Review at Launch for New to Market Medications

Policy Number: CS2022D0060G
Effective Date: November 1, 2022

Instructions for Use

Table of Contents **Page**

Related Community Plan Policy
- Off-Label/Unproven Specialty Drug Treatment

Commercial Policy
- Review at Launch for New to Market Medications

Related Document
- Review at Launch Medication List

Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Review at Launch for New to Market Medications (for Indiana Only)
Louisiana	Review at Launch for New to Market Medications (for Louisiana Only)
North Carolina	None

Coverage Rationale

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

This policy does not apply to:
- Medications used for the treatment of oncological conditions (these therapies are addressed by other policies/programs)
- Investigational/experimental medications
- Antibiotics/anti-infectives
- Nuclear pharmacy products (materials used in nuclear medicine procedures)
- Vaccines

All new medications that are identified as being subject to this policy will be placed on the Review at Launch Medication List 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 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 (ex. genetic testing, comorbid conditions); **and**
  - Compendia (if available); **and**
  - Current standard of care, as per evidenced based literature (if available)

The medications identified on the Review at Launch Medication List 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 will be reviewed against health plan benefits and for medical necessity, as per the above.

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, 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.goldstandard.com. Accessed August 30, 2022.
3. Micromedex 2.0 [database online]. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed August 30, 2022.
4. UpToDate [database online]. Available at: http://www.uptodate.com/. Accessed August 30, 2022.
5. InterQual® [website]. Available at: https://prod.cue4.com/help/InterQualOnline/BookViewHelp/content/.

Policy History/Revision Information

Date	Summary of Changes
09/01/2023	**Related Document** • Updated *Review at Launch Medication List*; added Eylea® HD (aflibercept) and Veopoz™ (pozelimab-bbfg)

Date	Summary of Changes
08/16/2023	**Related Document** • Updated *Review at Launch Medication List*; added Izervay™ (avacincaptad pegol intravitreal solution)
07/10/2023	**Related Document** • Updated *Review at Launch Medication List*; added Rystiggo® (rozanolixizumab-noli) and Roctavian™ (valoctocogene roxaparvovec-rvox)

07/01/2023	**Related Document**
	• Updated *Review at Launch Medication List*:
	  ○ Added:
	  ▪ Brixadi™ (buprenorphine)
	  ▪ Elevidys® (delandistrogene moxeparvovec-rokl)
	  ▪ Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
	  ○ Removed:
	  ▪ Aduhelm™ (aducanumab-avwa); prior authorization requirements effective Jul. 1, 2023
	  ▪ Leqembi™ (lecanemab-irmb); prior authorization requirements effective Jul. 1, 2023
	  ▪ Rebyota™ (fecal microbiota, live-jslm)
	  ▪ Sunlenca® (lenacapavir); prior authorization requirements effective Jul. 1, 2023
	  ▪ Syfovre™ (pegcetacoplan injection); prior authorization requirements effective Jul. 1, 2023

06/01/2023	**Related Document** • Updated *Review at Launch Medication List; a*dded Vyjuvek™ (beremagene geperpavec-svdt)
05/22/2023	**Related Document** • Updated *Review at Launch Medication List*; added Elfabrio® (pegunigalsidase alfa-iwxj)

05/01/2023	**Related Document**
	• Updated *Review at Launch Medication List*:
	  ○ Added Qalsody™ (tofersen)
	  ○ Removed Byooviz™ (ranibizumab-nuna), Cimerli™ (ranibizumab-eqrn), and Vabysmo™ (faricimab-svoa) (prior authorization requirements effective May 1, 2023)

04/01/2023	**Related Document** • Updated *Review at Launch Medication List*; removed Hemgenix® (etranacogene dezaparvovec-drlb) and Tzield™ (teplizumab-mzwv) (prior authorization requirements effective Apr. 1, 2023)
03/01/2023	**Related Document** • Updated *Review at Launch Medication List*; added Lamzede® (velmanase alfa-tycv) and Syfovre™ (pegcetacoplan injection)
01/12/2023	**Related Document** • Updated *Review at Launch Medication List*; added Briumvi™ (ublituximab-xiiy), Leqembi™ (lecanemab-irmb), Rebyota™ (fecal microbiota, live-jslm), and Sunlenca® (lenacapavir)
01/01/2023	**Related Document** • Updated *Review at Launch Medication List*; removed Amvuttra™ (vutrisiran), Skyrizi® (risankizumab-rzaa), Spevigo® (spesolimab-sbzo), and Xenpozyme® (olipudase alfa) (prior authorization requirements effective Jan. 1, 2023)
12/01/2022	**Related Document** • Updated *Review at Launch Medication List*; added Hemgenix® (etranacogene dezaparvovec-drlb) and Tzield™ (teplizumab-mzwv)
11/01/2022	**Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version CS2022D0060F

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.