefully consider and incorporate the clinical characteristics and circumstances of each individual client

INTRODUCTION: Cannabis is derived from plants in the Cannabaceae family**, t**he main active chemicals are delta-9 tetrahydro-cannabinol (THC) and cannabidiol (CBD) and their potencies and relative concentrations range widely between preparations. Specific cannabinoids, flavinoids, cannabinol and terpenoids vary between different cannabis strains. Cannabis can be ingested in a variety of ways including smoking the dried flowers, orally through edibles or beverages, or inhaled through vapes or dabs. Delta-8 THC is another psychoactive cannabinoid found in low concentrations in cannabis plants naturally. Products containing delta-8 are generally derived through synthetic chemical conversions and have not been evaluated or approved by the FDA for safe use in any context.

Cannabis is the most commonly used illicit drug in the United States. The 2023 National Survey on Drug Use and Health (NSDUH) found that 21.8% of people 12 or older used cannabis in the past year. While cannabis continues to be illegal at the federal level, 24 states, two territories and D.C. have legalized recreational use in adults over 21 years of age, and 38 states, three territories and D.C. have legalized medical cannabis. The 2020 NSDUH found that 27.4% of people aged 12 or older indicated they perceived that weekly cannabis use as risk for great harm.

Cannabis is used for a variety of social reasons, including enjoyment, experimentation, social enhancement, boredom, relaxation and conformity. It is also commonly used to self-treat a variety of physical and mental concerns, including chronic pain, anxiety, PTSD and insomnia. The efficacy of cannabis for some of these conditions varies and is not considered a first line or second line treatment for any condition.

There are a variety risks associated with cannabis use. A report from the National Academy of Sciences, Engineering, and Medicine found a significant association between cannabis smoking and a variety of negative outcomes including respiratory symptoms in long-term adult smokers, increased risk of motor vehicle crashes, lower birthweight in offspring, and the development of schizophrenia or other psychoses in adolescents. Psychotic disorders may be more likely to occur

in certain predisposed individuals. For example, a longitudinal study found a possible interaction between adolescent cannabis use and a functional polymorphism in the catechol-O-methyltransferase (COMT) gene leading to the development of psychotic disorders in adulthood. Additionally, cannabinoid hyperemesis syndrome is a risk of chronic cannabis use that can result in cyclical episodes of nausea and vomiting that can require emergency care. As with almost every substance with use disorder potential, earlier age of use onset is associated with the development of problem use later in life. With many US and Canadian jurisdictions moving towards legalized/regulated cannabis use, evidence-based "Lower Risk Cannabis Use Guidelines" (LRCUG) have emerged to reduce modifiable risk factors of cannabis-related adverse health outcomes. In general, current evidence suggests that individuals can substantially reduce their risk for adverse health outcomes if they delay the onset of cannabis use until after adolescence, avoid the use of high-potency (i.e., high percentage of THC) cannabis products and high-frequency/-intensity of use, and refrain from smoking routes for administration (see Appendix I).

Cannabis use disorder (CUD) occurs when recurrent use of cannabis leads to significant impairment. The 2023 NSDUH found that 6.8% of people aged 12 and older met criteria for CUD in the past year. The rate of CUD was noted to be highest in those aged 18-25 (16.6%) and those who identify as multi-racial (12.6%). A range of interventions should be considered for all people with CUD, including assessment and management of withdrawal and long-term strategies to reduce any medical and psychosocial harms of CUD. In addition, any co-occurring conditions that jeopardize a person's treatment success should be addressed.

DIAGNOSIS, ASSESSMENT AND INTERVENTION PLANNING:

The DSM-5-TR details diagnostic criteria for CUD (specifiers: in early remission, in sustained remission, in a controlled environment, mild, moderate, severe) in addition to cannabis intoxication (specifier: with perceptual disturbances), cannabis withdrawal, other cannabis-induced disorders, and unspecified cannabis-related disorder. See Appendix II for complete DSM diagnostic criteria.

Several assessment tools have been developed to assist in screening, assessing, and monitoring CUD. The Cannabis Use Disorders Identification Test-Revised (CUDIT-R, Appendix III) is a widely used instrument for screening and assessing cannabis use, validated for both adolescents and adults. The CUDIT-R consists of eight self-report items that assess cannabis consumption, cannabis-related behaviors and consequences, and symptoms of dependence. The Cannabis Abuse Screening Test (CAST, Appendix IV) is a 5-item, 15-point screen that has been validated for use in adolescents and young adults. The Cannabis Use Problems Identification Test (CUPIT, Appendix V) is a 16-item, 82-point instrument validated for use in adolescents and adults.

There are associations between mental health issues that contribute to cannabis use, as well as cannabis use contributing to mental health issues. Therefore, a specialized mental health evaluation may be beneficial at any point during the treatment of a client with CUD. Active use and withdrawal can complicate the evaluation and treatment of underlying primary mental health diagnoses.

