



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Name	2023 P 1074-8
Program	Prior Authorization/Notification
Medications	Oral chemotherapeutic agents
P&T Approval Date	3/9/2010, 1/2011, 9/2011, 11/2011, 1/2012, 4/2012, 8/2012, 2/2013, 11/2014, 11/2015, 7/2016, 11/2019, 11/2020, 11/2021, 5/2022, 10/2023
Effective Date	1/1/2024

**1. Background:**

The coverage criteria below provides parameters for coverage of specific oral oncology medications covered under the pharmacy benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium™. The Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

UnitedHealthcare recognizes indications and uses of oral oncology medications listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven.

UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years. The majority of pediatric patients receive treatments on national pediatric protocols that are similar in concept to the NCCN patient care guidelines.

**Additional Information:**

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to more than 97 percent of cancers affecting patients in the United States. In addition, separate guidelines provide recommendations for some of the key cancer prevention and screening topics as well as supportive care considerations, and specific populations. The guidelines are developed and updated by 60 individual panels, comprising over 1,700 clinicians and oncology researchers from the 31 NCCN member institutions.

NCCN categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines panel. Evidence of both efficacy and safety of interventions is considered by the panel.

The level of evidence for each recommendation depends upon the following factors:

- Quality of data based on trial design and how the results/observations were derived (e.g., randomized controlled trials [RCTs], non-RCTs, meta-analyses or systematic reviews, clinical case reports, case series)
- Quantity of data (e.g., number of trials, size of trials, clinical observations only),
- Consistency of data (e.g., similar, or conflicting results across available studies or observations)

**NCCN Categories of Evidence and Consensus:**

**Category 1:** The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the panel has reached uniform NCCN consensus (majority panel vote of at least 85%) that the intervention is appropriate.

**Category 2A:** The recommendation is based on lower-level evidence, but despite the absence of higher-level studies, there is uniform NCCN consensus (majority panel vote of at least 85%) that the intervention is appropriate.

**Category 2B:** The recommendation is based on lower-level evidence, and there is NCCN consensus (majority panel vote of at least 50%, but less than 85%) that the intervention is appropriate.

**Category 3:** Based on any level of evidence, regardless of the quality of evidence, there is major NCCN disagreement that the intervention is appropriate (a panel vote of at least 25% to include and designate a recommendation as Category 3 is required).

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria:**

- A. Select oral chemotherapeutic agents will be approved based on **one** of the following criteria:
1. Patient is under the age of 19 years
- OR-**
2. The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B
- OR-**
3. Patient is receiving treatment for a non-oncology indication that is recognized in the product labeling, a published compendium (e.g., Micromedex, Clinical Pharmacology), or is demonstrated as proven in the peer reviewed medical literature.

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- Supply limits and/or step therapy may be in place for certain products.
- Requests for initial therapy established via receipt of a manufacturer supplied sample or any other form of assistance shall be required to meet coverage criteria.

**4. References:**

1. The NCCN Drugs and Biologics Compendium (NCCN Compendium™).  
[http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed August 21, 2023.
2. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™).  
[http://www.nccn.org/professionals/physician\\_gls/f\\_guidelines.asp](http://www.nccn.org/professionals/physician_gls/f_guidelines.asp). Accessed August 21, 2023.

Program	Prior Authorization/Notification - Oral chemotherapeutic agents
<b>Change Control</b>	
11/2014	Annual review with no change to coverage.
11/2015	Annual review with minor revision to coverage criteria. Updated background.
7/2016	Program Retired.
11/2019	Program reinstated with minor revision to coverage criteria. Updated background.
11/2020	Annual review. No changes to coverage criteria.
11/2021	Annual review. No changes to coverage criteria. Updated background and references.
5/2022	Revision to additional clinical rules.
10/2023	Annual review. No changes to coverage criteria.