

Louisiana Fee-for-Service Medicaid Opiate Dependence Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for non-preferred agents. NOTE: The form should be completed in full, however, for SECTION VI, only the quantity limit information and attestations “C” and “L” are applicable when requesting authorization for opioid dependence agents.

See full prescribing information for individual agents for details on the information below:

† These agents have Black Box Warnings.

‡ These agents are subject to *Risk Evaluation and Mitigation Strategy (REMS)* under FDA safety regulations.

Additional Point-of-Sale (POS) Requirements

Generic Name (Brand Example)	AL	DX	MD	QL	TD	X
Buprenorphine Implant (Probuphine® Implant)† ‡	X	X		X	X	X
Buprenorphine Injection (Sublocade®)† ‡	X	X		X	X	X
Buprenorphine Sublingual Tablet (Generic) ‡	X	X	X	X	X	X
Buprenorphine/Naloxone Film (Bunavail®) ‡	X	X	X	X	X	X
Buprenorphine/Naloxone Film (Suboxone®) ‡	X	X	X	X	X	X
Buprenorphine/Naloxone SL Tablet (Generic; Zubsolv®) ‡	X	X	X	X	X	X
Naltrexone Extended-Release Injectable Suspension (Vivitrol®)	X	X		X		
Naltrexone Tablet (Generic)						
Naloxone Nasal Spray (Narcan®)				X		
Naloxone Syringe; Vial (Generic)				X		

AL - Use of these agents is limited to certain ages. There are no override provisions through the Point-of-Sale system using NCPDP service codes.

DX - An appropriate diagnosis code is required for these agents.

MD - Maximum daily doses apply to these agents.

QL - Quantity limits apply to these agents.

TD - When the recipient has an active prescription (the days' supply has not expired) for a benzodiazepine or any other opioid analgesic (including buprenorphine), an incoming prescription for this agent will deny when the prescriptions are written by different prescribers. When written by the same prescriber, the claim will deny as therapeutic duplication, and the pharmacist will have to contact the prescriber for authorization to assure the prescriber wants concurrent therapy.

X - Prescribers must meet enrollment and certification requirements.

Approval criteria, for both initial and reauthorization requests, for non-preferred agents – ALL of the following are required:

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- If the request is for a non-preferred buprenorphine/naloxone combination product, there is a clinical reason why a preferred buprenorphine/naloxone combination product cannot be used; **AND**
- The requested medication has been prescribed for an approved diagnosis (if applicable); **AND**
- Previous use - **ONE** of the following is required:
 - If the request is for a single-ingredient buprenorphine sublingual tablet:
 - The recipient is pregnant; **OR**
 - The recipient has had an *intolerable side effect* to naloxone; **OR**
 - If the request is **NOT** for a single-ingredient buprenorphine sublingual tablet:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**

- The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
- There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication.