ACUTE INTOXICATION: Cannabis results in frequent calls to poison control centers and visits to Emergency Departments. These trends have increased in the era of high-potency (high

concentrations of THC) cannabis and unregulated synthetic cannabinoids. While the specific effects may be dose-dependent, the psychotropic effects of inhaled cannabis use begin within minutes, plateau within 15-30 minutes, and subside within 2-3 hours. By comparison, the effects of ingested cannabis typically begin within 90 minutes, plateau between 2-3 hours and persist for 4-12 hours.

Signs and symptoms of acute cannabis intoxication may include:

1. Tachycardia
2. Hypotension
3. Nystagmus
4. Conjunctival injection
5. Lethargy
6. Decreased concentration
7. Decreased generalized psychomotor impairment
8. Anxiety/paranoia/panic attack
9. Agitation/irritability/aggression

In severe cases, acute psychosis, seizures, hyperthermia, rhabdomyolysis, and renal failure have been reported.

Treatment of acute cannabis toxicity is largely supportive and focuses on addressing the patient's symptoms. Most patients improve on their own with observation, although closer monitoring and medical intervention may be needed with severe and/or synthetic cannabinoid toxicity. Tachycardia may be treated with benzodiazepines and hydration. Agitation or acute psychosis may warrant treatment with benzodiazepines or antipsychotics, such as haloperidol or olanzapine. Haloperidol may be beneficial to reduce nausea and vomiting of cannabinoid hyperemesis syndrome.

WITHDRAWAL MANAGEMENT: After heavy or prolonged cannabis use, abrupt cessation can lead to clinically significant impairment or distress due to a withdrawal syndrome that can include:

1. Irritability, anger, or aggression
2. Nervousness or anxiety
3. Sleep difficulty (e.g., insomnia, disturbing dreams)
4. Decreased appetite or weight loss
5. Restlessness
6. Depressed mood
7. At least one of the following physical symptoms causing significant discomfort: abdominal pain, shakiness/tremors, sweating, fever, chills, or headache

Individual withdrawal symptoms have their own time course, but generally withdrawal symptoms begin a day or two after abstinence, peak by day 5-6, and can last up to 3 weeks or more. Approximately half of people who regularly use cannabis will experience at least mild withdrawal symptoms following cessation. Higher levels of dependence are associated with more severe and/or prolonged withdrawal after cannabis cessation. The Cannabis Withdrawal Scale (CWS, Appendix VI) is a 19-item measure that has been validated for use in both clinical and research settings to assess the severity of cannabis withdrawal. Higher withdrawal severity is

correlated with a higher degree of functional impairment in normal daily activities as well as the propensity for relapse to cannabis use.

While withdrawal symptoms and sleep disturbances contribute to functional impairment and propensity for relapse during the withdrawal period, the role of pharmacological management of withdrawal symptoms is not clear. No medication is approved specifically for the treatment of cannabis withdrawal. Generally, low-quality studies have shown some benefit on cannabis withdrawal sleep difficulties for gabapentin, lofexidine, mirtazapine, quetiapine, and zolpidem; however, further higher-quality studies are needed to confirm the utility of these medications (Refer to Community Behavioral Health Services guidelines for prescribing information).

MEDICATIONS FOR CANNABIS USE DISORDER

Clinical trials have not shown consistent evidence of efficacy for any medication in the treatment of CUD, and no medication is approved for this indication by the US Food and Drug Administration. Every study investigating medication for CUD reviewed here included psychosocial interventions, and as such, medication treatment alone is not recommended. Gabapentin, N-acetylcysteine (NAC), topiramate, and varenicline have yielded the most favorable results in clinical trials in reducing cannabis use. Trials with antidepressants have shown that they decrease cannabis abstinence rates while having no effects on decreasing use or withdrawal symptoms. Trials with other medications, including antipsychotics, anxiolytics, mood stabilizers, cognitive enhancers, anticonvulsants, antiemetics, and oxytocin, have shown mixed or negative findings.

GABAPENTIN: Gabapentin is a GABAergic agent that binds to receptors with GABA-like activity, modulating the release of excitatory neurotransmitters. The exact mechanism to aid in the treatment of CUD is not known, though some preclinical evidence suggests it may modulate the anxiogenic state of cannabis withdrawal. In one clinical trial, gabapentin led to reduced cannabis use and decreased withdrawal symptoms compared to placebo. It was also associated with greater performance on tests of overall executive function. See Appendix VII for dosing recommendations and client considerations.

Side effects: May include dizziness, drowsiness, ataxia, nausea, peripheral edema, and tremor.

