Review at Launch for New to Market Medications

Policy Number: 2024D0060H
Effective Date: April 1, 2024

Instructions for Use

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- Off-Label/Unproven Specialty Drug Treatment

Community Plan Policy
- Review at Launch for New to Market Medications

Related List
- Review at Launch Medication List

Coverage Rationale

See Benefit Considerations

This Medical Benefit Drug Policy applies to certain newly launched medical benefit medications that are healthcare provider administered, have not yet undergone review by UnitedHealthcare, and a utilization management strategy has not yet been put in place.

A medication will be subject to **review at launch** when the medication is listed on the Review at Launch Medication List.
A medication subject to review at launch will be:

- Excluded from coverage until the date the medication is reviewed by UnitedHealthcare and a utilization management strategy has been communicated as may be required by law or by December 31 of the following calendar year, whichever is earliest; **or**
- Reviewed against available clinical evidence, which includes applicable Medical Benefit Drug Policies; **or**
- For a U.S. Food and Drug Administration approved and launched biosimilar product not listed in a Medical Benefit Drug Policy, **one** of the following:
  - Excluded from coverage until the date the biosimilar product is reviewed by UnitedHealthcare and a utilization management strategy has been communicated as may be required by law or by December 31 of the following calendar year, whichever is earliest; **or**
  - **Both** of the following:
    - Reviewed against available clinical evidence; **and**
    - Provider attests that in their clinical opinion, the clinical response would be expected to be superior with the biosimilar product

Providers are strongly encouraged to seek a pre-determination on any new to market medications that are subject to review at launch to ensure coverage. Please be aware if a pre-determination is not requested, UnitedHealthcare may later deny the service or item as not medically appropriate or not covered. If a provider knows or has reason to believe that a service or item may not be covered, the provider must request a pre-service organization determination from UnitedHealthcare prior to providing or referring for the service or item. A provider may not collect payment from our commercial members for services not covered under the applicable benefit plan, unless the member provided written consent before the service was rendered. Refer to the UnitedHealthcare Care Provider Administrative Guide for more details.

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

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
C9399	Unclassified drugs or biologicals (hospital outpatient use only)
J3490	Unclassified drugs
J3590	Unclassified biologics

Background

The Review at Launch program provides UnitedHealthcare the ability to review, evaluate, and implement programs for new to market medications. The medication may move to a covered status once the medication has been evaluated by UnitedHealthcare and a utilization management strategy has been communicated as may be required by law.

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.

References

1. AHFS Drug information [website]. Available at: http://www.ahfsdruginformation.com/. August 30, 2023.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.goldstandard.com. August 30, 2023.
3. Micromedex 2.0 [database online]. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. August 30, 2023.
4. UpToDate [database online]. Available at: http://www.uptodate.com/. August 30, 2023.
5. InterQual® [website]. Available at: https://prod.cue4.com/help/InterQualOnline/BookViewHelp/content/home.htm#.

Policy History/Revision Information

Date	Summary of Changes
04/08/2024	**Related Document** • Updated *Review at Launch Medication List*; added Winrevair™ (sotatercept-csrk) and Alyglo™ (immune globulin intravenous, human-stwk)

Date	Summary of Changes

04/01/2024	**Related Document**
	• Updated *Review at Launch Medication List*:
	  ○ Added:
	  ▪ Tofidence™ (tocilizumab-bavi)
	  ▪ Tyenne® (tocilizumab-aazg)
	  ▪ Tyruko® (natalizumab-sztn)
	  ○ Removed (prior authorization requirements effective Apr. 1, 2024):
	  ▪ Adzynma (ADAMTS13, recombinant-krhn)
	  ▪ Omvoh™ (mirikizumab-mrkz)
	  ▪ Pombiliti™ (cipaglucosidase alfa)
	Coverage Rationale
	• Added language to indicate a U.S. Food and Drug Administration approved and launched biosimilar product not listed in a Medical Benefit Drug Policy:
	  ○ Will be excluded from coverage until the date the biosimilar product is reviewed by UnitedHealthcare and a utilization management strategy has been communicated as may be required by law or by Dec. 31 of the following calendar year, whichever is earliest; **or**
	  ○ Both of the following:
	  ▪ Will be reviewed against available clinical evidence; **and**
	  ▪ The provider attests that in their clinical opinion, the clinical response would be expected to be superior with the biosimilar product
	Supporting Information
	• Archived previous policy version 2023D0060G

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.