POLICY AND PROCEDURE

DEPARTMENT: Pharmacy Operations	**DOCUMENT NAME:** Clinical Policy for Medication Assisted Therapy Products: acamprosate (Campral®), disulfiram (Antabuse®), oral naltrexone (ReVia®), IM Naltrexone (Vivitrol®), buprenorphine (Subutex®) and buprenorphine/naloxone (Suboxone®)
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APPROVED DATE: 10/2015	**RETIRED:**
EFFECTIVE DATE: 10/2015	**REVIEWED/REVISED DATE**: 01/2017, 01/2018
PRODUCT TYPE: All	**REFERENCE NUMBER:** WA.PHAR.15

SCOPE:
Washington Health Care Authority (HCA), Coordinated Care Health Plan (Plan), and Envolve Pharmacy Solutions.

PURPOSE:

It is the goal of Coordinated Care to maximize opportunities for clients to receive effective and successful treatment for Substance Use Disorders. Substance Use Disorders are chronic remitting and relapsing diseases. Coordinated Care coverage of MAT prescribed outside of traditional substance use disorder treatment programs increases the number of access points for treatment and provides patients with additional flexibility in managing their illness. Improving access to medication assisted treatment for opioid use disorder is also important given what appears to be a transition from the high rates of prescription opioid use in Washington State to increasing rates of heroin use. In order to provide Coordinated Care Members with the widest range of treatment options, and with the recognition that substance use disorders are chronic conditions, Coordinated Care cover MAT products for the treatment of substance use disorders as an office based therapy, and allow indefinite continuation as maintenance treatment under the following conditions and recommended treatment protocols.

POLICY:
Plan will cover all drugs FDA labeled or prescribed as Medication Assisted Treatment (MAT) or maintenance therapy for substance use disorders, with the exception of drugs dispensed directly by opiate substitution treatment programs. Plan will cover all MAT products specified in this policy according to guidelines and requirements determined by HCA.

PROCEDURE:

<u>Ongoing Treatment beyond twelve months:</u>

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For all MAT products listed below, if treatment extends beyond twelve months, the Health Care Authority (HCA) requires prescribers to complete form HCA 13-333 Medication Assisted Therapy Patient Status form and keep it in the patient's record. Every twelve months thereafter, a new copy of the form should be completed.

- This requirement applies to ALL medications listed in this document and/or HCA published clinical guidelines for Medication Assisted Therapy, even if the product does not require authorization.
- Coordinated Care and Envolve are NOT required to validate or enforce the completion of this form, and authorization is not contingent upon its completion. Coordinated Care and Envolve have no obligation in regard to this document other than taking reasonable steps to ensure that prescribers are aware of the requirement by HCA.
- Coordinated Care and Envolve are NOT required to develop their own version of this particular form. The MAT Patient Status form is an HCA document and Coordinated Care and Envolve are not required to provide or maintain.
- HCA may request copies of MAT Patient Status forms and other patient records as needed to monitor quality of care and the success of treatment expansion at any time.

Coverage for acamprosate:

PA Criteria: No authorization or limitations. To be covered without restriction.

Claims processing / system requirements: None. Covered drug.

Operational requirements: None

Coverage for disulfiram

PA Criteria: No authorization or limitations. To be covered without restriction.

Claims processing / system requirements: None. Covered drug.

Operational requirements: None

Coverage for oral naltrexone:

PA Criteria:

- Covered without authorization for members 18 years of age and older. Naltrexone should not be prescribed for members who have used or have shown signs of acute opioid withdrawal in the last three days. Naltrexone should not be prescribed for members who are pregnant or have decompensated liver disease.
- Prior Authorization required for age 17 and under to validate diagnosis:
    - If prescribed for treatment of substance use disorder
        - Approve until member's 18th birthday.
        - Coordinated Care/Envolve should initiate case management to ensure at-risk youth physical, mental, and behavioral health needs are being met.
        - May be reauthorized every twelve months through members 18th birthday without further validation of diagnosis.
    - If prescribed for an off-label use:

- Coordinated Care may determine their own criteria when not prescribed for substance use disorders.
- After failure of other interventions, HCA has made exceptions and approved for self-injurious behavior in autistic members. Some evidence exists to support this use on an exception basis.
- After considering the unique needs of an individual member and any peer reviewed evidence supporting the use for any particular off-label use, Coordinated Care may deny as non-covered / not indicated for diagnosis other than substance use disorders.

