MEDICAL POLICY
Treatment of Opioid Dependence

GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Suboxone, Zubsolv (buprenorphine/naloxone) and buprenorphine are Schedule III narcotic medications available under the Drug Abuse Treatment Act (DATA) of 2000 for the treatment of opiate dependence. Under the Drug Abuse Treatment Act (DATA) of 2000, they can be used to treat opioid addiction outside of Opioid Treatment Programs. Only qualified doctors with the necessary DEA (Drug Enforcement Agency) identification number can prescribe or dispense Suboxone or Subutex for opioid addiction therapy. Qualified physicians should submit a Notification of Intent to the Center for Substance Abuse Treatment (CSAT, a component of SAMHSA) prior to starting therapy.

Buprenorphine hydrochloride for the treatment of opioid dependence is available as a sublingual tablet. Suboxone and Zubsolv contain naloxone, an opiate antagonist, to guard against misuse. Intravenously administered naloxone will block the effect of opiates and cause withdrawal symptoms. Since buprenorphine does not contain naloxone, it is often used for induction.

The Substance Abuse and Mental Health Administration (SAMHSA) recommends Suboxone (buprenorphine/naloxone) for induction, stabilization, and maintenance treatment for most patients due to the presence of naloxone in the formulation. However, pregnant women should be inducted and maintained on buprenorphine monotherapy, as naloxone can cause maternal and subsequently fetal hormonal changes. Other patients who are inducted on monotherapy should be switched to combination therapy as soon as possible to minimize the possibility of diversion of buprenorphine to abuse via injection. The use of buprenorphine for unsupervised administration during maintenance therapy should be limited to those patients who cannot tolerate Suboxone, for example those patients who have been shown to have a hypersensitivity to naloxone, and pregnant Women.

The safety of buprenorphine in pregnant women is currently being investigated but there is evidence that there are advantages in pregnancy and during lactation for the treatment of opioid dependence.

POLICY

| Suboxone, Zubsolv (buprenorphine/naloxone) and buprenorphine for the treatment of opioid dependence does not require prior authorization for HMO, PPO, Individual Marketplace, & Elite. |
| Suboxone, Zubsolv (buprenorphine/naloxone) and buprenorphine for the treatment of opioid dependence requires prior authorization for Advantage. |

HMO, PPO, Individual Marketplace, Elite
Suboxone, Zubsolv (buprenorphine/naloxone) and buprenorphine for the treatment of opioid dependence is covered. Medical records must reflect appropriate documentation and be provided upon request.

Advantage
Suboxone, Zubsolv (buprenorphine/naloxone) and buprenorphine for the treatment of opioid dependence will be approved if:

A. Treated by a "Board certified addictionologist or addiction psychiatrist" which means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:
   a. Subspecialty board certification in addiction psychiatry from the American board of psychiatry and neurology;
   b. Board certification in addiction medicine from the American board of addiction medicine;
   c. Certification from the American society of addiction medicine; or
   d. Board certification with additional qualification in addiction medicine from the American osteopathic association.
B. The physician provides Office Based Opioid Treatment (OBOT) in compliance with all the following guidelines:
   1. The physician shall comply with all federal and state laws applicable to OBOT;
   2. Prior to providing OBOT, the physician shall conduct an assessment meeting the following requirements:
      a. The assessment shall include, at a minimum, an appropriate history and physical, mental status exam, substance use history, appropriate lab tests, pregnancy test for women of childbearing years, toxicology tests for drugs and alcohol, and “hepatitis B” and “hepatitis C” screens.
      b. For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, hepatitis “B” and “C” screens and the pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a physical examination of the patient that was conducted by a physician within a reasonable period of time prior to the visit.
   3. The physician shall practice in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance and tapering.
      Acceptable protocols are any of the following:
      a. “Clinical Guidelines For the Use of Buprenorphine in the Treatment of Opioid Addiction” protocol approved by the substance abuse and mental health services administration in 2004, (available from the substance abuse and mental health services administration website at http://samhsa.gov/);
      b. The low dose protocol approved by the Ohio department of alcohol and drug addiction services in or about 2011 (available from the Ohio department of mental health and addiction services website at http://mha.ohio.gov/); or
      c. Any protocol for OBOT approved by the Ohio department of mental health and addiction services and available from the Ohio department of mental health and addiction services website at http://mha.ohio.gov.
   4. The physician shall diagnose an opioid disorder utilizing the criteria contained in the diagnostic and statistical manual of mental disorders, 4th or 5th edition.
   5. The physician shall develop an individualized treatment plan for each patient
   6. The physician shall require each patient to actively participate in appropriate behavioral counseling or treatment for their addiction and shall document at each visit that the patient is attending sufficient behavioral health treatment.
      a. The physician shall maintain meaningful interactions with the qualified chemical dependency professional, addiction treatment provider, or other behavioral health professional who is treating the patient.
      b. If the physician is a psychiatrist, board certified addictionologist, or board certified addiction psychiatrist, the physician may personally provide behavioral health treatment for the addiction.
      c. If the physician determines that the patient cannot reasonably be required to obtain professional treatment or if the patient has successfully completed professional treatment, the physician shall require the patient to actively participate in a recovery care program such as alcoholics anonymous, narcotics anonymous, or other appropriate twelve step program, and to document attendance at program meetings.
         i. For at least the first year the physician shall require the patient to attend the meetings at least three times weekly.
         ii. Following the first year, the physician shall determine the frequency with which the patient shall be required to attend the meetings.
         iii. The physician shall document in the patient record the reasons that the patient cannot reasonably be required to obtain professional treatment.
   7. The physician shall provide OBOT utilizing a drug product that has been specifically approved by the United States food and drug administration for use in maintenance and detoxification treatment. A physician shall not provide OBOT utilizing a drug product that has not been specifically approved by the United States food and drug administration for use in maintenance and detoxification treatment.
   8. The physician shall comply with all of the following:
      a. During the first twelve months of treatment, the physician shall not prescribe, personally furnish, or administer more than a thirty day supply of OBOT medications at one time.
      b. The physician shall personally meet with and evaluate the patient at each visit during the first twelve months of OBOT, and shall document an assessment and plan for continuing treatment.
      c. After twelve months of OBOT, the physician shall personally meet with and evaluate the patient at least every three months, unless more frequent meetings are indicated.
   9. The physician shall not provide OBOT to a patient whom the physician knows or should know is receiving other controlled substances for more than twelve consecutive weeks on an outpatient basis from any provider, without having consulted with a board certified addictionologist or addiction psychiatrist, who has recommended the patient receive OBOT. If the physician is a board certified addictionologist or addiction psychiatrist, the consultation is not required.
10. The physician shall not prescribe, personally furnish, or administer greater than 16 milligrams of buprenorphine per day to a patient, except in one of the following situations:
   a. The dosage greater than 16 milligrams was established before the effective date of this rule;
   b. The physician is a board certified addictionologist or addiction psychiatrist and has determined that a dosage greater than 16 milligrams is required for the patient, and has documented patient specific reasons for the need for a dosage greater than 16 milligrams in the patient’s record; or
   c. The physician has consulted with a board certified addictionologist or addiction psychiatrist who has recommended a dosage greater than 16 milligrams and that fact is documented in the patient’s medical record.

