UnitedHealthcare® Oxford
Administrative Policy

EXPERIMENTAL/INVESTIGATIONAL TREATMENT

Policy Number: EXPERIMENTAL 003.11 T2 **Effective Date**: January 1, 2018

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Related Policies

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

INSTRUCTIONS FOR USE

The services described in Oxford policies are subject to the terms, conditions and limitations of the member's contract or certificate. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify policies as necessary without prior written notice unless otherwise required by Oxford's administrative procedures or applicable state law. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

Certain policies may not be applicable to Self-Funded members and certain insured products. Refer to the member specific benefit plan document or Certificate of Coverage to determine whether coverage is provided or if there are any exclusions or benefit limitations applicable to any of these policies. If there is a difference between any policy and the member specific benefit plan document or Certificate of Coverage, the member specific benefit plan document or Certificate of Coverage will govern.

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[1]
Precertification with Medical Director Review Required	Yes[1,2]
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 review 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.

Coverage of experimental treatment is subject to the Member's benefits and exclusions under the member's Certificate with Oxford. This policy does not expand coverage to other items specifically excluded from coverage and items not listed as a covered benefit in the member's Certificate with Oxford.

For New Jersey Small Plans: Refer to Oxford's Experimental/Investigational Treatment for NJ Plans policy.

For New York Plans: The member's condition and/or disease are not required to be life threatening or disabling.

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

Experimental and/or Investigational Treatment

Oxford recognizes that peer reviewed documents in scientific and medical literature may establish that an experimental and/or investigational treatment or procedure may be better than the standard treatments available to treat a member's life threatening or disabling condition and/or disease. Oxford has determined that it will create a limited exception to the exclusion of experimental and investigational treatments and provide coverage for in-network experimental and investigational procedures that meet the criteria set forth in this policy. Such coverage is subject to the member's other benefits and exclusions. Oxford's determination of whether the criteria have been met will be based upon the opinion of an independent consultant/peer reviewer with expertise in the area of practice appropriate to treat the member's condition or disease.

Exception: For New York Plans, the member's condition and/or disease is not required to be life threatening or disabling.

Unproven Therapies

Under no circumstances will this policy extend coverage to unproven therapies. Unproven therapies are treatments or procedures that lack significant medical documentation to support their medical effectiveness. Oxford does not provide coverage for any treatment modality that has not been proven medically effective or is not generally recognized as effective or appropriate for the particular diagnosis or treatment of the member's particular condition.

The proposed experimental/investigational treatment must meet **all** of the criteria outlined below before approval is granted. In addition, documentation must be submitted to Oxford demonstrating that the criteria below have been satisfied. Without **all** such documentation, Oxford will deny any such request.

Coverage Criteria

***Note**: For New York Plans the member's condition and/or disease is not required to be life threatening or disabling.

- The member must have a life threatening or disabling condition or disease.* For purposes of this policy, a disabling condition means that the member is unable to engage in any substantial gainful activities by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve months. In the case of a child under the age of eighteen, disabling condition means that the child suffers from a medically determinable physical or mental impairment of comparable severity.
- The member's medical record, in conjunction with at least two (2) published peer-reviewed documents from the available scientific and medical evidence and any other pertinent information supplied, must establish that the proposed experimental or investigational treatment is likely to be more beneficial that any standard treatment(s) for the member's life-threatening or disabling condition or disease.*
- The opinion of the attending physician recommending that the treatment or procedure is likely to be more beneficial to the member than any covered standard health service or procedure, must be based upon at least two (2) peer-reviewed documents from the available medical and scientific evidence.
- In the absence of any evidence of a standard treatment with which to compare the experimental treatment, the attending physician's opinion must be based upon at least two (2) peer-reviewed medical and scientific publications which show a definite positive effect of the proposed treatment on health outcomes for the disease or condition from which the patient suffers or the diagnosis for which it is being prescribed. In other words, the literature must show that well designed investigations with measurable results (that can be duplicated) support that the treatment would be scientifically effective and that the beneficial effects of the treatment outweigh the harmful effects of the treatment.

