Medical Drug Clinical Criteria

Subject:	Naltrexone Implantable Pellets		
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Overview

This document addresses extended-release, implantable naltrexone. Naltrexone is an opioid antagonist that binds to opioid receptors, blocking the euphoric effects of exogenous opioids in those who have an opioid or alcohol use disorder. Currently available formulations of naltrexone implantable pellets are compounded by pharmacies using a bulk powder formulation and are not approved by the United States Food and Drug Administration (FDA).

Naltrexone extended-release formulations have been made available as implantable pellets and are most commonly used for the treatment of alcohol and opioid use disorders. Neither naltrexone implants, nor the bulk powder used to compound them, are approved by the FDA.

This document does not address the extended-release, injectable naltrexone (Vivitrol) or the oral formulation of naltrexone (Revia).

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Extended-release naltrexone implants (or pellets)

Extended-release naltrexone implants (or pellets) may not be approved for the treatment of alcohol and opioid use disorders (alcohol and opioid dependence) and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

11981	Insertion, non-biodegradable drug delivery implant [when specified as insertion of naltrexone pellets]
11983	Removal with reinsertion, non-biodegradable drug delivery implant [when specified as reinsertion of naltrexone pellets]
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue [when specified as insertion of biodegradable naltrexone pellets]
22999	Unlisted procedure, abdomen, musculoskeletal system [when specified as insertion of biodegradable naltrexone pellets]
49999	Unlisted procedure, abdomen, peritoneum and omentum

HCPCS

J3490	Unclassified drugs [when specified as implantable naltrexone pellets]
J7999	Compounded drug, not otherwise classified [when specified as implantable naltrexone pellets]

ICD-10 Diagnosis:	All diagnoses including, but not limited to, the following:
F10.10-F10.99	Alcohol related disorders
F11.10-F11.99	Opioid related disorders

Document History

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Document History:

- 08/18/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 08/19/2022 – Annual Review: No changes. Coding reviewed: No changes.
- 08/20/2021 – Annual Review: No changes. Coding reviewed: No changes.
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- 08/16/2019 – Annual Review: No changes. Coding reviewed: No changes
- 08/17/2018 – Annual Review: Initial Review of implantable naltrexone pellets; Annual review. No changes. Added HCPCS 49999 to the document.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 6, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.