Review at Launch for New to Market Medications

Policy Number: 2025D0060K
Effective Date: December 1, 2025

➲ Instructions for Use

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Related Commercial Policy
- 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 drug policy applies to new medications that are:
- U.S. Food and Drug Administration (FDA) approved; **and**
- Healthcare provider administered; **and**
- Reimbursable on a member's medical benefit

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 for medical necessity based on **both** of the following:
  - **One** of the following:
    - A UnitedHealthcare Pharmacy and Therapeutics (UHC P&T) approved medical benefit drug policy; **or**
    - **All** of the following:
      - FDA approved labeling, including but not limited to indication, patient age requirements, dosing recommendations, contraindications, and clinical trial inclusion criteria (e.g., genetic testing, comorbid conditions); **and**
      - Compendia (if available); **and**
      - Current standard of care, as per evidenced based literature (if available)

    and
  - Authorization will be up to the maximum FDA approved dose and frequency, and duration for no more than 6 months; **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**
  - **All** of the following:
    - Reviewed for medical necessity based on the following:
      - A UnitedHealthcare Pharmacy and Therapeutics (UHC P&T) approved medical benefit drug policy; **or**
      - **All** of the following:

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        - FDA approved labeling, including but not limited to indication, patient age requirements, dosing recommendations, contraindications, and clinical trial inclusion criteria (ex., genetic testing, comorbid conditions); **and**
        - Compendia (if available); **and**
        - Current standard of care, as per evidenced based literature (if available)

    and
- Provider attests that in their clinical opinion, the clinical response would be expected to be superior with the biosimilar product; **and**
- Authorization will be up to the maximum FDA approved dose and frequency, and duration for no more than 6 months

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.

References

1. AHFS Drug information [website]. Available at: http://www.ahfsdruginformation.com/.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.goldstandard.com.

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3. Micromedex 2.0 [database online]. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com.
4. UpToDate [database online]. Available at: http://www.uptodate.com/.
5. InterQual® [website]. Available at: https://prod.cue4.com/help/InterQualOnline/BookViewHelp/content/home.htm#.

Policy History/Revision Information

Date	Summary of Changes

10/01/2026	**Related Document**
	• Updated *Review at Launch Medication List*:
	  ○ Added:
	  ▪ Fayuvi™ (rebisufligene etisparvovec-hopf)
	  ▪ Isembyld™ (apitegromab-mstn)
	  ▪ Zanvastro™ (zilganersen)
	  ○ Removed:
	  ▪ Avlayah™ (tividenofusp alfa-eknm)
	  ▪ Bildyos® (denosumab-nxxp)
	  ▪ Bosaya™ (denosumab-kyqq)
	  ▪ Conexxence® (denosumab-bnht)
	  ▪ Enoby™ (denosumab-qbde)
	  ▪ Exdensur™ (depemokimab-ulaa)
	  ▪ Loargys® (pegzilarginase-nbln)
	  ▪ Ospomyv™ (denosumab-dssb)
	  ▪ Qivigy® (immune globulin intravenous, human-kthm)
	  ○ Updated list of applicable HCPCS codes for:
	  ▪ Ponlimsi™ (denosumab-adet); replaced C9399, J3490, and J3590 with Q5173
	  ▪ Wainua® (eplontersen); replaced C9399 with C9311

09/01/2026	**Related Document** • Updated *Review at Launch Medication List*; added Genglycos™ (pariglasgene brecaparvovec-opnr), Lytenava™ (bevacizumab-vikg), Omlyclo® (omalizumab-igec), and Pasatru™ (garetosmab-grts)
08/01/2026	**Related Document** • Updated *Review at Launch Medication List*; added Ranluspec™ (ranibizumab-hkdz)
07/15/2026	**Related Document** • Updated *Review at Launch Medication List*; added Lumvoa™ (veligrotug-vvze)

