EXPERIMENTAL / INVESTIGATIONAL TREATMENT FOR NJ PLANS

Policy Number: EXPERIMENTAL 002.11 T2
Effective Date: June 1, 2014

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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 enrollees. 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's plan of benefits 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's plan of benefits or Certificate of Coverage, the plan of benefits or Certificate of Coverage will govern.

CONDITIONS OF COVERAGE

<table>
<thead>
<tr>
<th>Applicable Lines of Business/Products</th>
<th>This policy applies to Oxford New Jersey plan membership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit Type</td>
<td>General benefits package</td>
</tr>
<tr>
<td>Referral Required</td>
<td>No</td>
</tr>
<tr>
<td>(Does not apply to non-gatekeeper products)</td>
<td></td>
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<tr>
<td>Authorization Required</td>
<td>Yes¹</td>
</tr>
<tr>
<td>(Precertification always required for inpatient admission)</td>
<td></td>
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<tr>
<td>Precertification with Medical Director Review Required</td>
<td>Yes¹²</td>
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<tr>
<td>Applicable Site(s) of Service</td>
<td>Inpatient, Outpatient, Office</td>
</tr>
<tr>
<td>(If site of service is not listed, Medical Director review is required)</td>
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<tr>
<td>Special Considerations</td>
<td>¹This medical policy must be reviewed in conjunction with Oxford's Clinical Trials policy ²Precertification with review by a Medical Director or their designee is required.</td>
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COVERAGE RATIONALE

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

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.

1. 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:
   - The American Medical Association Drug Evaluations; or
   - The American Hospital Formulary Service Drug Information; or
   - The United States Pharmacopoeia Drug Information, recognize 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.

2. 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;

3. 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;

4. 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; and

5. Proof as reflected in the published peer-reviewed medical literature must exist that
improvements in health outcomes, as defined in paragraph 3, 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:

a. Not of proven benefit for the particular diagnosis or treatment of a Member's particular condition; or
b. Not generally recognized by the medical community as effective or appropriate for the particular diagnosis or treatment of a Member's particular condition; or
c. Provided or performed in special settings for research purposes or under a controlled environment

REFERENCES

1. New Jersey Small and NJ Individual Certificates.
2. New Jersey Statutes Annotated (N.J.S.A.) 17B:27-46.1e

POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
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<tbody>
<tr>
<td>06/01/2014</td>
<td>• Routine review; no content changes</td>
</tr>
<tr>
<td></td>
<td>• Archived previous policy version EXPERIMENTAL 002.10 T2</td>
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