



Effective Date: 07/2013
Last P&T Approval/Version: 01/26/2021
Next Review Due By: 01/2022
Policy Number: C2902-A

Smoking Cessation

PRODUCTS AFFECTED

Nicotrol NS (Nicotine Nasal Spray), Nicotrol INHA(Nicotine Inhaler), Chantix (varenicline)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:

Tobacco Cessation

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. TOBACCO CESSATION:

1. Documentation member is currently smoking and will be utilizing Chantix(varenicline),Nicotrol NS or Nicotrol Inhaler for smoking cessation
AND
2. Documentation that the member has a contraindication or failure with a trial of an OTC nicotine replacement product (e.g., nicotine patch, nicotine gum, nicotine lozenges)
AND bupropion (Zyban)

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Drug and Biologic Coverage Criteria

AND

3. IF PATIENT HAS RELAPSED WITHIN THE PAST 365 DAYS: Prescriber attests to providing enhanced behavioral counseling, pharmacotherapy, or both. NOTE: Relapse is defined as: a patient smoking AFTER a continuous 4-week period of abstinence from smoking.

AND

4. IF STATE REGULATIONS REQUIRE OR BEHAVIORAL HEALTH PROGRAM EXISTS: Documentation the patient is currently participating in a behavioral tobacco cessation program (e.g., stop smoking help line, tobacco cessation help group, etc.)

CONTINUATION OF THERAPY:

A. TOBACCO CESSATION:

1. Documentation member has had a 4-week continuous abstinence of tobacco during the initial 12 weeks of treatment

DURATION OF APPROVAL:

Initial authorization: 3 months. Continuation of therapy: 3 months; Maximum duration of continual therapy of varenicline is 24 weeks ⁽⁷⁾

PRESCRIBER REQUIREMENTS:

No requirements

AGE RESTRICTIONS:

No requirements

QUANTITY:

Initial authorization: Chantix Starting Month Pak TABS 0.5 MG X 11 & 1 MG X 42 for first 28 days, THEN Chantix TABS 1MG #56/28 days

Nicotrol Inhaler (168 cartridges, 1 each Nicotine 10mg, Inhalation vapor, liquid) 1 package per 26 days
Nicotrol Nasal Spray (1 box, #4 bottles, 10 ml Nicotine 0.5mg/1 actuation, Nasal spray, solution); #4 per 20 days

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that intranasal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral, Intranasal

DRUG CLASS:

Smoking Deterrents

FDA-APPROVED USES:

For use as an adjunct to psychosocial interventions for tobacco cessation (smoking cessation)

COMPENDIAL APPROVED OFF-LABELED USES:

None

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APPENDIX

APPENDIX:

NA

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Tobacco cessation therapies are more likely to be successful for patients who are motivated to stop tobacco use and who are provided additional advice and support. Patients should be provided with appropriate educational materials and counseling to support the quit attempt. The patient should set a quit date.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Nicotrol NS(Nicotine Nasal Spray), Nicotrol INHA(Nicotine Inhaler), and Chantix (varenicline) are considered experimental/investigational and therefore, will follow Molina’s Off-Label policy.

OTHER SPECIAL CONSIDERATIONS:

No requirements

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Nicotrol NS SOLN 10MG/ML (Nicotine Nasal Spray 10 MG/ML (0.5 MG/SPRAY) , Nicotrol INHA 10MG (Nicotine Inhaler System 10 MG (4 MG Delivered), Chantix TABS 0.5MG, Chantix Continuing Month Pak TABS 1MG, Chantix TABS 1MG, Chantix Starting Month Pak TABS 0.5 MG X 11 &1 MG X 42, varenicline 0.5mg, 1mg

REFERENCES

1. Chantix (varenicline) [prescribing information]. New York, NY: Pfizer Labs; February 2019.
2. Nicotrol (nicotine) inhalation system [prescribing information]. New York, NY: Pfizer; September 2019.
3. Nicotrol NS (nicotine) nasal spray [prescribing information]. New York, NY: Pfizer; August 2019.
4. US Department of Health and Human Services. Clinical practice guideline for treating tobacco use and dependence: 2008 Update. Washington, DC: US Department of Health and Human Services; Am J Prev Med 2008;35(2)
5. Steinberg MB, Greenhaus S, Schmelzer AC, Bover MT, Foulds J, Hoover DR, et al. Triple Combination Pharmacotherapy for Medically Ill Smokers: A Randomized Trial. Ann Intern Med. 2009;150:447-454.
6. Rigotti NA. Strategies to Help a Smoker Who is Struggling to Quit. JAMA. 2012, 308(15);1573-1580.
7. Effect of maintenance therapy with varenicline on smoking cessation: a randomized controlled trial. Tonstad S, Tønnesen P, Hajek P, Williams KE, Billing CB, Reeves KR, Varenicline Phase 3 Study Group JAMA. 2006;296(1):64.