Claims processing / system requirements:

Limited to members 18 and older, requires prior authorization for 17 and under.

Operational requirements: Coordinated Care is free to develop their own process for authorization requests for patients 17 years of age and under, including using any generalized non-drug specific authorization process.

Coverage for naltrexone IM:

PA Criteria: No authorization or limitations. To be covered without restriction.

Claims processing / system requirements: None. Covered drug.

Operational requirements: None

Coverage for oral buprenorphine monotherapy:

PA Criteria: Member must meet one of the following criteria:

1. Member is pregnant
    a. Approve:
        - Through Member's Estimated Delivery Date (EDD)
        - Up to a maximum of 24mg per day
        - Up to a maximum of 7-days supply per prescription fill or refill
    b. If EDD is not provided, Coordinated Care may take additional steps to determine EDD
    c. If extension of authorization is requested due to pregnancy continuing beyond EDD, approve for one additional month
2. Member is breastfeeding: If *exception requests* are received to continue buprenorphine monotherapy while breastfeeding:
    a. Approve:
        - For up to 365 days
        - Up to a maximum of 24mg per day
        - Up to a maximum of 7-days supply per prescription fill or refill

    Note: Approval for breastfeeding is NOT coverage criteria, but is an exception to policy that <u>should be granted if requested</u>.
3. Member has naloxone allergy:
    a. Chart notes are required which document:
        - Nature of the allergic reaction; AND

- Direct observation of the allergic reaction by a health care professional (e.g.; may not be by Member report); AND

b. Allergic reaction is:

- Hives; or
- Angioedema; or
- Anaphylaxis; AND

c. If above conditions are met, approve:

- Indefinitely—use the date of 12/31/9999
- Up to a maximum of 24mg per day
- Up to a maximum of 7-days supply per prescription fill or refill
- May be reauthorized in twelve month intervals without further validation of allergy

4. If none of the above conditions are met, request should be denied as not covered / not indicated for unsupervised dispense to patients.
5. If otherwise approvable and prescribed for more than 24mg per day, criteria and process for 'Buprenorphine in excess of 24mg per day' applies.
6. Coordinated Care may develop their own criteria and process for coverage of diagnosis other than treatment of substance use disorder, so long as any authorization is limited to a maximum of a 7-day supply per prescription fill or refill.

Claims processing / system requirements:

- Prior Authorization required in all instances.
- When approved for payment, unless an exception is otherwise made, product should only be payable:
    - Up to a maximum of 24mg/day
    - Maximum of 7-days supply per prescription fill or refill

Operational requirements: None

- Coordinated Care is required to use a form substantially similar to the Medication Assisted Treatment Request for Buprenorphine Monotherapy form developed by HCA to initiate authorization.
- Coordinated Care should not seek additional validation of EDD when provided.
- Coordinated Care must require substantiating documentation of an allergic reaction if approving for naloxone allergy.
- **When prescribed for a labeled indication (MAT) Section 2 of the form MUST be signed and dated by patient receiving services.** Coordinated Care may not consider or approve authorization without explicit member consent. If information related to approval criteria, or any other substance use disorder information is submitted in absence of explicit signed consent, Coordinated Care must reject the request and inform the prescriber that it must be complete before the request can be accepted.

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Coverage for buprenorphine/naloxone:

PA Criteria: None (exception, see Buprenorphine in excess of 24mg per day).

Claims processing / system requirements:

- Maximum of 24mg/ day without authorization
- Approve indefinitely—use the date of 12/31/9999

Operational requirements: None (exception, see Buprenorphine in excess of 24mg per day).

