UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 4005-8
Program	Health Care Reform Tobacco Cessation – Supply Limit (Therapy Duration) Override – Kentucky Fully Insured
Medication	Varenicline (generic Chantix®), Nicotrol Inhaler® (nicotine inhalation system), and Nicotrol NS® (nicotine nasal spray)
P&T Approval Date	8/2017, 9/2018, 5/2019, 5/2020, 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 and Kentucky state mandates for tobacco cessation coverage at zero dollar cost share. Kentucky requires coverage of two quit attempts, defined as 180 days of therapy, in a 12 month period without implementation of any utilization management program. Once a member has received coverage for 180 days of tobacco cessation therapy, including any combination of products, coverage of continued therapy will be required to meet the below coverage criteria.

Coverage for continuation of Varenicline (generic Chantix) will bypass step therapy requirement if the member is currently on therapy without having undergone utilization management review.

2. Coverage Criteria for Continuation of Tobacco Cessation Therapy:

A. Varenicline (generic Chantix)

1. **Patients new to therapy (not currently on varenicline in the past 90 days as evidenced by claims)**

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

   (1) Patient is 18 years of age or older

   -AND-

   (2) Treatment is being requested for tobacco cessation

   -AND-

   (3) History of failure, contraindication, or intolerance to **one** of the following:
   i. Nicotine replacement patches OTC (e.g. Nicoderm CQ®-OTC)
   ii. Nicotine gum OTC (e.g. Nicorette® gum- OTC)

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

-AND-

(4) History of failure, contraindication, or intolerance to bupropion

Authorization will be issued for zero copay with deductible bypass for 3 months.

2. **Patients Established on Therapy (Patient has been on medication within the past 90 days as evidenced by claims)**

a. Varenicline will be approved for patients established on therapy for tobacco cessation.

Authorization will be issued for zero copay with deductible bypass for an additional 3 months.

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

-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

Authorization will be issued for zero copay with deductible bypass for 3 months.

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	HCR Tobacco Cessation Health Care Reform – Supply Limit (Therapy Duration) Override – Kentucky Fully Insured
Change Control	
Date	Change
8/2017	New program.
9/2018	Removed Commit and Thrive as examples of therapy. Brand names off the market. Revised language around concomitant use.
5/2019	Removed PA criteria for bupropion SR, and OTC NRT. Removed combination criteria for Chantix and Nicotrol NS. Removed counseling requirement. Revised footnotes.
5/2020	Updated references.
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.