Drug interactions: There are no clinically meaningful drug interactions with gabapentin. Side effects may be enhanced when combined with other CNS depressant medications and substances. There is increasing concern for gabapentin contributing to overdose deaths in recent years, given the increasing rates of prescribing of this agent.

N-ACETYLCYSTEINE (NAC): NAC is an N-acetyl prodrug of the naturally occurring amino acid cysteine. It is an agent typically used for acetaminophen overdose in its intravenous form or as a mucolytic in its inhaled form but has also been tested orally for the treatment of CUD. Oral NAC is available over the counter as a dietary supplement. NAC is hypothesized to reduce the reinstatement of drug-seeking behavior in animal models. In a placebo-controlled trial for adolescents with CUD, the NAC group was twice as likely to submit a negative urine drug screen and achieve end-of-treatment abstinence compared to the placebo group. Adult trials with NAC did not replicate similar findings. Given NAC's low-risk potential and limited evidence for efficacy, it may still be worthwhile to trial in specific clients with CUD (i.e., adolescents, young adults). See Appendix VII for dosing recommendations and client considerations.

Side effects: When given orally, side effects can include mild nausea, stomach upset, and vomiting. When used in trials, NAC was generally well tolerated.

Drug interactions: There are no clinically meaningful drug interactions with N-acetylcysteine.

TOPIRAMATE: Topiramate is an antiepileptic targeting several membrane ion channels and neurotransmitter receptors. In one study of adolescents and adults, topiramate plus psychosocial intervention did not decrease the percent use days but may have decreased grams used per day at the end of the study as there was a statistical trend towards this. The topiramate group had higher dropout rates compared to placebo group due to adverse events. See Appendix VII for dosing recommendations and client considerations.

Side effects: May include paresthesias, taste perversion, decreased appetite, weight loss, diarrhea, fatigue, drowsiness, and impaired concentration. Uncommonly, a serious side effect is metabolic acidosis.

Drug interactions: Side effects may be enhanced when combined with other CNS depressant medications and substances. Caution is advised with polypharmacy. Drug clearance may increase with CYP inducers.

VARENICLINE: Varenicline is a selective nicotinic receptor partial agonist FDA approved for smoking cessation. In one underpowered pilot RCT, varenicline decreased self-reported cannabis use and urine cannabinoid levels. See Appendix VII for dosing recommendations and client considerations.

Side effects: The most common side-effect associated with varenicline is nausea and other common side effects include headache, difficulty sleeping and abnormal dreams. Varenicline carried a boxed warning regarding potential neuropsychiatric side effects that was removed in 2016 after more recent studies demonstrated no difference in neuropsychiatric side effects compared with nicotine or bupropion. Neuropsychiatric effects included behavioral changes, hostility, agitation, depressed mood, and suicidal thoughts and attempts. Systematic reviews of varenicline in clients with mental health disorders reveal no significant difference in neuropsychiatric events compared to placebo; however, the included studies have smaller sample sizes and exclude clients with unstable psychiatric symptoms. Despite the removal of the warning, clients should be counseled on the potential exacerbation of psychiatric symptoms and report any changes in mood or behavior. In the event of new or worsening suicidal thoughts, varenicline should be stopped immediately.

Drug interactions: There are no known major drug interactions with varenicline.

DRONABINOL: Dronabinol (THC) is a CB1 receptor agonist approved for the treatment of HIV-induced anorexia and chemotherapy-associated nausea. Studies have shown that dronabinol decreases cannabis cravings and withdrawal symptoms, but increases sleep onset latency and does not decrease cannabis relapse compared to placebo. See Appendix VII for dosing recommendations and client considerations.

Side effects: More common side effects include clumsiness or unsteadiness, dizziness, drowsiness, false sense of well-being, nausea, trouble with thinking, and vomiting.

Hallucinations and delusions have also been reported, so dronabinol should be avoided in those at risk for psychosis.

Drug interactions: See Appendix VIII.

CANNABIDIOL: CBD is a CB2 receptor agonist, a CB1 receptor partial antagonist, and inhibits endocannabinoid hydrolysis and reuptake. In one study it was shown to have dose-dependent positive effects on cannabis use and abstinence, and withdrawal symptoms and craving, but treatment retentions were not measured in this study. See Appendix VII for dosing recommendations and client considerations.

Side effects: CBD can cause side effects such as dry mouth, diarrhea, reduced appetite, drowsiness and fatigue.

Drug interactions: See Appendix VIII.

DURATION OF TREATMENT WITH CUD PHARMACOTHERAPY: Clinical trials for CUD ranged in duration from 4-12 weeks, with unmedicated follow-up at 24 weeks. There are no long-term or discontinuation trials; therefore, the optimal duration of CUD medication treatment and termination strategies have not been established

NOVEL MEDICATIONS WITH LIMITED DATA:

BUSPIRONE: Buspirone is a 5HT-1A partial agonist FDA approved for generalized anxiety disorder. Studies show mixed results on self-reported decreased cannabis use, time to first negative UDS and urine concentration of cannabis. Common side effects include dizziness, nausea and sweating.

