INSTRUCTIONS FOR USE

This Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Drug Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Drug Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Drug Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

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. See the Policy and Procedure addressing the treatment of serious rare diseases.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.
**COVERAGE RATIONALE**

**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).

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

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

**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.

**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 Coverage Determination Guidelines may apply.

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<td>11982</td>
<td>Removal, non-biodegradable drug delivery implant</td>
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<tr>
<td>11983</td>
<td>Removal with reinsertion, non-biodegradable drug delivery implant</td>
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\(^{CPT\textsuperscript{®} is a registered trademark of the American Medical Association}\)

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<tr>
<td>J7999</td>
<td>Compounded drug, not otherwise classified</td>
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This policy does not apply to J2315 - Vivitrol® (naltrexone powder for suspension for injection, extended-release).

**CLINICAL EVIDENCE**

Larney S. et al., completed a systematic literature review to assess the safety and efficacy of naltrexone implants for treating opioid dependence.\(^2\) 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.
CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) specifically for the subcutaneously implantation of compounded naloxone pellets. Local Coverage Determinations (LCDs) do not exist at this time.

In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals. (Accessed November 28, 2018)

REFERENCES

1. FDA Compounding Laws and Policies.  

POLICY HISTORY/REVISION INFORMATION

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