07/01/2026	**Related Document**
	• Updated *Review at Launch Medication List*:
	  ○ Removed:
	  ▪ Avtozma® (tocilizumab-anoh)
	  ▪ Itvisma® (onasemnogene abeparvovec-brve)
	  ○ Updated list of applicable HCPCS codes for:
	  ▪ Boncresa™ (denosumab-mobz); replaced C9399, J3490, and J3590 with Q5171
	  ▪ Enoby™ (denosumab-qbde); replaced C9399, J3490, and J3590 with Q5167
	  ▪ Eydenzelt® (aflibercept-boav); replaced C9399, J3490, and J3590 with Q5170
	  ▪ Exdensur™ (depemokimab-ulaa); replaced C9399, J3490, and J3590 with J2361
	  ▪ Nufymco® (ranibizumab-leyk); replaced C9399, J3490, and J3590 with Q5168
	  ▪ Opuviz™ (aflibercept-yszy); replaced C9399, J3490, and J3590 with Q5153
	  ▪ Osvyrti® (denosumab-desu); replaced C9399, J3490, and J3590 with Q5166
	  ▪ Qivigy® (immune globulin intravenous, human-kthm); replaced J1599, J3490, and J3590 with J1577

06/01/2026	**Related Document** • Updated *Review at Launch Medication List*; added Wainua® (eplontersen)
05/01/2026	**Related Document** • Updated *Review at Launch Medication List*; added Avlayah™ (tividenofusp alfa-eknm) and Ponlimsi™ (denosumab-adet)

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Date	Summary of Changes

04/01/2026	**Related Document**
	• Updated *Review at Launch Medication List*:
	  ○ Added Loargys® (pegzilarginase-nbln)
	  ○ Removed:
	  ▪ Imaavy™ (nipocalimab-aahu)
	  ▪ Papzimeos™ (zopapogene imadenovec-drba)
	  ○ Updated list of applicable HCPCS codes for:
	  ▪ Bildyos® (denosumab-nxxp):
	  – Added Q5162
	  – Removed C9399, J3490, and J3590
	  ▪ Bosaya™ (denosumab-kyqq)
	  – Added Q5161
	  – Removed C9399, J3490, and J3590

03/01/2026	**Related Document** • Updated *Review at Launch Medication List*; added Boncresa™ (denosumab-mobz)
02/01/2026	**Related Document** • Updated *Review at Launch Medication List*; added Exdensur™ (depemokimab-ulaa) and Nufymco® (ranibizumab-leyk)

01/01/2026	**Related Document**
	• Updated *Review at Launch Medication List*:
	  ○ Added:
	  ▪ Eydenzelt® (aflibercept-boav)
	  ▪ Opuviz™ (aflibercept-yszy)
	  ▪ Osvyrti® (denosumab-desu)
	  ▪ Qivigy® (immune globulin intravenous, human-kthm)
	  ○ Removed:
	  ▪ Alhemo® (concizumab-mtci)
	  ▪ Azmiro™ (testosterone cypionate)
	  ▪ Bkemv™ (eculizumab-aeeb)
	  ▪ Epysqli® (eculizumab-aagh)
	  ▪ Imuldosa™ (ustekinumab-srlf)
	  ▪ Jubbonti® (denosumab-bbdz)
	  ▪ Starjemza™ (ustekinumab-hmny)
	  ▪ Stoboclo® (denosumab-bmwo)
	  ▪ Tyruko® (natalizumab-sztn)
	  ▪ Yimmugo® (immune globulin intravenous, human-dira)
	  ○ Updated list of applicable HCPCS codes for Imaavy™ (nipocalimab-aahu):
	  ▪ Added J9256
	  ▪ Removed C9305, J3490, and J3590

12/05/2025	**Related Document** • Updated *Review at Launch Medication List*; added Itvisma® (onasemnogene abeparvovec-brve)

12/01/2025	**Related Document**
	• Updated *Review at Launch Medication List*; updated list of applicable HCPCS codes for:
	  ○ Imaavy™ (nipocalimab-aahu); added J3490 and J3590
	  ○ Yimmugo® (immune globulin intravenous, human-dira); added J3490 and J3590
	Supporting Information
	• Archived previous policy version 2024D0060J

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.

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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.

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