Pharmacy Medical Necessity Guidelines: Smoking Cessation Products

Effective: July 14, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Chantix (varenicline) is a nicotine receptor partial agonist indicated for use as an aid to smoking cessation treatment.

Nicotrol Inhaler (nicotine inhaler) is indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms.

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 Plan's 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:

Chantix

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 Inhaler, 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. Approval for Chantix will be limited to 60 tablets per 30 days.

CODES

None

REFERENCES

1. Chantix (varenicline) [prescribing information]. New York, NY: Pfizer; February 2019.
2. Nicotrol Inhaler (nicotine inhalation system) [prescribing information]. New York, NY: Pharmacia and Upjohn; August 2019.
3. Nicotrol NS (nicotine nasal spray) [prescribing information]. New York, NH: Pfizer; August 2019.

APPROVAL HISTORY

May 9, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. July 10, 2018: No changes
2. August 13, 2019: Administrative changes made to template.
3. July 14, 2020: No changes.

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.