EXPERIMENTAL/INVESTIGATIONALTREATMENT FOR NJ PLANS

Policy Number: EXPERIMENTAL 002.14 T2 **Effective Date**: February 1, 2018

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Related Policies

- Clinical Trials
- Experimental/Investigational Treatment
- Off-Label/Unproven Specialty Drug Treatment

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 New Jersey Commercial plan membership.
Benefit Type	No
Referral Required (Does not apply to non-gatekeeper products)	Yes[1]
Authorization Required (Precertification always required for inpatient admission)	Yes[1,2]
Precertification with Medical Director Review Required	Inpatient, Outpatient, Office
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Inpatient, Outpatient, Office
Special Considerations	[1]This medical policy must be reviewed in conjunction with Oxford's Clinical Trials policy. [2]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.

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

Requests for treatments or therapies can be initiated by any of the following, including but not limited to:

- Member
- Provider
- Internal sources such as medical management coordinators, case managers, medical directors, sales representatives, marketing, etc.

Unless otherwise required by law with respect to drugs which have been prescribed for the treatment of a condition for which the drug has not been approved by the United States Food and Drug Administration (FDA), Oxford will not cover any services or supplies, including treatment, procedures, drugs, biological products or medical devices or any hospitalizations in connection with experimental or investigational services or supplies.

Oxford will also not cover any technology or any hospitalization in connection with such technology if such technology is obsolete or ineffective and is not used generally by the medical community for the particular diagnosis or treatment of a member's particular condition.

Note: Governmental approval of a technology is not necessarily sufficient to render it of proven benefit or appropriate or effective for a particular diagnosis or treatment of a member's particular condition, as explained below.

Oxford will apply the following five criteria in determining whether services or supplies are Experimental or Investigational:

a. Any medical device, drug, or biological product must have received final approval to market by the United States Food and Drug Administration (FDA) for the particular diagnosis or condition. Any other approval granted as an interim step in the FDA regulatory process, e.g., an Investigational Device Exemption or an Investigational New Drug Exemption, is not sufficient. Once FDA approval has been granted for a particular diagnosis or condition, use of the medical device, drug or biological product for another diagnosis or condition will require that one or more of the following established reference compendia:
   - American Hospital Formulary Service Drug Information
   - United States Pharmacopoeia Drug Information, recognizes the usage as appropriate medical treatment. As an alternative to such recognition in one or more of the compendia, the usage of the drug will be recognized as appropriate if it is recommended by a clinical study or recommended by a review article in a major peer-reviewed professional journal. A medical device, drug, or biological product that meets the above tests will not be considered experimental or investigational. In any event, any drug which the Food and Drug Administration has determined to be contraindicated for the specific treatment for which the drug has been prescribed will be considered experimental or investigational.

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b. Conclusive evidence from the published peer-reviewed medical literature must exist that the technology has a definite positive effect on health outcomes; such evidence must include well-designed investigations that have been reproduced by nonaffiliated authoritative sources, with measurable results, backed up by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale.

c. Demonstrated evidence as reflected in the published peer-reviewed medical literature must exist that over time the technology leads to improvement in health outcomes, i.e., the beneficial effects outweigh any harmful effects.

d. Proof as reflected in the published peer-reviewed medical literature must exist that the technology is at least as effective in improving health outcomes as established technology, or is usable in appropriate clinical contexts in which established technology is not employable.

e. Proof as reflected in the published peer-reviewed medical literature must exist that improvements in health outcomes, as defined in item "c." above, is possible in standard conditions of medical practice, outside clinical investigatory settings.

BACKGROUND

Experimental and investigational services are benefit exclusions and defined in the member's certificate of coverage.

Experimental or investigational services or supplies are those which Oxford determines to be:
- Not of proven benefit for the particular diagnosis or treatment of a member's particular condition.
- Not generally recognized by the medical community as effective or appropriate for the particular diagnosis or treatment of a member's particular condition.
- Provided or performed in special settings for research purposes or under a controlled environment or clinical protocol.

REFERENCES

New Jersey Small Certificates.

New Jersey Statutes Annotated (N.J.S.A.) 17B:27-46.1e.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description

02/01/2018	• Changed policy type classification from "Clinical" to "Administrative"
	• Added reference link to policy titled *Off-Label/Unproven Specialty Drug Treatment*
	• Revised coverage rationale; added language to indicate:
	  ○ Oxford will apply the [listed] five criteria in determining whether services or supplies are Experimental or Investigational
	  ○ Any drug which the Food and Drug Administration has determined to be contraindicated for the specific treatment for which the drug has been prescribed will be considered Experimental or Investigational
	• Updated supporting information to reflect the most current background information
	• Archived previous policy version EXPERIMENTAL 002.13 T2