

CHANTIX® (varenicline)**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:

- As an aid to smoking cessation treatment

II. Health Net Approved Indications and Usage Guidelines:

- Member is concurrently enrolled in a behavior modification program

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 December 2012, the FDA informed the public about the results of a large, combined analysis of clinical trials that compared patients who received the smoking cessation drug varenicline (Chantix) to patients who received placebo. A higher occurrence of major adverse cardiovascular events (a combined outcome of cardiovascular-related death, nonfatal heart attack, and nonfatal stroke) was observed in patients using varenicline compared to placebo. These events were uncommon in both the varenicline and placebo groups, and the increased risk was not statistically significant. Instruct patients to notify their health care providers of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.
- In July 2009, the FDA mandated a black box warning alerting providers to observe all patients on Chantix and Zyban for serious neuropsychiatric events. Patients should stop taking Chantix and contact a healthcare provider immediately if agitation, hostility, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior while taking Chantix or shortly after discontinuing Chantix.
- In comparative trials following 12 weeks of treatment, Zyban® naïve patients receiving Chantix were more likely to quit smoking than patients on Zyban (OR = 1.90, p < 0.001) or placebo (OR = 3.85, p < 0.001).
- In one Chantix 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 Chantix after a lapse in therapy following the initial 12-week course.
- Among patients who had stopped smoking after an initial 12 weeks of treatment with Chantix and received a second 12-week course, 70.5% remained smoke-free at 6 months compared to 49.6% who received placebo (OR = 2.48, p < 0.001) and 43.6% remained smoke-free at 1 year compared to 36.9% who received placebo (OR = 1.34, p = 0.02).
- The safety and efficacy of Chantix in combination with other smoking cessation therapies have not been studied.

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- Coverage is limited to plans under the Department of Managed Health Care oversight or plans with a specific smoking cessation rider.
- Over-the-counter alternatives are covered for California Medi-Cal members only.
- 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 and Medicare Advantage (including PFFS) members ONLY:**
 - May enroll in the Decision PowerSM 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 online 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![®] Online[™]
 - Pfizer sponsors a free phone and web based program (GET QUIT[™]) to smokers attempting to quit with Chantix. Members can enroll online at www.chantix.com or call 1-877-CHANTIX.
- 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:

Drug	Dosing Regimen	Dose/Limit/Maximum Dose
Nicotrol [®] NS* (nicotine nasal spray)	Initial Treatment (Up to 12 weeks): 2 - 4 sprays intranasally per hour, minimum effective dose is 16 sprays per day. Reduction: Dose may be reduced as nicotine withdrawal subsides.	40 mg/day (80 sprays)
Nicotrol [®] 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, up to 16 cartridges per day. Reduction (Up to 12 weeks): Patients should be encouraged to gradually reduce the number of cartridges used.	16 cartridges/day
bupropion hydrochloride sustained release* (Zyban [®])	150 mg PO daily for first 3 days, then increase to 150 mg PO BID for remainder of the treatment period	300 mg/day

* Requires Prior Authorization

VI. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
Chantix [®] (varenicline)	Titration schedule: 0.5 mg PO QD for 3 days, followed by 0.5 mg PO BID	Length of benefit (12 week course per calendar year)

Prior Authorization Protocol
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Drug	Dosing Regimen	Authorization Limit
	for 4 days, then 1 mg PO BID to complete 12 weeks of therapy	<p style="text-align: center;">HNOR</p> <p style="text-align: center;"><u>Initial</u>: 12 weeks</p> <p style="text-align: center;"><u>Continuation</u>: 12 weeks if the member is abstinent upon completing initial 12 weeks</p>

Product Availability:

Tablet: 0.5 mg and 1 mg, bottles of 56 tablets

Starting Month PAK: 53 tablets total (1 card of 0.5 mg x 11 tablets; 3 cards of 1 mg x 14 tablets)

Continuing Month PAK: 56 total tablets (4 cards of 1 mg x 14 tablets)

VII. References:

1. Chantix [Prescribing Information]. New York, NY: Pfizer; October 2014..
2. A clinical practice guideline for treating tobacco use and dependence. *JAMA*. 2000;283:3244-3254.
3. 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.
4. Gonzales D, Rennard SI, Nides M, et al. Varenicline, an $\alpha 4\beta 2$ nicotinic acetylcholine receptor partial agonist, vs sustained-release bupropion and placebo for smoking cessation. *JAMA*. 2006;296:47-55.
5. Tonstad S, Tonnesen P, Hajek P, et al. Effect of maintenance therapy with varenicline on smoking cessation. *JAMA*. 2006;296:64-71.
6. Zyban [Prescribing Information]. Greenville, NC: GlaxoSmithKline; January 2012..
7. Nicotrol NS [Prescribing Information]. New York, NY: Pfizer; June 2010.
8. Nicotrol Inhaler [Prescribing Information]. New York, NY: Pfizer; December 2008.
9. American Hospital Formulary Service Drug Information. AHFS Web site. Available at: <http://www.medicinescomplete.com/mc/ahfs/current/>. Accessed July 19, 2013.
10. Micromedex® 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.