

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2045-17
Program	Prior Authorization/HCR - Tobacco Cessation - Health Care Reform
Medication	Varenicline (generic Chantix®), Nicotrol Inhaler® (nicotine inhalation system), and Nicotrol NS® (nicotine nasal spray)
P&T Approval Date	10/2014, 2/2015, 10/2015, 5/2016, 11/2016, 5/2017, 5/2018, 9/2018, 11/2018, 5/2019, 12/2019, 5/2020, 3/2021, 8/2021, 9/2022, 11/2023, 3/2025
Effective Date	6/1/2025

1. 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.

This program is designed to meet Health Care Reform requirements for tobacco cessation coverage at zero dollar cost share.

2. Coverage Criteria*:

A. Varenicline (generic Chantix)

1. **Varenicline** will be approved based on **all** of the following criteria:

a. Patient is 18 years of age or older^a

-AND-

b. Treatment is being requested for tobacco cessation

-AND-

c. History of failure, contraindication, or intolerance to **one** of the following:

(1) Nicotine replacement patches OTC (e.g. Nicoderm CQ®-OTC)

(2) Nicotine gum OTC (e.g. Nicorette® gum- OTC)

(3) Nicotine lozenge or mini-lozenge OTC (e.g. Nicorette® lozenge-OTC)

-AND-

d. History of failure, contraindication, or intolerance to bupropion

-AND-

- e. Treatment duration has not exceeded a total of 2 (3 month) cycles of Tobacco Cessation Therapy per 12 month period^b

Authorization will be issued for zero copay with deductible bypass for 3 months per 12 month period. Maximum coverage is 2 (3 month) cycles of Tobacco Cessation Therapy per 12 month period^b

B. Nicotrol NS or Nicotrol Inhaler

1. **Nicotrol NS or Nicotrol Inhaler** will be approved based on **all** of the following criteria:

- a. Patient is 18 years of age or older^a

-AND-

- b. Treatment is being requested for tobacco cessation

-AND-

- c. History of failure, contraindication, or intolerance to **one** of the following:

- (1) Nicotine replacement patches OTC (e.g. Nicoderm CQ-OTC)
- (2) Nicotine gum OTC (eg Nicorette gum- OTC)
- (3) Nicotine lozenge or mini-lozenge OTC (e.g. Nicorette lozenge-OTC)

-AND-

- d. History of failure, contraindication, or intolerance to bupropion

-AND-

- e. Treatment duration has not exceeded a total of 2 (3 month) cycles of Tobacco Cessation Therapy per 12 month period^b

Authorization will be issued for zero copay with deductible bypass for 3 months per 12 month period. Maximum coverage is 2 (3 month) cycles of Tobacco Cessation Therapy per 12 month period^b

*** Review not required for plans situated in the state of California, Colorado, Illinois, New York or West Virginia**

^a **Age is 15 years or older for plans situated in the state Oregon**

^b **Pharmacist review is required for more than 2 cycles per 12 month period. One cycle is defined as more than 1 month of medication. If only one month of medication is filled, 2 additional cycles of medication may be authorized in the 12 month period**

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Nicotrol NS [package insert]. New York, NY: Pharmacia and Upjohn; June 2024.
2. Nicotrol Inhaler [package insert]. New York, NY: Pharmacia and Upjohn; July 2024.
4. Chantix [package insert]. New York, NY: Pfizer, Inc.; February 2019.
5. 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)

Program	Prior Authorization/-HCR- Tobacco Cessation- Health Care Reform
Change Control	
Date	Change
10/2014	New program
2/2015	Policy renamed from Smoking Cessation to Tobacco Cessation. Administrative changes.
10/2015	Annual review. Updated references. Updated criteria for Chantix to allow for coverage if currently using bupropion for an indication other than tobacco cessation.
1/2016	Administrative update for California requirements.
5/2016	Update for Massachusetts and Oregon requirements. Medication names updated for OTC products to generics.
11/2016	Update for Indiana, Louisiana and New Mexico requirements.
5/2017	Removed Habitrol from first line options - product no longer available.
5/2018	Annual Review. Updated references.
9/2018	Removed Commit and Thrive as examples of therapy. Brand names off the market. Revised language around concomitant use and tobacco cessation requirements.
11/2018	Add West Virginia and California to bypass of prior authorization requirements.
5/2019	Removed PA criteria for bupropion SR, and OTC NRT. Removed combination criteria for Chantix and Nicotrol NS. Removed counseling requirement. Revised footnotes.
12/2019	Added Colorado and New York to bypass of prior authorization requirements.
5/2020	Updated references.
3/2021	Added criteria for treatment duration not to exceed 2 (3 month) cycles of Tobacco Cessation Therapy per 12 month period.
8/2021	Updated to reflect generic launch of Chantix
9/2022	Annual review. No changes.
11/2023	Annual review. No changes.

3/2025	Removed reference to Zyban due to product becoming obsolete. Updated references.
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