**REVIEW AT LAUNCH FOR NEW TO MARKET MEDICATIONS**

**Policy Number:** CS2019D0060C  
**Effective Date:** October 1, 2019

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**Coverage Rationale**

**This drug policy applies to NEW medications that are:**

- 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.

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**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-

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*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
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 Coverage Determination Guidelines may apply.

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<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
</tr>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
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**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**


**POLICY HISTORY/REVISION INFORMATION**

<table>
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<tr>
<th>Date</th>
<th>Action/Description</th>
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| 03/01/2020   | Related Document  
• Updated **Review at Launch Medication List**; added Avasola™ (infliximab-axxq)                                                                |
| 02/01/2020   | Related Document  
• Updated **Review at Launch Medication List**; added Monoferric™ (ferric derisonmaltose) and Tepezza™ (teprotumumab-trbw)                      |
| 01/22/2020   | Related Document  
• Updated **Review at Launch Medication List**; removed Cutaquig® [Immune Globulin Subcutaneous (Human) – hipp] and Xembify® [Immune Globulin Subcutaneous (Human) – k1hw] [prior authorization requirements apply Jan. 1, 2020; refer to the Medical Benefit Drug Policy titled Immune Globulin (IVIG and SCIG) for coverage guidelines] |
| 12/16/2019   | Related Document  
• Updated **Review at Launch Medication List**; added Givlaari™ (givosiran) and Vyondys 53™ (golodirsen)                                            |
| 11/25/2019   | Related Document  
• Updated **Review at Launch Medication List**; added Adakveo® (crizanlizumab-tmca) and Reblozyl® (luspatercept-aamt)                               |
| 10/01/2019   | **Template Update**  
• Reorganized policy template; relocated Background section  
**Supporting Information**  
• Updated References section to reflect the most current information; no change to Coverage Rationale or Applicable Codes  
• Archived previous policy version CS2019D0060B                                                                 |

**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
 Review at Launch for New to Market Medications  
UnitedHealthcare Community Plan Medical Benefit Drug Policy  
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