A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

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<th>Plan: PA Health &amp; Wellness</th>
<th>Submission Date: 01/13/2020</th>
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<tr>
<td>Policy Number: PHW.PDL.145.01</td>
<td>Effective Date: 01/01/2020</td>
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<tr>
<td>Policy Name: Opioid Dependence Treatments</td>
<td>Revision Date: 01/13/2020</td>
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**Type of Submission – Check all that apply:**

- [ ] New Policy
- [ ] Revised Policy*
- [ ] Annual Review - No Revisions
- [x] Statewide PDL - Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any changes or clarifying information for the policy below:

**Per direction from DHS, removing criteria for an oral buprenorphine Opioid Dependence Treatment when used in combination with a benzodiazepine or CNS depressant**

**Name of Authorized Individual (Please type or print):**

Francis G. Grillo, MD

**Signature of Authorized Individual:**

[Signature]

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Clinical Policy: Opioid Dependence Treatments

It is the policy of health plans affiliated with PA Health and Wellness® that Opioid Dependence Treatments are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Opioid Dependence Treatments

A. Prescriptions That Require Prior Authorization

   Prescriptions for Opioid Dependence Treatments that meet any of the following conditions must be prior authorized:

   1. An oral buprenorphine Opioid Dependence Treatment without naloxone.
   2. A non-oral buprenorphine Opioid Dependence Treatment.
   3. A non-preferred Opioid Dependence Treatment.
   4. An Opioid Dependence Treatment with a prescribed quantity that exceeds the quantity limit.

   **REMINDER:** A prescription for a benzodiazepine, opioid analgesic, sedative hypnotic, or skeletal muscle relaxant requires prior authorization when a beneficiary has a concurrent prescription for a buprenorphine Opioid Dependence Treatment.

   **REMINDER:** A prescription for an opioid analgesic requires prior authorization when a beneficiary has a concurrent prescription for Vivitrol.

B. Review of Documentation for Medical Necessity

   In evaluating a request for prior authorization of a prescription for an Opioid Dependence Treatment, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

   1. Is prescribed the Opioid Dependence Treatment for treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling OR a medically accepted indication; **AND**
2. For an oral buprenorphine Opioid Dependence Treatment that does not contain naloxone, one of the following:

   a. Is prescribed the agent for induction therapy,
   b. Is pregnant,
   c. Is breastfeeding;

   AND

3. One of the following:

   a. For a non-oral buprenorphine Opioid Dependence Treatment, prescribed the agent consistent with package labeling
   
   b. For a non-preferred oral Opioid Dependence Treatment, one of the following:
      
      i. For an oral buprenorphine Opioid Dependence Treatment, has a history of therapeutic failure, contraindication, or intolerance of the preferred oral buprenorphine Opioid Dependence Treatments
      ii. For an alpha2-adrenergic agonist Opioid Dependence Treatment, has a history of therapeutic failure, contraindication, or intolerance of the preferred alpha2-adrenergic agonist Opioid Dependence Treatments;

   AND

4. Has documentation that the prescriber or the prescriber’s delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program for the beneficiary’s controlled substance prescription history; AND

5. One of the following:

   a. If a prescription for a non-oral Opioid Dependence Treatment is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override,

   b. If a prescription for an oral Opioid Dependence Treatment that does not contain buprenorphine is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override,

   c. If a prescription for an oral buprenorphine Opioid Dependence Treatment is for a quantity that exceeds the quantity limit, all of the following:
      
      i. Is prescribed a quantity consistent with medically accepted prescribing practices and standards of care,
ii. Has documentation of an evaluation by a licensed Drug & Alcohol (D&A) provider or a Single County Authority to determine the recommended level of care,

iii. Has documentation of participation with a licensed D&A or behavioral health provider at the recommended level of care until successful completion of the program AND, upon successful completion of the program, participation in a substance abuse or behavioral health counseling or treatment program or an addictions recovery program,

iv. Demonstrates compliance with oral buprenorphine therapy as documented by a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodeone, fentanyl, tramadol, and carisoprodol) that is both of the following:
   a) Positive for buprenorphine and norbuprenorphine
   b) Consistent with prescribed controlled substances.

NOTE: If the beneficiary does not meet the clinical review guidelines and quantity limit guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Opioid Dependence Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Approval Duration: 12 months

E. References

3. Psychiatric Services in Advance, November 18, 2013;


11. CSAT’s TIP 42: Substance Abuse Treatment for Persons With Co-Occurring Disorders; 2005.


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