

**Prior Authorization Protocol**

**ZYBAN<sup>®</sup> (bupropion hydrochloride sustained release), NICOTROL<sup>®</sup> NS (nicotine nasal spray), NICOTROL<sup>®</sup> INHALER (nicotine inhaler), NICODERM CQ<sup>®</sup> (nicotine transdermal patch), NICORETTE<sup>®</sup> (nicotine polacrilex)**

**NATL**

Coverage of drugs is first determined by the member's pharmacy or medical benefit. Please consult with or refer to the Evidence of Coverage document.

**I. FDA Approved Indications:**

- Zyban is indicated as an aid to smoking cessation treatment
- Nicotrol NS and Nicotrol Inhaler are indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms.
- Nicoderm CQ and Nicorette are indicated to reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking.

**II. Health Net Approved Indications and Usage Guidelines:**

- Member is concurrently enrolled in a behavior modification program  
AND
- Member is not currently taking any formulation of bupropion (Wellbutrin SR<sup>®</sup>) or Nicotine Replacement products in combination with Zyban<sup>®</sup>  
AND
- Over the counter (OTC) products are excluded for most benefit plan types

**III. Coverage Is Not Authorized For:**

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section unless there is sufficient documentation of efficacy and safety in the published literature
- Concurrent therapy with other smoking cessation products
- Members without smoking cessation coverage

**IV. General Information:**

- In July 2009, the FDA mandated a black box warning alerting providers to observe all patients on Zyban and Chantix for neuropsychiatric symptoms including changes in behavior, hostility, agitation, depressed mood, and suicide related events, including ideation, behavior, and attempted suicide.
- Zyban treatment should be initiated while patient is still smoking. Once initiated a "target quit date" should be set for within the first two weeks of treatment.
- If a patient has not achieved complete abstinence by the seventh week with Zyban, it is unlikely that he or she will quit during this attempt, and treatment should be discontinued.
- Zyban contains the same active ingredient as Wellbutrin<sup>®</sup>, Wellbutrin<sup>®</sup> SR/XL. It should not be taken concurrently with other bupropion products. Zyban is contraindicated in individuals with a history of seizures, eating disorders, undergoing abrupt discontinuation of alcohol or sedatives, or currently taking monoamine oxidase inhibitors (MAOI).

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- In one comparative trial, the quit rates for the combination of Zyban and Nicotine were not significantly higher than Zyban alone (p > 0.05). A higher incidence of treatment emergent hypertension was reported in patients treated with combination therapy.
- The safety and efficacy of using Chantix (varenicline) in combination with other smoking cessation therapies (Zyban, Nicotrol) has not been established.
- Coverage is limited to plans under the Department of Managed Health Care oversight or plans with a specific smoking cessation rider..
- In Arizona, coverage up to 12 weeks of smoking cessation products is reimbursable with concurrent enrollment in a comprehensive smoking cessation behavioral support program.
- All members are eligible for The American Cancer Society and The American Lung Association smoking cessation programs.
- **Commercial members:**
  - May enroll in the Decision Power<sup>SM</sup> smoking and tobacco cessation program by calling 1-800-893-5597 or TTY/TDD for hearing and speech-impaired assistance at 1-800-276-3821
  - Have on line access to a 10-session smoking cessation program that is self-paced at <http://www.healthnet.com> >> Decision Power Health and Wellness >> [left navigation bar] Quit Smoking >> Ready, Set, Stop!<sup>®</sup> Online<sup>TM</sup>
- The member is responsible for any program fees or copayments when enrolling in a behavioral modification program other than those offered through Health Net.