SEMAGLUTIDE: Semaglutide is a GLP-1 receptor agonist FDA approved for type 2 diabetes mellitus and obesity. A retrospective cohort study of electronic health records found that clients prescribed semaglutide had a lower incidence of CUD developing or recurring. Common side effects include nausea, constipation, diarrhea and headaches.

CANNABINOID DRUG INTERACTIONS:

THC and CBD are two pharmacologically active cannabinoids found in cannabis. Both may contribute to potential pharmacokinetic drug-drug interactions involving cytochrome P450 (CYP) enzymes responsible for drug metabolism (see Appendix VIII). Pharmacodynamic interactions may also be seen when cannabis is used concomitantly with other medications.

SPECIAL POPULATIONS:

Pregnancy: The American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Academy of Breastfeeding Medicine advise avoiding cannabis use during pregnancy due to concerns for the neurodevelopmental impact on the fetus. Chemical products from cannabis use are transferred across the placenta.

Gabapentin crosses the placenta, and adverse effects have been observed in animal reproduction studies. Pregnancy registry outcome data following maternal use of gabapentin during pregnancy

are limited. Folic acid supplementation is recommended before and during pregnancy in women using gabapentin.

Adverse events have not been observed with NAC use in animal reproduction studies. Based on limited reports using NAC to treat acetaminophen overdose in pregnant women, NAC has been shown to cross the placenta.

Topiramate should be avoided in those who are pregnant or may become pregnant due to the risk of teratogenicity.

For varenicline, there is inadequate human data available to assess risk to the fetus but there is some animal data indicating potential for decreased fetal weight.

Both dronabinol and cannabidiol should be avoided in pregnancy.

Lactation: Cannabis is transferred into breast milk and may be present up to 6 days after maternal use.

Gabapentin is present in breast milk. The decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of treatment to the mother. The potential risks of exposure for the infant include drowsiness, inadequate weight gain, and delay in developmental milestones.

It is not known if NAC is excreted in breast milk. The decision to continue or discontinue breastfeeding during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of treatment to the mother.

Limited data suggest that maternal topiramate generally results in low levels in infant serum; however, diarrhea and sedation have been reported on occasion.

There is no human data available to assess the risk to infants of breastfeeding mothers taking varenicline, so mothers who choose to take varenicline while breastfeeding should monitor their infants for seizures and abnormal vomiting.

There is very little to no human data assessing risk to infants or on milk production for dronabinol (some indication of potential delayed psychomotor development for infants) or cannabidiol, so these should be avoided during breastfeeding.

Adolescents: Only NAC, topiramate, and cannabidiol have been studied in teenagers under 18 years of age, and therefore, these agents should be considered first for treating CUD in this population.

PSYCHOSOCIAL THERAPIES:
A 2016 Cochrane review looked at the efficacy of various psychosocial interventions for treating CUD in the ambulatory setting. The selection included 23 randomized controlled studies involving 4045 participants from the United States, Australia, Switzerland, Canada, Brazil, and Ireland. While the generalizability of the findings was limited due to the homogeneous nature of the treatment seekers in each locality and other study limitations, psychosocial intervention

compared with minimal treatment controls reduced the frequency of use and severity of dependence in the short-term.

The most substantial evidence of efficacy for the use of psychosocial interventions was for cognitive-behavioral therapy (CBT), motivational enhancement therapy (MET), and their combination, provided in more than four sessions delivered over four to six months. Contingency management (CM) interventions were found to contribute to improvements in CUD when combined with CBT or MET + CBT. MET may be beneficial when working with individuals with lower motivation to change their cannabis use who are just beginning treatment.

We recommend the use of psychopharmacological interventions as an adjunct to structured behavioral and motivational enhancing therapies. The interventions utilized will be based on client preference and actual treatment availability. See Appendix IX for other psychosocial resources and supports.

APPENDIX I: LOWER RISK CANNABIS USE

Appendix I: Abridged from Fischer B., Robinson T., Bullen C., et al "Lower-Risk Cannabis Use Guidelines (LRCUG) for reducing health harms from non-medical cannabis use: A comprehensive evidence and recommendations update," Int J. of Drug Policy, 99 (2022)

Textbox 1. The LRCUG' Recommendations

General Precaution A: People who use cannabis (PWUC) need to know that there is no universally safe level of cannabis use; thus, the only reliable way to avoid any risk for harm from using cannabis is to abstain from its use.

[Evidence Grade: Conclusive]

Recommendation #1: The initiation of cannabis use should be delayed until after late adolescence, or the completion of puberty, to reduce development-related vulnerabilities for harm.