Documentation: Necessary Information

The following supporting documentation must be provided by the member and/or the member's provider for consideration:

- Certification from the Member's attending physician which includes:
  - A statement that the Member has a life threatening or disabling condition or disease for which (a) standard health service or procedures have been ineffective or would be medically inappropriate; or (b) there does not exist a more beneficial standard health service or procedure covered by the health care plan
  - A statement of the evidence relied upon to recommend the proposed treatment or procedure and a statement of why the standard therapy available would not be beneficial, would be ineffective or would be inappropriate, including an assessment of the risks and benefits of the proposed treatment
  - Citation to two documents from the available medical and scientific evidence, upon which the attending physician based his recommendation for the proposed treatment and an explanation why, in the opinion of the physician, these documents establish that the treatment or procedure is likely to be more beneficial to the member than any covered standard health service or procedure or would provide a positive effect on the member's condition or illness and that the benefits outweigh the harmful effects the treatment
    - The attending physician must be a board certified or board eligible physician qualified to practice in the area of practice appropriate to treat the member's condition
    - A copy of the two documents from the available medical and scientific evidence, upon which the attending physician based his recommendation for the proposed treatment

- A written description of the proposed treatment (or protocol if available), which must include:
  - Specific goals
  - A rational and background for the plan
  - Criteria for patient selection
  - Specific directions for administering the therapy or intervention
  - Specific directions for the monitoring of patients
  - A definition of quantitative measures for determining treatment or intervention response; and
  - Methods for documenting and treating adverse reactions to the treatment or intervention

- A copy of the member's informed consent form
- A copy of the member's medical and treatment records, including results of tests or studies, showing the member's current condition and any treatment the member has received for the condition
- The available clinical or pre-clinical data that indicate the treatment's effectiveness for treatment, prevention, or palliation of the member's condition

Additional Information

- The outside consultant or Oxford, depending upon the nature of the proposed treatment and/or the member's condition or disease, may require additional documentation to review the requested treatment.
- Oxford will also accept and consider any additional pertinent clinical documentation, peer review publications and/or relevant data concerning the protocol that the member and/or the member's physician would like to provide in support of the request for the experimental treatment.

Connecticut Plans Only

For members having a Connecticut Plans, Oxford will also provide coverage, under this policy, for:

- Off-label use of cancer drugs for another type of cancer, unless specifically contraindicated by the Food and Drug Administration; **and**
- Procedures, treatments or usage of any drug, if the procedure, treatment or usage has successfully completed a Phase III clinical trial of the FDA for (a) the illness or condition being treated or (b) the diagnosis for which it is being prescribed

New York Plans Only

When an anti-cancer drug is being used to treat a type of cancer for which it is not specifically FDA approved, NY insurance law requires coverage if the drug/cancer combination is recognized in **any** of the following pharmaceutical reference compendia:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- Elsevier Gold Standard's Clinical Pharmacology
- NCCN Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Other authoritative compendia as identified by the Federal Secretary of Health and Human Services or the Centers for Medicare & Medicaid Services (CMS); or recommended by review article or editorial comment in a major peer reviewed professional journal

BACKGROUND

Coverage for experimental and investigational treatments and procedures is specifically excluded under the member's Certificate with Oxford. Oxford will cover in-network experimental/investigational treatment (not meeting the requirements of a clinical trial, as defined in Oxford's Clinical Trials policy) when the criteria outlined in this policy is met. In general, experimental and investigational treatments and procedures are those medical treatments and procedures that have not successfully completed a Phase III trial, have not been approved by the FDA and are not generally recognized as the accepted standard treatment for the disease or condition from which the patient suffers. Experimental and investigational treatments include off label therapies. Off-label therapies are those medical therapies that use a FDA approved drug or procedure for a non-indicated use. Refer to Oxford's Off-Label/Unproven Specialty Drug Treatment policy.

REFERENCES

Consensus Document of the New Jersey Working Group to Improve Outcomes in Cancer Patients: Signed by Norman C. Payson, MD and 8 other NJ health plan CEOs. This voluntary agreement was announced by the Governor of the State of New Jersey on December 16, 1999.

CT Managed Care Accountability Act, Public Act No. 99-284 sec. 15.

NY Insurance Law §§ 4900, 4910, 4914; NY Social Services Law § 208.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2018	• Added reference link to policy titled *Off-Label/Unproven Specialty Drug Treatment* • Archived previous policy version EXPERIMENTAL 003.10 T2