Buprenorphine in excess of 24mg per day:

PA Criteria:

1. Clinical documentation showing member's continued use of illicit opioids such as labs, urine drug tests—i.e., inability to abstain from opioids at a dose of 24mg/day; AND
2. Documented compliance with scheduled visits, requests to return for pill counts, and providing samples for lab tests when asked; AND
3. Evidence by urine test that buprenorphine and its metabolite are present in the urine;
4. If all of the above conditions are met, Approve
    - Indefinitely—use the date of 12/31/9999
    - Up to a maximum of 32mg per day
    - Up to a maximum of 30 day supplies

- May be reauthorized in twelve month intervals without further validation of medical necessity

5. If criteria not met:
    a. If #1 is not satisfied, Coordinated Care may deny with alternative recommended = dose under 24mg.
    b. If #2 or #3 are not satisfied, Coordinated Care may deny on the basis of potential for diversion at high doses.

Claims processing / system requirements: See Buprenorphine monotherapy and buprenorphine/naloxone above.

Operational requirements:

- Coordinated Care is required to use a form substantially similar to the Medication Assisted Treatment Request for Buprenorphine > 24mg/day form developed by HCA to initiate authorization.
- Coordinated Care must require substantiating documentation (labs, drug screens, chart notes, etc…) validating that medical necessity criteria are satisfied

When prescribed for a labeled indication (MAT) Section 2 of the form MUST be signed and dated by patient receiving services. Coordinated Care may not consider or approve authorization without explicit patient consent. If information related to approval criteria, or any other substance use disorder information is submitted in absence of explicit signed consent, Coordinated Care must reject the request and inform the prescriber that it must be complete before the request can be accepted.

Additional Information:

- Patients may remain on medication assisted treatment with buprenorphine for as long as they are stable and evidence abstinence or reduced use from their baseline. As members will differ in terms of their preferences and ability to manage their substance use disorder with time limited or continuous treatment, the length of treatment should be determined by the member and their provider.
- Members who discontinue or reduce their opioid use but demonstrate continued use of other illicit drugs after stabilization on buprenorphine, usually one to two months, must receive increased intensity of services to achieve abstinence from illicit drugs. If on site services do not exist to meet the need for higher intensity services, members should be referred to a licensed Opioid Treatment Program (OTP), a Chemical Dependency Professional or to an Addiction Medicine Physician for evaluation and determination of the appropriate ASAM level of treatment placement.
- Members should be maintained on the lowest dose necessary to achieve a reduction of their symptoms and abstinence or a reduction in their use of opioids. It is recognized that some members may require doses above 16 mg to achieve this state. Requests for doses greater than 24mg require prior authorization.
- Use of other opioids or controlled substances while being treated with buprenorphine should be closely monitored by the prescribing physician. Members must consult with and receive approval from their buprenorphine prescriber for any medically necessary use of other opioids during the course of their treatment.
- There is no lifetime limit on the duration of buprenorphine treatment.
- Individual members may not go through more than 3 buprenorphine inductions in a calendar year without consultation from an addiction medicine provider.

- Full record reviews may be requested by HCA or Coordinated Care staff if there are concerns regarding the appropriateness of continued buprenorphine treatment in a particular patient.
- Representatives of HCA or Coordinated Care will also periodically review records of patients in the Prescription Monitoring Program to assure they are not receiving additional opioids or other types of controlled substances from other providers.

Payment for buprenorphine will be stopped if:

- Patient is found to be diverting some or all of their buprenorphine
- Patient is found to be selling their buprenorphine to others

REFERENCES:
Washington Apple Health – Managed Care Contract, Medication Assisted Treatment (MAT)

ATTACHMENTS:
CCW Clinical Guidelines and Coverage Limitations for Medication Assisted Treatment (MAT)

DEFINITIONS:

REVISION LOG:	**DATE**
Updated US Script (USS) name to Envolve Pharmacy Solutions Updated HCA web link Updated coverage for Naltrexone IM	01/13/2017

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Updated the requirement for prescribers to complete MAT Patient Status form from every 6 months to every 12 months. Updated approval timeframe for ongoing treatment.	1/29/2018

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in Compliance 360, Centene's P&P management software, is considered equivalent to a physical signature.

VP of Quality Improvement: _____ Approval on File:_____

Chief Medical Director:_____ Approval on File:_____