nh healthy families

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** varenicline (Chantix®)
PAGE: 1 of 5	**REFERENCE NUMBER:** NH.PMN.18
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 12/14, 08/16, 07/17
PRODUCT TYPE: All	**REVISED:** 11/09, 10/10, 11/11, 11/12, 11/13

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

Description: Chantix is indicated for smoking cessation. The active ingredient, varenicline tartrate, is a molecular entity that binds with high affinity and selectivity at α4ß2 neuronal nicotinic acetylcholine receptors. The efficacy of this medication in smoking cessation is believed to be the result of varenicline's activity at sites in the brain affected by nicotine and may provide some nicotine effect to ease the withdrawal symptoms and by blocking the effects of nicotine from cigarettes if they resume smoking.

Brand: varenicline (Chantix®): 0.5mg, 1mg tablets in 1st month and continued therapy packs

FDA Labeled Indications: Aid in smoking cessation treatment

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Criteria for Approval:

A. Current smoker; ≥18 years of age; wanting to stop and agrees on a "Stop Date"; **and**
B. Failed a 3 month trial of adherent use of combination nicotine replacement therapy (a patch plus a short acting form such as the nicotine gum), unless contraindicated **and**
C. Failed a 3 month trial of adherent use of bupropion, unless contraindicated or intolerant
D. Chantix® must be used as mono-therapy, **and**
E. Enrolled in a behavioral support plan (e.g., The GETQUIT Support Plan through Pfizer)

Approval:

Initial Approval: 12 week course
Continued Approval: 12 week course

NOTE: Coverage varies by plan based on state mandates.

Special Instructions

> Not to be used in patients < 18 years of age.
> See boxed warning on increased risk of suicide.
> Varenicline may be associated with a small, increased risk of certain cardiovascular events in patients with cardiac disease.
> Pregnancy Category C risk.
> Administer Varenicline after eating with a full glass of water.
> Encourage patients to read the Medication Guide they receive along with the prescription

References:

1. Management of Smoking Cessation in Adults, UpToDate, Accessed Sept 2014, www.uptodate.com
2. Chantix® prescribing information and GETQUIT Support Program, Accessed Sept 2014, www.chantix.com.
3. FDA boxed warning labeling requirement, July, 2009.

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http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170100.htm 2011. Accessed September 2014.

4. FDA Drug Safety Communication: Updated efficacy and safety information in COPD and cardiovascular disease, July, 2011. http://www.fda.gov/Drugs/DrugSafety/ucm259161.htm, Accessed October 2014.
5. Varenicline monograph. Clinical Pharmacology. Accessed October 2014.
6. Pharmacotherapy for smoking cessation in adults, UpToDate, Accessed October 2014
7. U.S. Department of Health and Human Services. Clinical Practice Guideline: Treating Tobacco Use and Dependence: 2008 Update. http://bphc.hrsa.gov/buckets/treatingtobacco.pdf. Accessed October 2014.

Revision Log	
Revision	**Date**
Removed "Medical condition necessitating immediate smoking cessation; **and**" as a "Criteria for Approval".	11/09
Added "Chantix® to be used as mono-therapy, **and**" as a "Criteria for Approval".	11/09
Updated Reference section to reflect current literature search and reference documents.	11/09
Updated Reference section to reflect current literature search and reference documents.	10/10
Updated Reference section to reflect current literature search and reference documents.	11/11
Updated Reference section to reflect current literature search and reference documents.	11/12
Added "≥18 years of age" as a "Criteria for Approval": approved by	11/13

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the Food and Drug Administration for use in adults 18 and over	
Changed "Criteria for Approval: B" to combination nicotine therapy, per UPTODATE/clinical guideline for smoking cessation. The nicotine patch is the primary NRT product to control baseline nicotine withdrawal symptoms. Adding a short-acting form of NRT helps to control cravings and withdrawal symptoms during the day on an as needed basis. This has been called the "patch plus" regimen. Randomized trials have found that combining the nicotine patch with the gum, inhaler, nasal spray, or lozenge has better efficacy than the use of a single product [6,7]. In a meta-	11/13
analysis of 9 trials, the combination of nicotine patch with a short-acting NRT product (gum, spray or inhaler) was more effective than a single type of NRT; also added "unless contraindicated".	
Removed Bupropion criteria from "Criteria for Approval, B" and Created "Criteria for Approval: C"-"Failed a 3 month trial of Bupropion" and also added "unless contraindicated or intolerant".	11/13
Added "Special Instructions" about cardiovascular precaution, administration, and Medication Guide.	11/13
Added and Updated Reference section to reflect current literature search and reference documents.	11/13
Removed reference from Micromedex-unable to access at this time.	11/13
Updated references.	12/14
Removed the requirement that patient remains off cigarettes during first course for continued approval	06/15
Annual Review, No changes	08/16
Annual Review, No Changes	07/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

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V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file

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