Prior Authorization Protocol

Therapeutic Class: Smoking Cessation Aids

Formulary Status: On Formulary
Medication Classes:
- Nicotine Replacement Products (NRT)
- Antidepressants
- Nicotine Receptor Agonist

Agents:
- Nicotine Patch - Nicoderm CQ®, Nicotrol®, Habitrol®
- Nicotine Nasal Spray - Nicotrol NS®
- Nicotine Inhaler - Nicotrol Inhaler®
- Nicotine Gum - Nicorette®
- Nicotine Lozenge - Commit®
- Bupropion - Wellbutrin®, Wellbutrin XL®, Zyban®
- Varenicline - Chantix®

I. FDA Approved Indications
All products are FDA approved as aids for smoking cessation treatment and to help reduce withdrawal symptoms, including nicotine craving.

II. Guidelines for Approval
The following criteria apply to AHCCCS members choosing to receive a tobacco cessation product.

a. Members are encouraged to enroll in a tobacco cessation program through ADHS. To enroll in an ADHS cessation program the member must call 1-800-55-66-222.

b. Members must contact their primary care provider (PCP) to obtain a prescription for a tobacco cessation product. The PCP will identify an appropriate tobacco cessation product. In order to be covered by AHCCCS all tobacco use medications require a prescription. This includes all tobacco cessation products, including those that are available over-the-counter.

c. The maximum supply a member may receive of a tobacco cessation product is a 12-week supply in a six month time period. The six month time period begins the date the first prescription is filled for the tobacco cessation product.
III. Prior authorization will be required for the following:
   a. Members under the age of 18 years old
   b. Brand name medications when a generic product is available
   c. Bupropion 24 hour / Wellbutrin XL

IV. Coverage is Not Authorized For:
   a. Non-Title XIX Members
   b. Indications other than for as an aid for smoking cessation
   c. Doses greater than the FDA Maximum Allowable
   d. Combination treatment with more than one of the above agents
   e. Specific drug-disease condition contraindications

V. Coverage for Dual Eligibles:
   a. Medications that are available by prescription only and bear the federal legend, “Federal Law
      Prohibits Dispensing Without a Prescription” are to be obtained from and covered by the
      Medicare Part D Plan.
   b. Medication that are available over-the-counter are to be covered by the AHCCCS Contracted
      Health Plans and ordered in accordance with Section II- Guidelines for Approval.

VI. Therapeutic Alternatives

<table>
<thead>
<tr>
<th>Smoking Cessation Product</th>
<th>Dosing Regimen</th>
<th>Maximum Daily Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine Nasal Spray</td>
<td>2-4 sprays per hour</td>
<td>40mg</td>
</tr>
<tr>
<td>(Nicotrol® NS)</td>
<td>Minimum effective dose is 16 sprays per day</td>
<td>80 sprays per day</td>
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<tr>
<td></td>
<td>80 sprays = ½ bottle</td>
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<tr>
<td>Nicotine Inhaler</td>
<td>6-16 cartridges a day individualized dosing as needed.</td>
<td>16 cartridges per day</td>
</tr>
<tr>
<td>(Nicotrol® Inhaler)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nicotine Patch</td>
<td>7 mg / 24 hours</td>
<td>21mg per 24 hours</td>
</tr>
<tr>
<td>(Nicoderm® CQ,</td>
<td>14 mg / 24 hours</td>
<td></td>
</tr>
<tr>
<td>Nicotrol®, Habitrol®)</td>
<td>21 mg / 24 hours</td>
<td></td>
</tr>
<tr>
<td>Nicotine Gum</td>
<td>1 piece every 1-2 hours weeks 1-6, then</td>
<td>24 pieces of gum or lozenges per day</td>
</tr>
<tr>
<td>(Nicorette®, OR Lozenge</td>
<td>1 piece every 2-4 hours weeks 7-9, then</td>
<td></td>
</tr>
<tr>
<td>Commit®)</td>
<td>1 piece every 4-8 hours weeks 10-12.</td>
<td></td>
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<tr>
<td>Bupropion HCl SR</td>
<td>150mg orally every day for the first 3 days, may increase to 150mg twice a day if tolerated.</td>
<td>300mg per day</td>
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<tr>
<td>(Zyban® / Wellbutrin SR®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verenicline</td>
<td>Titration Schedule:</td>
<td>2mg per day</td>
</tr>
<tr>
<td>(Chantix®)</td>
<td>0.5mg orally daily for 3 days then,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.5mg twice daily for 4 days then, 1mg twice daily to completed the 12 week course of therapy</td>
<td></td>
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</table>
VII. **General Information**

a. **Nicotine (NRT)**
   i. Dependence has been recognized as a chronic, relapsing disease
   ii. Any form is can be toxic and addictive
   iii. Smoking-Drug interactions are costly to the health care system

b. **Bupropion (Wellbutrin, Wellbutrin XL & Zyban)**
   i. Mechanism of action is unknown
   ii. In comparative data trials, efficacy is superior to NRT
   iii. Reduces weight gain after smoking cessation
   iv. Has several contraindications, precautions and warnings
   v. The study, *A Controlled Trial of Sustained-Release Bupropion, a Nicotine Patch, or Both For Smoking Cessation. 1999*, found that sustained release bupropion alone or in combination with a nicotine patch resulted in significantly higher long-term rates of smoking cessation as compared to the use of either the nicotine patch alone or placebo. Abstinence rates were higher with combination therapy than with bupropion alone but the difference was not statistically significant.

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c. **Verenicline (Chantix)**
   i. Represents a new class for smoking cessation therapy and acts as a nicotinic partial receptor agonist.
   ii. Dose dependent nausea has been reported in up to 40% of utilizing patients.
   iii. Long-term safety is unknown.
   iv. Does not reduce weight gain after smoking cessation.
   v. Efficacy of Verenicline as compared to NRT is currently unknown.
   vi. In comparative trials following 12 weeks of treatment, bupropion naïve patients receiving Verenicline were more likely to quit smoking than patients on bupropion.
   vii. In one Verenicline study, an additional 12-week course of therapy was given to abstinent patients immediately after the first 12-week course had elapsed. There is currently no data to support the efficacy of re-starting Verenicline after a lapse in therapy following the initial 12-week course.
   viii. No contraindications (other than drug allergy)
   ix. Extreme caution should be taken when evaluating a person with serious mental illness for a trial of Verenicline.

d. Abstinence rates were consistently higher with all products when combined with a behavioral modification program.

e. Based on the clinical trials of all of the products, an assumption can be drawn that Verenicline is superior over Bupropion over NRT.

**References:**

- AHCCCS Smoking Cessation Policy, October 2009
- Chantix Prescribing Information, Pfizer Labs, May 2006.
- Bupropion Monograph, Drug Facts and Comparisons, May 2009
- Central Nervous system Agents, Smoking Deterrants, Nicotine, Drug Facts and Comparisons, May 2009