Review at Launch for New to Market Medications (for Indiana Only)

Policy Number: CSIND0060.07
Effective Date: December 1, 2024

➲ Instructions for Use

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Related List

- Review at Launch Medication List (for Indiana Only)

Application

This Medical Benefit Drug Policy only applies to the state of Indiana.

Coverage Rationale

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

All new medications that are identified as being subject to this policy will be placed on the Review at Launch Medication List (for Indiana Only) and reviewed upon FDA approval.

Medications will be reviewed based on:
- Health plan benefits and whether the medication is a covered/reimbursable service; **and**
- Medical necessity

Medical necessity reviews will be conducted using both of the following:
- **One** of the following:
  - A UnitedHealthcare Pharmacy and Therapeutics (UHC P&T) approved medical benefit drug policy; **or**
  - Medicaid State criteria as required; **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

The medications identified on the Review at Launch Medication List (for Indiana Only) will be subject to this policy until such time that UnitedHealthcare determines pre-service reviews are no longer necessary or the drugs are added to the Prior Authorization List.

Claims submitted for a medication identified on the Review at Launch Medication List (for Indiana Only) will be reviewed against health plan benefits and for medical necessity, as per the above.

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.

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. Services determined to be experimental, investigational, unproven, or not medically necessary by the clinical evidence may not be 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 federal, state, or contractual requirements 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
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. Additionally, it provides the opportunity to assess the coverage status of these new medications, and properly re-direct providers to State Medicaid Fee-For-Service programs when appropriate. The medications may be added to the Prior Authorization List once they have been evaluated by the UnitedHealthcare Pharmacy and Therapeutics Committee and a final utilization management strategy has been determined.

References

1. AHFS Drug information [website]. Available at: http://www.ahfsdruginformation.com/. Accessed August 30, 2023.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.goldstandard.com. Accessed August 30, 2023.
3. Micromedex 2.0 [database online]. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed August 30, 2023.
4. UpToDate [database online]. Available at: http://www.uptodate.com/. Accessed 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

07/01/2025	**Related Document**
	• Updated *Review at Launch Medication List*:
	  ○ Added
	  ▪ Encelto™ (revakinagene taroretcel-lwey)
	  ▪ Stoboclo® (denosumab-bmwo)

Date	Summary of Changes
	○ Removed ▪ Hympavzi™ (marstacimab-hncq) (prior authorization requirements effective Jul. 1, 2025) ▪ Niktimvo™ (axatilimab-csfr) (prior authorization requirements effective Jul. 1, 2025) ▪ Wyost® (denosumab-bbdz)
06/01/2025	**Related Document** • Updated *Review at Launch Medication List*: ○ Added Added Imaavy™ (nipocalimab-aahu) ○ Removed (prior authorization requirements effective Jun. 1, 2025): ▪ Otulfi™ (ustekinumab-aauz) (intravenous) ▪ Steqeyma® (ustekinumab-stba) (intravenous) ▪ Yesintek™ (ustekinumab-kfce) (intravenous)
05/01/2025	**Related Document** • Updated *Review at Launch Medication List*: ○ Added: ▪ Azmiro™ (testosterone cypionate) ▪ Qfitlia™ (fitusiran) ○ Removed (prior authorization requirements effective May 1, 2025): ▪ Pyzchiva® (ustekinumab-ttwe) ▪ Selarsdi™ (ustekinumab-aekn) ▪ Wezlana™ (ustekinumab-auub)
04/01/2025	**Related Document** • Updated *Review at Launch Medication List*: ○ Added: ▪ Bkemv™ (eculizumab-aeeb) ▪ Epysqli® (eculizumab-aagh) ○ Removed (prior authorization requirements effective Apr. 1, 2025): ▪ Pavblu™ (aflibercept-ayyh) ▪ Piasky® (crovalimab-akkz) ▪ Ocrevus Zunovo™ (ocrelizumab/hyaluronidase-ocsq)
02/14/2025	**Related Document** • Updated *Review at Launch Medication List*; added ○ Alhemo® (concizumab-mtci) ○ Imuldosa™ (ustekinumab-srlf) (intravenous) ○ Niktimvo™ (axatilimab-csfr) ○ Otulfi™ (ustekinumab-aauz) (intravenous) ○ Steqeyma® (ustekinumab-stba) (intravenous) ○ Yesintek™ (ustekinumab-kfce) (intravenous)
02/01/2025	**Related Document** • Updated *Review at Launch Medication List*; removed Tremfya® (guselkumab) (intravenous) (prior authorization requirements effective Feb. 1, 2025)
01/01/2025	**Related Document** • Updated *Review at Launch Medication List*: ○ Added: ▪ Pyzchiva® (ustekinumab-ttwe) (intravenous) ▪ Selarsdi™ (ustekinumab-aekn) (intravenous) ○ Removed Kisunla™ (donanemab-azbt); prior authorization requirements effective Jan. 1, 2025
12/01/2024	**Related Document** • Updated *Review at Launch Medication List*; added Hympavzi™ (marstacimab-hncq) **Coverage Rationale** • Added language to indicate authorization will be up to the maximum FDA-approved dose and frequency, and duration for no more than 6 months **Supporting Information** • Archived previous policy version CSIND0060.06

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The 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.