Subcutaneous Implantable Naltrexone Pellets

Policy Number: 2023D0078E
Effective Date: January 1, 2023

Instructions for Use

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Related Policies
None

Coverage Rationale

See Benefit Considerations

Compounded Implantable Drug Pellets: Compounded drugs, including compounded naltrexone pellets are not FDA approved.[1] Compounded drug pellets, including but not limited to compounded naltrexone, are not proven nor medically necessary for any indication.

This policy does not apply to Vivitrol® (naltrexone powder for suspension for injection, extended-release).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

This policy does not apply to J2315 - Vivitrol® (naltrexone powder for suspension for injection, extended-release).

CPT Code	Description
11981	Insertion, drug-delivery implant (i.e., bioresorbable, biodegradable, non-biodegradable)
11982	Removal, non-biodegradable drug delivery implant
11983	Removal with reinsertion, non-biodegradable drug delivery implant

HCPCS Code	Description
J3490	Unclassified drugs
J7999	Compounded drug, not otherwise classified

Background

Naltrexone is an opiate antagonist which can displace or block opiate agonists from opiate receptors, resulting in elimination and inhibition of the euphoric effect of opiate agonists. Naltrexone is available in the following FDA approved formulations: oral tablet and powder for suspension for injection, extended-release.

Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. Refer to the Policy and Procedure addressing the treatment of serious rare diseases.

Clinical Evidence

Larney S. et al., completed a systematic literature review to assess the safety and efficacy of naltrexone implants for treating opioid dependence.[3] The authors included studies that compared naltrexone implants with other interventions, as well as placebo. Outcomes included induction to treatment, retention in treatment, opioid and non-opioid use, adverse events, non-fatal overdose and mortality. Quality of the evidence was assessed using the Grading of Recommendations Assessment, Development, and Evaluation approach. Meta-analysis was used to combine data from randomized studies. The review included 5 randomized trials (n = 576) and four non-randomized studies (n = 8358). The quality of the evidence ranged from moderate to very low. The evidence on safety and efficacy of naltrexone implants is limited in quantity and quality, and the evidence has little clinical utility in settings where effective treatments for opioid dependence are used. The authors concluded that better designed research is needed to establish the safety and efficacy of naltrexone implants. Until such time, their use should be limited to clinical trials.

The Australian National Health and Medical Research Council completed a review of evidence available around the use of naltrexone implants for the treatment of opioid dependence.[2] After reviewing available evidence, the authors reported that studies were of small sample sizes, included an inadequate duration of treatment and follow-up, the comparators are inappropriate and many studies reported on the same cohort. Because of this, the authors concluded that naltrexone implants are an experimental product, more studies are needed, and the efficacy of the treatment cannot be determined.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Compounded naltrexone pellets are not currently FDA approved and there has not been an FDA submission for approval of these products.

References

1. FDA Compounding Laws and Policies. https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm606881.htm. Accessed October 26, 2022.
2. National Health and Medical Research Council. Naltrexone implant treatment for opioid dependence. NHMRC Literature Review. 2011.
3. Larney S, Gowing L, Mattick RP, et al. A systematic review and meta-analysis of naltrexone implants for the treatment of opioid dependence. Drug Alcohol Rev. 2014;33(2):115-128.
4. Clinical Pharmacology. www.clincialpharmacology.com. Elsevier/Gold Standard. Accessed October 26, 2022.

Policy History/Revision Information

Date	Summary of Changes
01/01/2023	• Routine review; no change to coverage guidelines • Archived previous policy version 2022D0078D

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.