

**Louisiana 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.

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Additional Point-of-Sale edits may apply.

Some medications in this therapeutic class have **Black Box Warnings** and/or are subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.

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**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.

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X – Prescribers must meet enrollment and certification requirements.

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

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- For single-ingredient buprenorphine sublingual tablet:
  - The recipient is pregnant; **OR**
  - The recipient has had an *intolerable side effect to naloxone*; **AND**
- For ~~Buprenorphine~~ buprenorphine/Naloxone sublingual film (generic for Suboxone® sublingual film) – there has been a treatment failure or intolerable side effect with or contraindication to brand Suboxone® sublingual film; **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**

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- 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 – see POS Edits); **AND**
- Previous use - **ONE** of the following is required if the request is NOT for a single-ingredient buprenorphine sublingual tablet:
  - ~~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.

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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	24mg/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 Initial and Reauthorization Approval for Non-Preferred Opiate Dependence Agents

- **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](http://www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf).*

### References

Bunavail® (buprenorphine and naloxone) [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc; ~~February 2018~~ October 2019.  
[https://bunavail.com/hcp/assets/pdfs/BUNAVAIL\\_Full\\_Prescribing\\_Information.pdf](https://bunavail.com/hcp/assets/pdfs/BUNAVAIL_Full_Prescribing_Information.pdf)

Naloxone injection [package insert]. Lake Forest, IL: Hospira, Inc; ~~May~~ September, 2019.  
<http://labeling.pfizer.com/ShowLabeling.aspx?id=4541>

Naltrexone tablet [package insert]. Webster Groves, MO: Mallinckrodt SpecGX LLC; September 2017. <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; February 2017.  
<https://s3-us-west-2.amazonaws.com/narcan-assets-uswest/NARCAN-Prescribing-Information.pdf>

Probuphine® (buprenorphine) [package insert]. Princeton, NJ: ~~February 2018~~ October 2019.  
<https://probuphine.com/wp-content/uploads/2019/11/Probuphine-PI-PROAW00009-R1-Oct2019-06Nov2019.pdf>

Sublocade® (buprenorphine) [package insert]. North Chesterfield, VA: AMRI; ~~April 2019~~ February 2020. <https://www.sublocade.com/Content/pdf/prescribing-information.pdf>

Suboxone® (buprenorphine and naloxone) [package insert]. North Chesterfield, VA: Indivior Inc; ~~February 2018~~ October 2019. <https://www.suboxone.com/pdfs/prescribing-information.pdf>

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Buprenorphine [package insert]. Eatontown, NJ: Hikma Pharmaceuticals USA Inc; ~~April-November~~ 2019. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1bf8b35a-b769-465c-a2f8-099868dfcd2f&type=display>

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Vivitrol® (naltrexone) [package insert]. Waltham, MA: Alkermes, Inc; ~~July-November~~ 2019. <https://www.vivitrol.com/content/pdfs/prescribing-information.pdf>

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Zubsolv® (buprenorphine and naloxone) [package insert]. Morristown, NJ: Orexo US, Inc; ~~December 2018~~ ~~October 2019~~, <https://www.zubsolv.com/prescribinginformation>

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## **REMS**

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

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

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Revision	Date
Modified maximum daily dose for buprenorphine/naloxone agents	May 2019
Modified quantity limits	June 2019
Modified maximum daily dose for buprenorphine agents, added specific wording for use of Suboxone® sublingual film.	November 2019
<del>Removed POS information, formatting changes, updated references</del>	<del>July 2020</del>

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