Medical Benefit Therapeutic Equivalent Medications - Excluded Drugs

Policy Number: 2024D0113C
Effective Date: October 1, 2024

➲ Instructions for Use

Table of Contents **Page**

Related Commercial Policies

- Immune Globulin (IVIG and SCIG)
- Medical Therapies for Enzyme Deficiencies
- Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors
- Sodium Hyaluronate

Related List

- Medical Benefit Therapeutic Equivalent Medications – Excluded Drug List with Preferred Alternatives

Coverage Rationale

➲ See Benefit Considerations

This Medical Benefit Drug Policy applies to certain medical benefit medications that are healthcare provider administered, that have been deemed therapeutically equivalent by the UnitedHealthcare Pharmacy and Therapeutics (P&T) Committee. Therapeutic equivalence is defined as having essentially the same efficacy and adverse effect profile to another covered medication/product.

A medication will be subject to **medical drug exclusion** when the medication is listed on the Medical Benefit Therapeutic Equivalent Medications – Excluded Drug List with Preferred Alternatives and as allowed by the member's benefit documents and by law.

A medication subject to medical drug exclusion will be (Medicare Reviews: Refer to the CMS section):

- Excluded from coverage; **or**
- When allowable by the member's benefit plan design, excluded medications may be approved based on **all** the following criteria:
  - Reviewed against available clinical evidence, which includes applicable Medical Benefit Drug Policies; **and**
  - Submission of medical records documenting history of trial and failure, inadequate response, or intolerance to the therapeutically equivalent covered medications as listed in Medical Benefit Therapeutic Equivalent Medications – Excluded Drug List with Preferred Alternatives; **and**
  - **One** of the following:
    - Provider explanation of potential rationale for how the excluded medication will work if stating the patient failed on the covered therapeutically equivalent product which has the same active ingredient or is highly similar to a reference product (e.g., a biosimilar); **or**
    - Member had an adverse reaction to an inactive ingredient in the alternative product

Medical Benefit Drug Policies express UnitedHealthcare's determination of whether a health service is proven to be effective based on published clinical evidence. They are also used to decide whether a given health service is medically necessary under the member's benefit plan. Services determined to be experimental, investigational, unproven or not medically necessary by the clinical evidence are typically not covered.

Background

UnitedHealthcare benefit documents define therapeutically equivalent as when medications/products have essentially the same efficacy and adverse effect profile. This determination is made by the UnitedHealthcare P&T Committee and is not intended to imply therapeutic equivalence as defined by the FDA Orange Book. Drugs are considered to be Therapeutically Equivalent to the reference product when the following are met:

- Drugs approved via a 505(b)(2) application without submission of clinical efficacy trials.
- Branded drugs approved via an abbreviated new drug application (ANDA) (listed as a single-source brand by listing services, e.g., MediSpan).
- Product extensions (e.g., new strengths, new manufacturer, new generic).
- Multiple packaging products (consisting of two or more distinct products packaged together in such a way that may not be separated by a pharmacy with at least one prescription-only component).

Therapeutically equivalent medications are generally excluded in the benefit documents in the instances outlined below:

- A pharmaceutical product that contains (an) active ingredient(s) available in and therapeutically equivalent (having essentially the same efficacy and adverse effect profile) to another covered pharmaceutical product. Such determinations may be made up to six times during a calendar year.
- A pharmaceutical product that contains (an) active ingredient(s) which is (are) a modified version of and therapeutically equivalent (having essentially the same efficacy and adverse effect profile) to another covered pharmaceutical product. Such determinations may be made up to six times during a calendar year.
- A pharmaceutical product with an approved biosimilar or a biosimilar and therapeutically equivalent (having essentially the same efficacy and adverse effect profile) to another covered pharmaceutical product. For the purpose of this exclusion a "biosimilar" is a biological pharmaceutical product approved based on showing that it is highly similar to a reference product (a biological pharmaceutical product) and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Such determinations may be made up to six times per calendar year.
- Certain pharmaceutical products for which there are therapeutically equivalent (having essentially the same efficacy and adverse effect profile) alternatives available, unless otherwise required by law or approved by us. Such determinations may be made up to six times during a calendar year.

Benefit plan designs may allow a clinical review for certain prescription medications. Certain members or providers may request a clinical review for these medications when state mandates or regulatory requirements apply. Coverage criteria will require history of failure, contraindication or intolerance to preferred products.

Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. Refer to the Policy and Procedure addressing the treatment of serious rare diseases (refer to the Related Commercial Policy outlined above).

Centers for Medicare and Medicaid Services (CMS)

**Preferred therapy criteria is not applicable for Medicare Advantage members.

References

1. AHFS Drug information [website]. Available at: http://www.ahfsdruginformation.com/. March 29, 2023.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.goldstandard.com. March 29, 2023.
3. Micromedex 2.0 [database online]. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. March 29, 2023.
4. UpToDate [database online]. Available at: http://www.uptodate.com/. March 29, 2023.

5. InterQual® Specialty Rx (Oncology and Non-Oncology), Ambulatory Care Planning Criteria, 2023 Release. Accessed May 6, 2024.

Policy History/Revision Information

Date	Summary of Changes
10/01/2024	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled *Medical Therapies for Enzyme Deficiencies* **Supporting Information** • Archived previous policy version 2023D00113B

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.