[Evidence Grade: Moderate]

Recommendation #2: PWUC should use 'low-potency' cannabis products, i.e., cannabis products with ideally lower total THC content, or a high CBD/THC content ratio.

[Evidence Grade: Substantial to Moderate]

Recommendation #3: All main available modes-of-use options come with some risk for harm; PWUC should refrain from cannabis 'smoking' and employ alternative routes-of-use for pulmonary health protection.

[Evidence: Substantial to Moderate]

Recommendation #4: If use occurs by inhalation, PWUC should avoid "deep inhalation", prolonged breath-holding, or similar inhalation practices.

[Evidence Grade: Limited]

Recommendation #5: PWUC should refrain from frequent (e.g., daily or near-daily) or intensive (e.g., binging) cannabis use, and instead limit themselves to less frequent or occasional use.

[Evidence Grade: Substantial]

Recommendation #6: Where circumstances allow, PWUC should use legal and quality-controlled cannabis products and use devices.

[Evidence grade: Limited]

Recommendation #7: PWUC who experience impaired cognitive performance should consider temporarily suspending or substantially reducing the intensity (e.g., frequency/potency) of their cannabis use.

[Evidence: Limited]

Recommendation #8: PWUC should avoid driving a motor-vehicle or operating machinery while under the influence of cannabis because of acute impairment and elevated risk of crash involvement, including injury or death; however, the severity and duration of impairment vary depending on multiple factors.

[Evidence Grade: Substantial to Moderate]

Recommendation #9: It is prudent for people who intend to procreate and for women who are pregnant or breastfeeding to abstain from cannabis use towards reducing possible risks for reproduction and of health harm to offspring, respectively.

[Evidence Grade: Limited]

Recommendation #10: PWUC should exercise general caution in combining other psychoactive substances with cannabis use.

[Evidence Grade: Moderate to Limited]

APPENDIX II: CANNABIS USE DISORDER DIAGNOSIS

DSM 5 Diagnostic Criteria: Cannabis Use Disorder	
A problematic pattern of cannabis use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:	
1	Cannabis is often taken in larger amounts or over a longer period than was intended.
2	There is a persistent desire or unsuccessful efforts to cut down or control cannabis use.
3	A great deal of time is spent in activities necessary to obtain cannabis, use cannabis, or recover from its effects.
4	A great deal of time is spent in activities necessary to obtain cannabis, use cannabis, or recover from its effects.
5	Craving, or a strong desire or urge to use cannabis.
6	Recurrent cannabis use resulting in a failure to fulfill major role obligations at work, school, or home.
7	Important social, occupational, or recreational activities are given up or reduced because of cannabis use.
8	Recurrent cannabis use in situations in which it is physically hazardous.
9	Cannabis use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by cannabis.
10	Tolerance, as defined by either of the following:
	a. A need for markedly increased amounts of cannabis to achieve intoxication or desired effect.
	b. Markedly diminished effect with continued use of the same amount of cannabis.
11	Withdrawal, as manifested by either of the following:
	a. The characteristic withdrawal syndrome for cannabis
	b. Cannabis (or a closely related substance) is taken to relieve or avoid withdrawal symptoms.
Severity: 2-3 symptoms (mild), 4-5 symptoms (moderate) or 6+ symptoms (severe). **Early remission**: met full criteria, and then none of the criteria have been met for at least 3 months but less than 12 months. **Sustained remission**: met full criteria, and then none of the criteria have been met for 12+ months.	

APPENDIX III: CUDIT-R

APPENDIX III: CANNABIS USE DISORDERS IDENTIFICATION TEST - REVISED (CUDIT-R)

Please answer the following questions about your cannabis use over the last 6 months.

1. How often do you use cannabis?

Never Monthly or less 2-4 times a month 2-3 times a week 4+ times/week

2. How many hours were you "stoned" on a typical day when you were using cannabis?

Less than 1 1 or 2 3 or 4 5 or 6 7 or more

3. How often during the last 6 months did you find that you were not able to stop using cannabis once you had started?

Never Less than monthly Monthly Weekly Daily or almost daily

4. How often during the last 6 months did you fail to do what was normally expected from you because of using cannabis?

Never Less than monthly Monthly Weekly Daily or almost daily

5. How often in the past 6 months have you devoted a great deal of your time to getting, using or recovering from cannabis?

Never Less than monthly Monthly Weekly Daily or almost daily

6. How often during the last 6 months have you had a problem with your memory or concentration after using cannabis?

Never Less than monthly Monthly Weekly Daily or almost daily

7. How often do you use cannabis in situations that could be physically hazardous, such as driving, operating machinery, or caring for children?

