Pharmacy Medical Necessity Guidelines: Smoking Cessation Products

Effective: January 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Varenicline is a nicotine receptor partial agonist indicated for use as an aid to smoking cessation treatment.

Nicotrol NS (nicotine nasal spray) is an aqueous solution of nicotine intended for administration as a metered spray in the nose. It is indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms.

The Plans preferred smoking cessation agents include generic nicotine replacement therapies (e.g., transdermal patch, gum, lozenge) and generic bupropion SR (Zyban).

COVERAGE GUIDELINES

The plan may authorize coverage of a nonpreferred smoking cessation products for Members when the following criteria are met:

Varenicline

1. During the previous 12-month period the Member has had an inadequate response to at least a six week trial of generic bupropion SR **OR** the member has previously had an intolerance to bupropion SR or is unable to take bupropion SR due to a comorbid condition (e.g., seizure disorder, history of anorexia or bulimia)

AND

2. During the previous 12-month period the Member has had an inadequate response or intolerance to at least a six week trial of one generic nicotine replacement therapy product (e.g., nicotine gum, nicotine lozenge, nicotine patch)

Nicotrol Nasal Spray

1. Within the last 12-month period the Member has had an inadequate response or intolerance to at least 6 weeks of therapy with two preferred generic smoking cessation agents (e.g., bupropion SR, nicotine patch, nicotine gum, nicotine lozenge) OR the Member is unable to take all available generic smoking cessation agents due to a comorbid condition or contraindication

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.

CODES

None

REFERENCES

1. Nicotrol Inhaler (nicotine inhalation system) [prescribing information]. New York, NY: Pharmacia and Upjohn; August 2019.
2. Nicotrol NS (nicotine nasal spray) [prescribing information]. New York, NY: Pharmacia and Upjohn; August 2019.
3. Varenicline [prescribing information]. Weston, FL: Apotex Corp.; October 2022.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 14, 2023: Updated Pharmacy Utilization Management fax number. No criteria changes
2. November 12, 2024: No changes
3. December 9, 2025: Effective 1/1/26, removed Nicotrol Inhaler from the MNG due to product discontinuation.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.