



***Our first care is your health care***  
ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

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## **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<sup>®</sup>, Nicotrol<sup>®</sup>, Habitrol<sup>®</sup>
- Nicotine Nasal Spray - Nicotrol NS<sup>®</sup>
- Nicotine Inhaler - Nicotrol Inhaler<sup>®</sup>
- Nicotine Gum - Nicorette<sup>®</sup>
- Nicotine Lozenge - Commit<sup>®</sup>
- Bupropion - Wellbutrin<sup>®</sup>, Wellbutrin XL<sup>®</sup>, Zyban<sup>®</sup>
- Varenicline - Chantix<sup>®</sup>

#### **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:**
- Members under the age of 18 years old
  - Brand name medications when a generic product is available
  - Bupropion 24 hour / Wellbutrin XL

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

- V. **Coverage for Dual Eligibles:**
- 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.
  - 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**

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

## 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.

### c. Varenicline (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 Varenicline as compared to NRT is currently unknown.
  - vi. In comparative trials following 12 weeks of treatment, bupropion naïve patients receiving Varenicline were more likely to quit smoking than patients on bupropion.
  - vii. In one Varenicline 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 Varenicline 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 Varenicline.
- 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 Varenicline is superior over Bupropion over NRT.

## References:

- AHCCCS Smoking Cessation Policy, October 2009
- Chantix Prescribing Information, Pfizer Labs, May 2006.
- Varenicline Monograph, Drug Facts and Comparisons, May 2009
- Bupropion Monograph, Drug Facts and Comparisons, May 2009
- Zyban Prescribing Information, GlaxoSmithKline, December 2008.
- Central Nervous system Agents, Smoking Deterrants, Nicotine, Drug Facts and Comparisons, May 2009
- Jorenby DE, Hays JT, Rigotti NA, et al. Efficacy of varenicline, an  $\alpha 4\beta 2$  nicotinic acetylcholine receptor partial agonist, vs placebo or sustained-release bupropion for smoking cessation. *JAMA*. 2006;296:56-63.