**V. Therapeutic Alternatives:**

<b>Drug</b>	<b>Dosing Regimen</b>	<b>Dose/Limit/Maximum Dose</b>
Chantix <sup>®*</sup> (varenicline)	Titration schedule: 0.5 mg PO QD for 3 days, followed by 0.5 mg PO BID for 4 days, then 1 mg PO BID to complete 12 weeks of therapy	2 mg/day; 12 week course of therapy
nicotine gum** (Nicorette <sup>®</sup> )	Chew orally as follows: 1 piece every 1-2 hours week 1-6 then, 1 piece every 2-4 hours week 7-9 then, 1 piece every 4-8 hours weeks 10-12	24 pieces/day
nicotine patches** (Nicoderm CQ)	1 patch changed daily >10 cigarettes per day: 21 mg patch weeks 1-6 then 14 mg weeks 7-8 then 7 mg weeks 9-10 10 or less cigarettes per day: 14 mg patch weeks 1-6 then 7mg weeks 7-8	8-10 weeks
nicotine lozenge** (Commit <sup>®</sup> )	Slowly dissolve orally as follows: 1 lozenge every 1-2 hours weeks 1-6 then, 1 lozenge every 2-4 hours weeks 7-9 then, 1 lozenge every 4-8 hours weeks 10-12	20 lozenges/day

\*\* Coverage of OTC agents may vary with plan formulary and benefit design

\* Requires Prior Authorization

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**VI. Recommended Dosing Regimen and Authorization Limit:**

<b>Drug</b>	<b>Dosing Regimen</b>	<b>Authorization Limit</b>
Nicotrol <sup>®</sup> NS (nicotine nasal spray)	Initial: 2-4 sprays intranasally per hour (up to a max of 80 sprays per day), studies suggest a minimum of 16 sprays per day was most effective. Reduction: Dose may be reduced as nicotine withdrawal subsides	12 week course per calendar year  <u>HNOR</u> <u>Initial:</u> 12 weeks
Nicotrol <sup>®</sup> Inhaler (nicotine inhaler)	Initial Treatment (Up to 12 weeks): At least 6 cartridges via oral inhalation daily for 3-6 weeks. Additional cartridges may be used if needed. Maximum of 16 cartridges per day. Reduction (Up to 12 weeks): Patients should be encouraged to gradually reduce the number of cartridges used.	Continuation: 12 weeks if the member is abstinent upon completing initial 12 weeks
bupropion hydrochloride sustained release (Zyban <sup>®</sup> )	150 mg PO daily for the first 3 days, then 150 mg PO twice daily for 7-12 weeks. Maximum dose is 300 mg/day.	

**VII. Product Availability:**

Nicotrol NS Nasal Spray: 10 mg/ml bottle, 0.5 mg/spray; 200 sprays per unit; pkg of 4 x 10 ml  
 Nicotrol Inhaler: 168 cartridges each containing 10 mg nicotine (4 mg delivered)  
 Nicoderm CQ transdermal patch: 7 mg/24hr, 14 mg/24hr, 21 mg/24hr  
 Nicorette gum and lozenge: 2 mg, 4 mg  
 Zyban tablet: 150 mg

**VIII. References:**

1. Zyban [Prescribing Information]. Greenville, NC: Glaxo Smith Kline; January 2015.
2. Nicotrol Nasal Spray [Prescribing Information]. New York, NY: Pfizer; June 2010.
3. Nicotrol Inhaler [Prescribing Information]. New York, NY: Pfizer; December 2008.
4. A clinical practice guideline for treating tobacco use and dependence. *JAMA*. 2000;283:3244-3254.
5. Watts SA, Noble SL, Smith PO, and Disco M. First-line Pharmacotherapy for Tobacco Use and Dependence. *JABFP*. 2002;15(6):489-497.
6. Anderson JE, Jorenby DE, Scott WJ, and Fiore MC. Treating Tobacco Use and Dependence: An Evidence-Based Clinical Practice Guideline for Tobacco Cessation. *Chest*. 2002;121:932-941.
7. Dale LC, Glover EF, Sachs DP, et al. Bupropion for Smoking Cessation: Predictors of Successful Outcome. *Chest*. 2001;119:1357-1364.

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8. Chantix [Prescribing Information]. New York, NY: Pfizer; February 2013
9. Nicoderm CQ [Prescribing Information]. Glaxo Smith Kline; April 2015.
10. Nicorette [Prescribing Information]. Moon Township, PA: Glaxo Smith Kline; November 2014.
11. Clinical Pharmacology Website. Available at: <http://www.clinicalpharmacology-ip.com/Default.aspx>. Accessed January 7, 2016.
12. Micromedex<sup>®</sup> Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 7, 2016.

*The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.*