Policy: Smoking Cessation Products

Reference Number: OR.CP.PMN.1008
Effective Date: 01.01.22
Last Review Date: 11.24
Line of Business: Medicaid – Trillium Oregon Health Plan

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The following are smoking cessation treatments requiring prior authorization: nicotine replacement therapy (NRT) beyond 6 months, bupropion hydrochloride sustained release (Zyban®) beyond 180 days, varenicline (Chantix) beyond 180 days.

FDA approved indications
- Zyban is indicated as an aid to smoking cessation treatment.
- Chantix is indicated as an aid to smoking cessation treatment.
- Nicotrol NS and Nicotrol Inhaler are indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms.
- Nicoderm CQ and Nicorette are indicated to reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of Trillium Oregon Health Plan that smoking cessation products past the formulary limitation are **medically necessary** when the following criteria are met:

I. Approval Criteria

A. Smoking Cessation Aid (must meet all)**:**

1. Member had documented tobacco dependence;
2. One of the following (a or b):
   a. Member has quit smoking;
   b. Member is currently enrolled in a behavior modification program (e.g. Quit Line at: 800-QUIT-NOW [800-784-8669]);
3. Member is not currently taking any formulation of bupropion (Wellbutrin SR®) or Nicotine Replacement products in combination with Zyban;
4. If request is for varenicline, total weeks of continuous treatment does not exceed 24 weeks;

Approval duration:

Nicotine Replacement Therapy: 6 months;
Bupropion SR: 12 weeks;
Varenicline: up to 12 weeks; not to exceed 24 total weeks of continuous treatment

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy:

A. All Indications:

1. Initial criteria must be met for continued coverage; see Section I for requirements.
   Approval duration:
   Nicotine Replacement Therapy: 6 months;
   Bupropion SR: 12 weeks;
   Varenicline: up to 12 weeks; not to exceed 24 total week of continuous treatment

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents;
B. Concurrent therapy with other smoking cessation products;
C. Members without smoking cessation coverage.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key: N/A

Appendix B: General Information

- In July 2009, the FDA mandated a black box warning alerting providers to observe all patients on Zyban and Chantix for neuropsychiatric symptoms including changes in behavior, hostility, agitation, depressed mood, and suicide related events, including ideation, behavior, and attempted suicide.
- Zyban treatment should be initiated while patient is still smoking. Once initiated a "target quit date" should be set for within the first two weeks of treatment.
- If a patient has not achieved complete abstinence by the seventh week with Zyban, it is unlikely that he or she will quit during this attempt, and treatment should be discontinued.
- Zyban contains the same active ingredient as Wellbutrin®, Wellbutrin® SR/XL. It should not be taken concurrently with other bupropion products. Zyban is contraindicated in

individuals with a history of seizures, eating disorders, undergoing abrupt discontinuation of alcohol or sedatives, or currently taking monoamine oxidase inhibitors (MAOI).

- In one comparative trial, the quit rates for the combination of Zyban and Nicotine were not significantly higher than Zyban alone ($p > 0.05$). A higher incidence of treatment emergent hypertension was reported in patients treated with combination therapy.
- The safety and efficacy of using Chantix (varenicline) in combination with other smoking cessation therapies (Zyban, Nicotrol) has not been established.
- Coverage is limited to plans under the Department of Managed Health Care oversight or plans with a specific smoking cessation rider.
- All members are eligible for The American Cancer Society and The American Lung Association smoking cessation programs.

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Chantix® (varenicline)	Titration schedule: 0.5 mg PO QD for 3 days, followed by 0.5 mg PO BID for 4 days, then 1 mg PO BID to complete 12 weeks of therapy	2 mg/day; 12 week course of therapy
nicotine gum (Nicorette®)	Chew orally as follows: 1 piece every 1-2 hours week 1-6 then, 1 piece every 2-4 hours week 7-9 then, 1 piece every 4-8 hours weeks 10-12	24 pieces/day
nicotine patches (Nicoderm CQ®)	1 patch changed daily >10 cigarettes per day: 21 mg patch weeks 1-6, then 14 mg weeks 7-8, then 7 mg weeks 9-10 10 or less cigarettes per day: 14 mg patch weeks 1-6 then 7mg weeks 7-8	8-10 weeks
nicotine lozenge (Commit®)	Slowly dissolve orally as follows: 1 lozenge every 1-2 hours weeks 1-6 then, 1 lozenge every 2-4 hours weeks 7-9 then, 1 lozenge every 4-8 hours weeks 10-12	20 lozenges/day

V. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Nicotrol NS (nicotine nasal spray)	Initial: 2-4 sprays intranasally per hour; studies suggest a minimum of 16 sprays per day was most effective.	80 sprays per day

	Reduction: Dose may be reduced as nicotine withdrawal subsides	
Nicotrol Inhaler (nicotine inhaler)	Initial (Up to 12 weeks): At least 6 cartridges via oral inhalation daily for 3-6 weeks; additional cartridges may be used if needed. Reduction (Up to 12 weeks): Patients should be encouraged to gradually reduce the number of cartridges used.	16 cartridges per day
Zyban (bupropion hydrochloride sustained release)	150 mg PO daily for the first 3 days, then 150 mg PO twice daily for 7-12 weeks.	300 mg per day

VI. Product Availability

Drug	Availability
Chantix® (varenicline)	Oral Tablet: 0.5 mg, 1 mg
Nicotrol NS (nicotine nasal spray)	10 mg/ml bottle, 0.5 mg/spray; 200 sprays per unit; package of 4 x 10 ml
Nicotrol Inhaler (nicotine inhaler)	168 cartridges each containing 10 mg nicotine (4 mg delivered)
Nicotine patches (Nicoderm CQ®)	Transdermal Patch: 7 mg/24hr, 14 mg/24hr, 21 mg/24hr
Nicotine gum (Nicorette®)	Gum and lozenge: 2 mg, 4 mg
bupropion hydrochloride sustained release (Zyban®)	Tablet: 150 mg

VII. References

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Reviews, Revisions, and Approvals	Date	Plan Approval Date
Policy created: adapted from previously approved policy TCHP.PHAR.18002 Smoking Cessation Products. No clinically significant changes.	09.21.21	10.21.21
4Q 2022 annual review: no significant changes; references reviewed and updated.	09.16.22	10.06.22
4Q 2023 annual review: no significant changes; template changes applied to other diagnoses/indications; added continued therapy section to clarify that initial coverage criteria must be met for continued coverage; references reviewed and updated.	09.21.23	11.21.23
4Q 2024 annual review: no significant changes; references reviewed and updated.	10.02.24	11.19.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.