

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
Pharmacy Phone: _____

Complete the Clinical Assessment:

The patient must be enrolled in a smoking cessation program in order for approval to be considered. This program must include formal weekly counseling and support (either face-to-face or by telephone).

An example of a free smoking cessation program is the Colorado Quit Line (800-784-8669)

STEP
2

Clinical Consideration	Approved prior authorizations cover one 12 week course of therapy. No more than two 12 week courses of therapy will be approved.
	<p>If this request is for the FIRST 12 week course of therapy:</p> <input type="checkbox"/> Patient 18 years of age or older <input type="checkbox"/> Patient enrolled in Smoking Cessation Program or receiving formal cessation support. <p>Which program is the patient enrolled in? _____</p> <input type="checkbox"/> Patient has not previously been treated with Chantix <input type="checkbox"/> Patient has been treated with Chantix. Length of time: _____
Supporting Documentation	<p>If this request is for a SECOND 12 week course of therapy: Second 12 weeks is indicated to aid in <i>continued abstinence</i> only. Did patient quit smoking during first 12 weeks, and is pt still abstinent? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
	Diagnosis: ICD-9 Code #/ Description / J Code (required):
	Please attach a copy of the prescription or provide ALL of the information below: Chantix [®] (varenicline) Strength _____ Sig _____ Qty _____ Refills _____
Please attach all relevant medical records and test results. <p style="text-align: center;">Incomplete forms will not be processed.</p>	

STEP 3

I certify that the above is correct and accurate to the best of my knowledge (please sign and date).

Prescriber Signature

Date

STEP 4

Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:

970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/05/11

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Chantix (varenicline)

CLASSIFICATION

- Smoking Cessation Agent

DESCRIPTION

- Varenicline is a partial agonist selective for alpha-4-beta-2 nicotinic acetylcholine receptor subtypes. It binds with high affinity and selectivity at alpha-4-beta-2 neuronal nicotinic acetylcholine receptors. Its binding produces agonist activity at a sub-type of the nicotinic receptor, but at a significantly lower level than nicotine. Varenicline also prevents nicotine binding to alpha-4-beta-2 receptors, which prevents stimulation of the central nervous mesolimbic dopamine system (the mechanism responsible for the reinforcement and reward experience associated with smoking)
- Varenicline (44%) produced a superior rate of smoking abstinence compared to placebo (18%) and bupropion SR (30%) in two 12-week randomized, double-blind clinical studies. Nausea was the most commonly reported adverse effect associated with varenicline and was more common than bupropion and placebo. However, varenicline was associated with less insomnia than bupropion. In both studies, the urge to smoke was reduced in both the varenicline group and the bupropion SR group compared to placebo. Weight gain was lowest among subjects in the bupropion SR group and similar between the varenicline and placebo groups. In both studies discontinuation rates due to adverse effects were slightly higher in the bupropion SR groups compared to the varenicline and placebo groups
- Varenicline also appears to be effective in maintaining smoking abstinence compared to placebo. Patients given varenicline for 12 additional weeks after initial smoking cessation treatment demonstrated superior continuous abstinence rates (70.5%) compared to placebo (49.6%). At 28 weeks post-treatment, abstinence rates continued to be higher for varenicline (54%) versus placebo (39%). Weight gain and adverse effects were similar to placebo. Prolonged varenicline treatment may help prevent smoking relapse.
- In the pivotal clinical trials in which efficacy was established, patients were provided with reading material and received standardized smoking cessation counseling for 10 minutes at each weekly visit.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	T2
Commercial Formulary:	T2
Medicare Part D coverage:	T3 (Preferred brand)

COVERAGE CRITERIA

Chantix (varenicline) meets the definition of **medical necessity** for the following:

- Patients aged 18 and older **AND**
- Smoking cessation assistance:
 - One 12-week course will be approved at a time
 - Patients must be enrolled in a formal smoking cessation program (defined as formal support and counseling on at least a weekly basis, either face-to-face or by telephone) **OR**
- Maintenance of smoking abstinence:
 - One 12-week course will be approved

Chantix (varenicline) is considered **experimental** for the following:

- Patients aged 17 and younger
- Patients not concurrently receiving smoking cessation support and counseling
 - Web-only or web-based programs that do not provide person-to-person counseling are not considered formal smoking cessation programs
- Long term therapy or repeated attempts

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy has not been determined for ages < 18 years old:

- Smoking cessation assistance: initial, 0.5 mg ORALLY once daily for days 1 through 3, then 0.5 mg twice daily for days 4 through 7, then 1 mg twice daily; duration of treatment is 12 weeks; an additional 12 weeks in patients who have successfully stopped smoking may increase the likelihood of long-term abstinence

Dose adjustments:

- Renal impairment: creatinine clearance < 30 mL/min, initial dose 0.5 mg orally once daily; titrate up to 0.5 mg twice daily
- Hemodialysis, end-stage renal disease: maximum dose is 0.5 mg orally once daily, if well tolerated

PRECAUTIONS:

- Black Box Warning:
 - Serious neuropsychiatric events (eg, depression, suicidal ideation, suicide attempt and completed suicide) have been reported in patients taking varenicline. All patients being treated with varenicline should be observed for neuropsychiatric symptoms including changes in behavior, hostility, agitation, depressed mood, and suicide-related events, including ideation, behavior, and attempted suicide. Drug discontinuation, ongoing monitoring, and supportive care is advised if symptoms develop. These symptoms, as well as worsening of preexisting psychiatric illness and completed suicide, have been reported in some patients attempting to quit smoking while taking varenicline in the postmarketing experience. The risks of varenicline should be weighed against the benefits of its use.

- Neuropsychiatric symptoms, even after discontinuation of therapy, may be complicated by nicotine withdrawal
- Psychiatric illness, preexisting; risk of worsening symptoms
- Hypersensitivity (ie, Stevens-Johnson syndrome, erythema multiforme, and life-threatening angioedema) has been reported
- Intolerable nausea; dose reduction should be considered
- Renal impairment; dose adjustment recommended for severe impairment
- Smoking cessation may alter the pharmacokinetics or pharmacodynamics of some drugs, including theophylline, warfarin and insulin

Billing/Coding information

- n/a

COST

- AWP (April 2010): Chantix 0.5mg or 1mg tabs (56): \$143.36

COMMITTEE APPROVAL:

July 28, 2010

GUIDELINE UPDATE INFORMATION:

April 2010	Medical Policy created

REFERENCES:

- DRUGDEX®, accessed 04/05/2010
- Product Information: CHANTIX(R) oral tablets, varenicline oral tablets. Pfizer Labs, New York, NY, 2009.