Never Less than monthly Monthly Weekly Daily or almost daily

8. Have you ever thought about cutting down, or stopping, your use of cannabis?

Never Yes, but not in the past 6 months Yes, during the past 6 months

This questionnaire was designed for self-administration and is scored by adding each of the 8 items. Questions 1-7 are scored on a 0-4 scale. Question 8 is scored 0, 2 or 4. A score 8 or more indicate hazardous cannabis use, while scores of 12 or more indicate a possible cannabis use disorder for which further intervention may be required.

APPENDIX IV: CANNABIS ABUSE SCREENING TEST (CAST)

In the last 12 months, have you smoked cannabis? Yes □ No □

In the last 12 months…	Never	Rarely	From time to time	Fairly often	Very often
Have you smoked cannabis before midday?	□ 0	□ 1	□ 2	□ 3	□ 4
Have you smoked cannabis when you were alone?	□ 0	□ 1	□ 2	□ 3	□ 4
Have you had memory problems when you smoked cannabis?	□ 0	□ 1	□ 2	□ 3	□ 4
Have friends or members of your family told you that you ought to reduce your cannabis use?	□ 0	□ 1	□ 2	□ 3	□ 4
Have you tried to reduce or stop your cannabis use without succeeding?	□ 0	□ 1	□ 2	□ 3	□ 4
Have you had problems because of your use of cannabis (argument, fight, accident, bad result at school, etc)?	□ 0	□ 1	□ 2	□ 3	□ 4
Which ones?					

To calculate a score, the responses are coded on a scale of 0 to 4. The total score obtained (which can range from 0 to 24) indicates if the questioned users are at risk. A score of less than 3 indicates no addiction risk. A score of 3 or less than 7 indicates low addiction risk, and a score of 7 or above indicates high addiction risk.

SCORE	

APPENDIX V: CANNABIS USE PROBLEMS IDENTIFICATION TESTI (CUPIT)

Some people can use cannabis without developing any serious problems. Others can experience health problems, or other kinds of problems. If you answer the questions below, it can help you to work out if you are having any problems with cannabis. There are no right or wrong answers. For each question, select the answer closest to your cannabis use over the past 12 months.

1. On how many days have you used cannabis during the past 12 months? (If there was no pattern to your cannabis use, please make your best estimate.)
    a. 1 – 6 days (less than one day a month)
    b. 7 – 12 days (an average pattern of one day a month)
    c. 13 – 36 days (an average pattern of 2 – 3 days a month)
    d. 37 – 52 days (an average pattern of one day a week)
    e. 53 – 104 days (an average pattern of 2 days a week)
    f. up to 208 days (an average pattern of 3-4 days a week)
    g. up to 312 days (an average pattern of 5-6 days a week)
    h. up to 365 days (daily/most days)
2. Now please think about your recent cannabis use. On how many days have you used cannabis over the past 3 months (90 days)?
    a. no days
    b. 1 – 2 days (less than one day a month)
    c. 3 – 4 days (an average pattern of one day a month)
    d. 5 – 9 days (an average pattern of 2 – 3 days a month)
    e. 10 – 15 days (an average pattern of one day a week)
    f. 16 – 26 days (an average pattern of 2 days a week)
    g. 27 – 52 days (an average pattern of 3 – 4 days a week)
    h. 53 – 78 days (an average pattern of 5 – 6 days a week)
    i. 79 – 90 days (daily/most days)
3. How many times would you use cannabis on a typical day when you were using? (Note: at least one hour between each new ‘use’)
    a. once
    b. twice
    c. 3 – 4 times
    d. 5 – 6 times
    e. 7 – 9 times
    f. 10 or more times
4. How often have you used cannabis first thing in the morning?
    a. never
    b. once or twice
    c. less than monthly
    d. monthly
    e. one day a week
    f. several days a week
    g. daily/always
5. How much of the average day do you spend/or feel stoned?
    a. 0 hours
    b. 1 – 2 hours
    c. 3 – 4 hours
    d. 5 – 6 hours
    e. 7 – 8 hours
    f. 9 or more hours
6. How difficult do you think you would find it to stop using or go without cannabis altogether?
    a. not at all difficult
    b. a bit difficult
    c. quite difficult

