UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2141-8
Program	Prior Authorization/Medical Necessity
Medication	Opioid-containing cough medicines (including but not limited to: Tuxarin ER™, codeine/phenylephrine/promethazine, codeine/promethazine, hydrocodone/homatropine, hydrocodone bitartrate/guaifenesin, hydrocodone polistirex/chlorpheniramine polistirex, hydrocodone bitartrate/chlorpheniramine, Hycodan®)
P&T Approval Date	3/2018, 3/2019, 8/2019, 8/2020, 8/2021, 3/2023, 3/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Opioid (codeine or hydrocodone) containing cough and cold products are FDA labeled for use in adults 18 years of age and older. Use of prescription opioid cough and cold medicines containing codeine or hydrocodone should be limited in children younger than 18 years old due to serious risks associated with use. Coverage for patients age 18 or older will process automatically.

2. Coverage Criteria:

A. <u>Authorization</u>

1. **Opioid-containing cough and cold products** will be approved based on **<u>all</u>** of the following criteria:

   a. Prescriber attests they are aware of FDA labeled contraindications regarding use of opioid -containing cough and cold products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use).

   -AND-

   b. Patient does not have a comorbid condition that may impact respiratory depression (e.g., asthma or other chronic lung disease, sleep apnea, body mass index > 30)

   -AND-

   c. Patient has tried and failed at least one non-opioid containing cough and cold remedy

Authorization will be issued for one month.

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.

4. References:

1. Approach to Chronic Cough in Children. UpToDate. October 2024. Accessed March 25, 2025.
2. FDA Drug Safety Communication (2018a). FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. US Food and Drug Administration website. https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-requires-labeling-changes-prescription-opioid-cough-and-cold. Published January 11, 2018. Accessed March 25, 2025.

Program	Prior Authorization/Medical Necessity – Opioid-containing cough medicines
Change Control	
Date	Change
3/2018	New program.
3/2019	Annual review. Updated references.
8/2019	Added Tuxarin ER and TussiCaps as in scope. Updated references.
8/2020	Annual review. Updated references.
8/2021	Annual review. Updated references. Revised formatting on in scope drugs.
3/2023	Removed Obredon and Zutripo as they are no longer on the market. Updated references.
3/2024	Removed Tuzistra XR as it is no longer on the market. Updated references.
5/2025	Removed Tussicaps as it is no longer on the market. Added Hycodan. Updated references.