This Clinical Policy applies to certain newly launched medical benefit medications that are healthcare provider administered, have not yet undergone review by Oxford, 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 Oxford 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 Clinical Policies.

Providers are strongly encouraged to seek precertification on any new to market medications that are subject to review at launch to ensure coverage. Be aware if precertification is not requested, Oxford may later deny the service or item as not medically necessary 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 precertification from Oxford 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. See Oxford Commercial Supplement to the UnitedHealthcare Provider Administrative Guide for more detail.

Clinical Policies express Oxford’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 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 may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals (hospital outpatient use ONLY)</td>
</tr>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
</tr>
</tbody>
</table>

**BACKGROUND**

The Review at Launch program provides Oxford 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 Oxford and a utilization management strategy has been communicated as may be required by law.

**BENEFIT CONSIDERATIONS**

State mandate and/or member specific benefit plan document may contain language that prohibits review at launch.

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 Administrative Policy titled [Acquired Rare Disease Drug Therapy Exception Process](#).

**REFERENCES**

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare Pharmacy, Clinical Pharmacy Program that was researched, developed and approved by the UnitedHealth Group National Pharmacy & Therapeutics Committee. [2019D0060B]

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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 Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical 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.