11. The physician shall access OARRS for each patient no less frequently than every ninety days, and shall document receipt and assessment of the information received.

12. The physician shall provide ongoing toxicological testing in compliance with all of the following:
   a. The physician shall assure that any in office kit used is “Clinical Laboratory Improvement Amendments” waived.
   b. The physician shall require toxicological testing be performed at least monthly for the first six months, then randomly at least once every three months thereafter.
   c. The physician may accept the results of toxicological testing performed by a treatment program or pursuant to a court order to satisfy the requirements of paragraph (12)(b).
   d. A screen is failed if the result is inconsistent with the treatment plan. A physician shall address failed screens in a clinically appropriate manner.

13. Each physician who provides OBOT shall complete at least eight hours of “Category I” continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this rule shall be accepted toward meeting the physician’s “Category I” continuing medical education requirement for biennial renewal of the physician’s certificate.

C. A physician may provide OBOT to a pregnant patient during the term of her pregnancy and for two months thereafter, in compliance with the minimal standards of care.

For the Advantage product line only: Additional reimbursement is warranted for complicated care management (i.e., pregnancy, multiple illnesses, complex diseases and morbidities) when providing opioid dependence management. HCPCS code H0016 may be used during the treatment process using Suboxone, Zubsolv (buprenorophine/naloxone) and buprenorophine with office based management, (99202-99204, 99212-99214), of opioid dependence when indicated. Medical records must reflect documentation complexity of increased time and management. This code will go into effect on November 1, 2014 and will not be retroactively paid. H0016 will only be reimbursed for diagnosis of opioid dependence (listed below).

**CODING/BILLING INFORMATION**
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>Description</th>
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<tbody>
<tr>
<td>H0016</td>
<td>Alcohol and/or drug services; medical/somatic (medical intervention in ambulatory setting)</td>
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<tr>
<td>ICD-9-CM CODES</td>
<td></td>
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<tr>
<td>304.00</td>
<td>Opioid type dependence, unspecified</td>
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<tr>
<td>304.01</td>
<td>Opioid type dependence, continuous</td>
</tr>
<tr>
<td>304.02</td>
<td>Opioid type dependence, episodic</td>
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<tr>
<td>ICD-10-CM CODES; EFFECTIVE 10/01/2015</td>
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<tr>
<td>F11.20</td>
<td>Opioid dependence, uncomplicated</td>
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<tr>
<td>F11.21</td>
<td>Opioid dependence, in remission.</td>
</tr>
<tr>
<td>F11.220</td>
<td>Opioid dependence with intoxication, uncomplicated</td>
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<tr>
<td>F11.221</td>
<td>Opioid dependence with intoxication delirium</td>
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<tr>
<td>F11.222</td>
<td>Opioid dependence with intoxication with perceptual disturbance</td>
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<tr>
<td>F11.229</td>
<td>Opioid dependence with intoxication, unspecified</td>
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<tr>
<td>F11.23</td>
<td>Opioid dependence with withdrawal</td>
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<tr>
<td>F11.24</td>
<td>Opioid dependence with opioid-induced mood disorder</td>
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<tr>
<td>F11.250</td>
<td>Opioid dependence with opioid-induced psychotic disorder with delusions</td>
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<tr>
<td>F11.251</td>
<td>Opioid dependence with opioid-induced psychotic disorder with hallucinations</td>
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<td>F11.259</td>
<td>Opioid dependence with opioid-induced psychotic disorder, unspecified</td>
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<td>F11.281</td>
<td>Opioid dependence with opioid-induced sexual dysfunction</td>
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<tr>
<td>F11.282</td>
<td>Opioid dependence with opioid-induced sleep disorder</td>
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<tr>
<td>F11.288</td>
<td>Opioid dependence with other opioid-induced disorder</td>
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REVISION HISTORY EXPLANATION
11/11/14: Policy created to reflect most current clinical evidence per Medical Policy Steering Committee.
07/14/15: Reviewed ODM 4731-11-12 guidelines. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.