



## Naltrexone Implants/Pellets

**Policy #** 00615

**Original Effective Date:** 04/18/2018

**Current Effective Date:** 05/13/2024

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

## Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers naltrexone implants or pellets to be **investigational**.\*

*\*\*Note that some plans may have contractual exclusions for compounded prescriptions in which the active ingredient is being mixed together in a manner inconsistent with FDA approved labeling (e.g. active ingredient approved for intramuscular use being used in an implantable manner). \*\**

## Background/Overview

Naltrexone is a pure opioid antagonist, and therefore blocks the effects of opioids on the mu opioid receptors. Naltrexone, as part of a tablet or intramuscular injectable suspension, is a Food and Drug Administration (FDA) approved product for indications such as alcohol and opioid dependence. Other versions of naltrexone do exist, however these versions are not Food and Drug Administration approved as they are bulk chemicals that are compounded into an implant or pellet formulation. There is a lack of safety and efficacy data for the use of naltrexone implants or pellets and therefore these drugs are not approved by the FDA.

## FDA or Other Governmental Regulatory Approval

### U.S. Food and Drug Administration (FDA)

Naltrexone pellets are not approved by the FDA. There are two versions of naltrexone (as the sole ingredient) that are approved by the FDA and those are an intramuscular injectable suspension (Vivitrol®)<sup>†</sup> and the generic naltrexone tablets. Vivitrol carries FDA indications for alcohol dependence and opioid dependence. The generic tablets are indication for the treatment of alcohol dependence and for the blockade of the effects of exogenously administered opioids.

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### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The intent of this medical policy is to ensure that the use of the non-FDA approved drug product, naltrexone pellets, is not allowed due to the lack of evidence of safety and efficacy of these products.

### **References**

1. UpToDate. Naltrexone.
2. Drugs@FDA.

### **Policy History**

Original Effective Date: 04/18/2018

Current Effective Date: 05/13/2024

04/05/2018	Medical Policy Committee review
04/18/2018	Medical Policy Implementation Committee approval. New policy.
04/04/2019	Medical Policy Committee review
04/24/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. No change to coverage.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023	Medical Policy Committee review

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04/12/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

04/04/2024 Medical Policy Committee review

04/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2025

## **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)®, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	22999, 49999
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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