



AMPM CHAPTER 300, MEDICAL POLICY FOR COVERED SERVICES

**EXHIBIT 320-K - 1, PRIOR AUTHORIZATION PROTOCOL THERAPEUTIC
CLASS: SMOKING CESSATION AIDS**

THERAPEUTIC CLASS: SMOKING CESSATION AIDS FORMULARY STATUS: ON FORMULARY		
EDUCATION CLASSES	AGENTS	
NICOTINE REPLACEMENT THERAPY (NRT) PRODUCTS	Nicotine Patch	Nicoderm CQ [®] Nicotrol [®] Habitrol [®]
	Nicotine Nasal Spray	Nicotrol NS [®]
	Nicotine Inhaler	Nicotrol Inhaler [®]
	Nicotine Gum	Nicorette [®]
	Nicotine Lozenge	Commit [®]
ANTIDEPRESSANTS	Bupropion Bupropion SR Bupropion 24 hours	Wellbutrin [®] Wellbutrin SR [®] , Zyban [®] Wellbutrin XL [®]
NICOTINE RECEPTOR AGONIST	Verenicline	Chantix [®]

A. FEDERAL DRUG ADMINISTRATION (FDA) APPROVED INDICATIONS

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

B. GUIDELINES FOR APPROVAL

The following criteria apply to AHCCCS members choosing to receive a tobacco cessation product.

1. Members are encouraged to enroll in a tobacco cessation program through Arizona Department of Health Services (ADHS). To enroll in an ADHS cessation program the member must call 1-800-556-6222.
2. 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.
3. 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.



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C. PRIOR AUTHORIZATION WILL BE REQUIRED FOR THE FOLLOWING:

1. Members under the age of 18 years old,
2. Brand name medications when a generic product is available, and
3. Bupropion 24 hour / Wellbutrin XL.

D. COVERAGE IS NOT AUTHORIZED FOR:

1. Non-Title XIX Members,
2. Indications other than for as an aid for smoking cessation,
3. Doses greater than the FDA Maximum Allowable,
4. Combination treatment with more than one of the above agents, or
5. Specific drug-disease condition contraindications.

E. COVERAGE FOR DUAL ELIGIBLES:

Medications that are available by prescription only and bear the federal legend, Federal Law Prohibits Dispensing Without a Prescription¹ are to be obtained from and covered by the Medicare Part D Plan.

Medications that are available over-the-counter are to be covered by the AHCCCS Contracted Health Plans and ordered in accordance with Section B, Guidelines for Approval.



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F. THERAPEUTIC ALTERNATIVES

SMOKING CESSATION PRODUCT	DOSING REGIMEN	MAXIMUM DAILY DOSE
NICOTINE NASAL SPRAY (<i>Nicotrol[®] 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[®] Inhaler</i>)	6-16 cartridges a day individualized dosing as needed.	16 cartridges per day
NICOTINE PATCH (<i>Nicoderm[®] CQ, Nicotrol[®], Habitrol[®]</i>)	7 mg / 24 hours 14 mg / 24 hours 21 mg / 24 hours	21mg per 24 hours
NICOTINE GUM (<i>Nicorette[®]</i>), OR Lozenge (<i>Commit[®]</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[®] / Wellbutrin SR[®]</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[®]</i>)	Titration Schedule: 0.5mg orally daily for 3 days, then 0.5mg twice daily for 4 days, then 1mg twice daily to complete the 12 week course of therapy	2mg per day

G. GENERAL INFORMATION

1. Nicotine Replacement Therapy (NRT)
 - a. Dependence has been recognized as a chronic, relapsing disease
 - b. Any form can be toxic and addictive
 - c. Smoking-drug interactions are costly to the health care system



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2. Bupropion (Wellbutrin, Wellbutrin XL & Zyban)
 - a. Mechanism of action is unknown
 - b. In comparative data trials, efficacy is superior to NRT
 - c. Reduces weight gain after smoking cessation
 - d. Has several contraindications, precautions and warnings
 - e. 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.
3. Varenicline (Chantix)
 - a. Represents a new class for smoking cessation therapy and acts as a nicotine partial receptor agonist.
 - b. Dose dependent nausea has been reported in up to 40% of utilizing patients.
 - c. Long-term safety is unknown.
 - d. Does not reduce weight gain after smoking cessation.
 - e. Efficacy of Varenicline as compared to NRT is currently unknown.
 - f. In comparative trials following 12 weeks of treatment, bupropion naïve patients receiving Varenicline were more likely to quit smoking than patients on bupropion.
 - g. 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.
 - h. No contraindications (other than drug allergy).
 - i. Extreme caution should be taken when evaluating a person with serious mental illness for a trial of Varenicline.
4. Abstinence rates were consistently higher with all products when combined with a behavioral modification program.



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5. Based on the clinical trials of all of the products, an assumption can be drawn that Varenicline is superior to Bupropion and NRT.

REFERENCES

1. AHCCCS Smoking Cessation Policy, October 2009.
2. Chantix Prescribing Information, Pfizer Labs, May 2006.
3. Varenicline Monograph, Drug Facts and Comparisons, May 2009.
4. Bupropion Monograph, Drug Facts and Comparisons, May 2009.
5. Zyban Prescribing Information, GlaxoSmithKline, December 2008.
6. Central Nervous system Agents, Smoking Deterrents, Nicotine, Drug Facts and Comparisons, May 2009.
7. 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.