Point-of-Sale (POS) Edits for Opiate Dependence Agents	Quantity Limit	Maximum Daily Dose §	Minimum Age	Covered Diagnosis Code(s)
Probuphine®	2 kits/720 days		16 years	F11.2*
Sublocade®	1 unit/30 days		18 years	F11.2*
Buprenorphine SL Tablet 2mg	2 units/day	16mg/day	16 years	F11.2*
Buprenorphine SL Tablet 8mg	3 units/day			
Bunavail® 2.1mg/0.3mg	1 unit/day	12.6mg/day	16 years	F11.2*
Bunavail® 4.2mg/0.7mg	3 units/day			
Bunavail® 6.3mg/1mg	2 units/day			
Suboxone® 2mg/0.5mg SL Tab	2 units/day	24mg/day	16 years	F11.2*
Suboxone® 2mg/0.5mg SL Film	1 unit/day			
Suboxone® 4mg/1mg SL Film	1 unit/day			
Suboxone® 8mg/2mg SL Film/Tab	3 units/day			
Suboxone® 12mg/3mg SL Film	2 units/day			
Zubsolv® 0.7mg/0.18mg	1 unit/day	17.1mg/day	16 years	F11.2*
Zubsolv® 1.4mg/0.36mg	1 unit/day			
Zubsolv® 2.9mg/0.71mg	1 unit/day			
Zubsolv® 5.7mg/1.4mg	3 unit/day			
Zubsolv® 8.6mg/2.1mg	2 units/day			
Zubsolv® 11.4mg/2.9mg	1 unit/day			
Vivitrol®	1 unit/28 days		18 years	F10.2*, F11.2*
Narcan®	2 units/90 days		No Minimum Age	
Naloxone Injectable Solution/Cartridge 0.4mg/ml	2 units/90 days		No Minimum Age	
Naloxone Injectable Solution Syringe 1mg/ml	2 units/90 days		No Minimum Age	
Naloxone Injectable Solution (5ml, 10ml, 20ml) 1mg/ml	1 unit/90 days		No Minimum Age	
Naloxone Injectable Solution (10ml) 0.4mg/ml	1 unit/90 days		No Minimum Age	
Naltrexone Tablet			No Minimum Age at POS	

§ Maximum daily dose limits are based on the amount of buprenorphine or the buprenorphine equivalent. Refer to specific product prescribing information for buprenorphine equivalent dosing.

* Any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10-CM diagnosis code.

F10.2* - alcohol dependence; F11.2* - opioid dependence

Duration of Authorization Approval for Non-Preferred Opiate Dependence Agents

Initial and Reauthorization:

- **Single-Ingredient Sublingual Buprenorphine for Non-Pregnant Recipients: 4 months**
- **Single-Ingredient Sublingual Buprenorphine for Pregnant Recipients: 6 months**
- **All Other Non-Preferred Opiate Dependence Agents: 6 months**

Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf

References

Bunavail (buprenorphine and naloxone) [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc; 2018. Retrieved from https://bunavail.com/hcp/assets/pdfs/BUNAVAIL_Full_Prescribing_Information.pdf

Naloxone injection [package insert]. Lake Forest, IL: Hospira, Inc; 2018. Retrieved from <http://labeling.pfizer.com/ShowLabeling.aspx?id=4541> ,
<http://labeling.pfizer.com/ShowLabeling.aspx?id=4542> ,
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Naltrexone tablet [package insert]. Webster Groves, MO: Mallinckrodt SpecGX LLC; 2017. Retrieved from <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=06ff2d5a-e62b-4fa4-bbdb-01938535bc65&type=display>

Narcan Nasal Spray (naloxone) [package insert]. Radnor, PA: Adapt Pharma, Inc; 2017. Retrieved from <https://www.narcan.com/pdf/NARCAN-Prescribing-Information.pdf>

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Sublocade (buprenorphine) [package insert]. North Chesterfield, VA: AMRI; 2018. Retrieved from <https://www.sublocade.com/Content/pdf/prescribing-information.pdf>

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Subutex (buprenorphine) [package insert]. North Chesterfield, VA: Indivior Inc; 2018. Retrieved from https://www.suboxone.com/content/pdfs/SUBUTEX_Prescribing_Information.pdf

Vivitrol (naltrexone) [package insert]. Waltham, MA: Alkermes, Inc; 2015. Retrieved from <https://www.vivitrol.com/content/pdfs/prescribing-information.pdf>

Zubsolv (buprenorphine and naloxone) [package insert]. Morristown, NJ: Orexo US, Inc; 2018. Retrieved from <https://www.zubsolv.com/wp-content/uploads/2015/01/ZubsolvFullPrescribingInformation.pdf>

REMS

Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) REMS
<https://www.btodrems.com/SitePages/Welcome.aspx>

SUBOXONE Film, the Authorized Generic of SUBOXONE Film, SUBOXONE Tablet, and SUBUTEX Tablet REMS <http://www.suboxonerems.com/>