    d. very difficult
    e. impossible
7. What was the longest time you went without using cannabis?
    a. 6 months or longer
    b. 3 – 5 months
    c. 1 – 2 months
    d. 2 – 3 weeks
    e. one week
    f. 4 – 6 days
    g. 2 – 3 days
    h. one day
    i. no days at all
8. Have you felt that you needed cannabis?
    a. never
    b. sometimes
    c. quite often
    d. very often
    e. always/all the time
9. Have you been able to stop using cannabis when you wanted to?
    a. never/at no time
    b. sometimes (not often)
    c. quite often (half the time)
    d. very often (usually)
    e. always/all the time
10. Have you found it difficult to get through a day without using cannabis?
    a. never
    b. sometimes
    c. quite often
    d. very often
    e. always/all the time
11. Did your use of cannabis ever interfere with (get in the way of) your work at school, your job, or your home life?
    a. never
    b. sometimes
    c. quite often
    d. very often
    e. always/all the time
12. Have you lacked the energy to get things done in the way you used to?
    a. never
    b. sometimes
    c. quite often
    d. very often
    e. always/all the time
13. Have you given up things you used to enjoy or were important because of cannabis? (e.g., work, school, sports, hobbies, being with family and friends, etc.)
    a. none at all/nothing
    b. one or two things
    c. quite a few things
    d. lots of things
    e. everything
14. Has anything you had planned, or were expected to do, not happened after using cannabis? (e.g., a family outing, chores, taking care of children, homework, an assignment, appointment, job interview, training, attending school or work, etc.)
    a. never
    b. sometimes

c. quite often
d. very often
e. always/all the time

15. Have you had problems concentrating and remembering things?
    a. never
    b. sometimes
    c. quite often
    d. very often
    e. always/all the time
16. Did you ever use cannabis after you had decided not to?
    a. never
    b. sometimes
    c. quite often
    d. very often
    e. always/all the time

CUPIT screens for: cannabis use in past 12 months (frequency, intensity - see response to Q1), cannabis use in past three months (see response to Q2), cannabis-induced problems (score of 12 or higher) and risk of harm (current or 12-month) and dependence (score of 20 or higher)

Cut Off Scores

12 – 20 = Those at risk of developing cannabis use disorder in the following 12 months
20+ = Adult or adolescent meets the criteria for current cannabis use disorder (CUD)
82 = The highest score a person can get.

APPENDIX VI: CANNABIS WITHDRAWAL SCALE

Instructions: This version of the CWS asks about symptoms experienced over the last 24 hours, and can be administered by an interviewer OR by self-report.

The following statements describe how you have felt over the last 24 hours. Please **circle the number** that most closely represents your personal experiences for each statement. For each statement, please rate its negative impact on normal daily activities on the same scale (0 = Not at all to 10 = Extremely), writing the number in the right-hand column.

	Not at all				Moderately						Extremely		Negative Impact on daily activity (0 – 10)
1	The only thing I could think about was smoking some cannabis	0	1	2	3	4	5	6	7	8	9	10	
2	I had a headache	0	1	2	3	4	5	6	7	8	9	10	
3	I had no appetite	0	1	2	3	4	5	6	7	8	9	10	
4	I felt nauseous (like vomiting)	0	1	2	3	4	5	6	7	8	9	10	
5	I felt nervous	0	1	2	3	4	5	6	7	8	9	10	
6	I had some angry outbursts	0	1	2	3	4	5	6	7	8	9	10	
7	I had mood swings	0	1	2	3	4	5	6	7	8	9	10	
8	I felt depressed	0	1	2	3	4	5	6	7	8	9	10	
9	I was easily irritated	0	1	2	3	4	5	6	7	8	9	10	
10	I had been imagining being stoned	0	1	2	3	4	5	6	7	8	9	10	
11	I felt restless	0	1	2	3	4	5	6	7	8	9	10	
12	I woke up early	0	1	2	3	4	5	6	7	8	9	10	
13	I had a stomach ache	0	1	2	3	4	5	6	7	8	9	10	
14	I had nightmares and/or strange dreams	0	1	2	3	4	5	6	7	8	9	10	
15	Life seemed like an uphill struggle	0	1	2	3	4	5	6	7	8	9	10	
16	I woke up sweating at night	0	1	2	3	4	5	6	7	8	9	10	
17	I had trouble getting to sleep at night	0	1	2	3	4	5	6	7	8	9	10	
18	I felt physically tense	0	1	2	3	4	5	6	7	8	9	10	
19	I had hot flashes	0	1	2	3	4	5	6	7	8	9	10	

