

# REVIEW AT LAUNCH FOR NEW TO MARKET MEDICATIONS

Policy Number: PHARMACY 302.1 T2

Effective Date: January 1, 2018

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- Related Policy**
  - [Off-Label/Unproven Specialty Drug Treatment](#)
- Related Document**
  - [Review at Launch Medication List](#)

## INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, 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.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

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

## CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General Benefits Package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes
Precertification with Medical Director Review Required	Yes <sup>1</sup>
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	All
Special Considerations	<sup>1</sup> Precertification with review by a Medical Director or their designee is required.

## BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable. 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: [Acquired Rare Disease Drug Therapy Exception Process](#).

### **Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

### **COVERAGE RATIONALE**

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.** Please 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 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.

### **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.

### **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.

HCPCS Code	Description
C9399	Unclassified drugs or biologicals (hospital outpatient use ONLY)
J3490	Unclassified drugs
J3590	Unclassified biologics

## 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. [2017D0060A]

1. AHFS Drug information [website]. Available at: <http://www.ahfsdruginformation.com/>. Accessed August 17, 2017.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <http://www.goldstandard.com>. Accessed August 17, 2017.
3. Micromedex 2.0 [database online]. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: <http://www.micromedexsolutions.com>. Accessed August 17, 2017.
4. UpToDate [database online]. Available at: <http://www.uptodate.com/>. Accessed August 17, 2017.
5. MCG™ Care Guidelines, Ambulatory Care, 21<sup>st</sup> Edition. Available at: <http://careweb.careguidelines.com/>. Accessed August 17, 2017.

## POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2018	<ul style="list-style-type: none"><li>• New policy</li></ul>