UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1049-11
Program	Prior Authorization/Notification
Medication	Interim New Product Coverage Criteria
P&T Approval Date	5/2013, 5/2014, 7/2014, 5/2015, 3/2016, 8/2016, 8/2017, 8/2018, 8/2019, 8/2020, 8/2021, 10/2023
Effective Date	1/1/2024

1. Background:

The purpose of this guideline is to establish a procedure by which to review requests for newly FDA-approved drug products that require notification. This general criterion will apply only until drug-specific criteria can be developed and implemented for claims processing. Once drug-specific criteria are available, and the authorization provided from this general criterion expires, the subsequent coverage review will be completed using the Initial Authorization section of the drug-specific criteria. UnitedHealthcare Pharmacy (UHCP) will designate the specific medications which are subject to this criterion and inform the Pharmacy Benefits Administrator (PBA). Oral oncology products will use the Oral Chemotherapeutic Agent Prior Authorization Program criteria for review.

2. Coverage Criteria:

A. Guideline

1. For recent FDA-approved drug products for which drug-specific criteria are unavailable, the requested drug will be approved based on **both** of the following criteria:

   a. Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert)
   b. Additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information (or package insert) have been met (e.g. first line therapies have been tried and failed; any testing requirements have been met, etc.)

Authorization will be issued for 6 months and should allow a quantity ceiling limit up to the maximum FDA approved dose unless otherwise noted on tracking grid or unless the FDA approved treatment duration is less than 6 months.

- **If FDA approved treatment duration is less than 6 months utilize the approved duration for authorization period.**
- **Requests for higher quantity beyond the FDA approved maximum dosing are not separately reviewable by the PA department.**

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:
N/A

Program	Interim New Product Coverage Criteria
Change Control	
5/2014	Annual review. Increased approval period from 3 to 6 months. Added language to clarify authorization term for oral oncology medications.
7/2014	Added criteria for additional requirements listed in prescribing information. Added supply limit ceiling limit up to FDA approved maximum dosing to approval.
5/2015	Annual review. No changes to coverage criteria
3/2016	Annual review. Increased authorization period for oral oncology drugs to 12 months.
8/2016	Updated background section to remove reference to general oral oncology criteria.
8/2017	Updated authorization period to clarify quantity limit.
8/2018	Annual review. Revised authorization language for oncology.
8/2019	Annual review. Updated background section to indicate oral oncology drugs utilize the Oral Chemotherapeutic Agent Prior Authorization Program. Removed oral chemotherapy from authorization duration instructions.
8/2020	Annual review. No changes.
8/2021	Annual review. No changes.
10/2023	Review. No changes.