APPENDIX VII: OFF-LABEL CUD MEDICATION ASSISTED TREATMENT

Product	Dosage	Common Side Effects	Renal Dosing	Hepatic Dosing	Monitoring
Gabapentin 100mg, 300mg, 400mg capsules 600mg, 800mg tablets 250mg/5ml oral solution	Day 1 300mg qHS Day 2 300 mg BID Day 3 300 mg TID Day 4: 300 mg qAM and qMiday and 600mg qEvening (target). Subjects maintained the 1200 mg/day dose until week 11.	Dizziness, drowsiness, ataxia, peripheral edema, abnormal gait, confusion, weight gain, nausea, diarrhea, xerostomia, tremor, nystagmus.	CrCl 30-59ml/min: 200 to 700mg BID CrCl 16-29ml/min: 200 to 700mg daily CrCl 15ml/min: 100 to 300mg daily CrCl <15ml/min: reduce daily dose in proportion to CrCl based on dose for CrCl of 15 ml/min.	No adjustment necessary.	Cr at baseline.
N-acetylcysteine OTC: 600mg capsules	1200mg BID	Mild nausea, stomach upset, and vomiting.	No adjustments necessary.	No adjustments necessary.	None.
Topiramate 15mg, 50mg, 100mg, 200mg tablets	Days 1-7 25mg daily Days 8-14 50mg daily Days 15-17 75mg daily Days 18-21 100mg daily Days 22-24 125mg daily Days 25-28 150mg daily Days 29-42 200mg daily (target) Days 43-44 100mg daily (taper) Days 45-46 50mg daily (taper) Day 45 0mg (off)	Paresthesias, taste perversion, anorexia and weight loss, diarrhea, fatigue and drowsiness, impaired concentration, uncommon but serious metabolic acidosis.	CrCl <70ml/min decrease dose by 50%.	Not defined, caution advised.	Cr and bicarbonate at baseline.
Varenicline 0.5mg, 1mg tablets	Days 1-3 0.5mg daily Days 4-7 0.5mg BID Days 8-42 1mg BID (target) [Dose reduced to 0.5mg BID for tolerability.]	Nausea, headache, difficulty sleeping and abnormal dreams, psychiatric exacerbation.	CrCl <30ml/min start 0.5mg daily, 0.5mg BID max.	No adjustments necessary.	Cr at baseline.
Dronabinol	10mg daily titrated to 20mg BID as	Clumsiness or unsteadiness, dizziness,	Not defined.	Not defined.	Avoid if risk for psychosis.

2.5mg, 5mg, 10mg capsules	tolerated in first week.	drowsiness, false sense of well-being, nausea, trouble with thinking, and vomiting			
Cannabidiol 100mg/mL solution	200mg BID Or 400mg BID	Dry mouth, diarrhea, reduced appetite, drowsiness and fatigue	No adjustments necessary.	Child-Pugh Class B: start 1.25mg/kg/dose bid, increase to 2.5-5 mg/kg/dose bid max. Child-Pugh Class C: start 0.5mg/kg/dose bid, increase to 1—2 mg/kg/dose bid max.	AST, ALT, TBili at baseline, 1month, 3month, 6month, then periodically and within 1month of dose changes, concurrent hepatotoxic medication changes, or more frequently if on valproate or elevated baseline LFTs.

APPENDIX VIII: CANNABINOID DRUG INTERACTIONS.

Cannabinoid levels can be increased by other medications that inhibit CYP metabolism	• THC is metabolized by CYP3A4 and CYP2C9 • Cannabidiol is metabolized by CYP3A4 • CYP3A4 and CYP2C9 inhibitors could augment the psychoactive effects of THC and cannabidiol through prolonged exposure
Cannabinoids can affect the levels of other medications	• Cannabidiol inhibits CYP2C19 (and possibly CYP3A4/5) • Medications metabolized by CYP2C19 (e.g., warfarin) could have levels elevated
Smoking cannabis can increase clearance of some medications	• Smoked cannabis has been reported to increase the clearance of medications metabolized by CYP1A2 (e.g., theophylline, clozapine, olanzapine) with regular cannabis use (>2 joints per week) • Increased drug clearance results in decreased drug levels
Additive pharmacodynamic effects can occur with other medications	• Additive effects can occur when cannabis is combined with sympathomimetics (↑ tachycardia, ↑ hypertension), central nervous system depressants such as alcohol and opioids (↑ sedation, ↑ ataxia), and anticholinergics (↑ tachycardia, ↑ confusion)

APPENDIX XI: LOCAL RESOURCES & INFORMATION:

Individuals can learn more about seeking treatment through:

- Behavioral Health Access Line (BHAL) - 888-246-3333
- Behavioral Health Access Center (BHAC)
    - 1380 Howard St. 1st Floor San Francisco, CA 94103
    - https://www.sf.gov/location--behavioral-health-access-center-bhac
- Marijuana Anonymous (MA), online meetings available: https://marijuana-anonymous.org/

Additional information for clients can be found at

- Marijuana Lit: A Fact-Based Toolkit for Prevention: https://attcnetwork.org/centers/network-coordinating-office/marijuana-lit-infographics
- California DPH: Let's Talk Cannabis: https://www.cdph.ca.gov/Programs/DO/letstalkcannabis/Pages/LetsTalkCannabis.aspx
- NIDA: Cannabis Facts for Teens https://nida.nih.gov/sites/default/files/teens_brochure_2013.pdf
- [CANNABIS] DECODED: https://www.smchealth.org/cannabis
- Systematically Testing the Evidence on Cannabis: https://www.cannabisevidence.org/evidence-syntheses/

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