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Developed By: Medical Criteria Committee	

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Approved: Csaba Mera, MD Date: 02/17/09

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**Description:**

Investigational or experimental services or supplies are those not recognized by ODS Health Plan as standard medical care for a condition, disease, illness or injury.

A clinical trial is a research study designed to answer specific questions about new therapies, diagnostic tests, screenings and disease prevention through testing on people. Clinical trials are used to determine whether new drugs or treatments are safe and effective. An investigational diagnostic test, procedure, supply or medication may be the subject of one or more studies published in peer reviewed medical (or dental) literature.

**Policy Guidelines:**

ODS considers a service or supply to be investigational or experimental if **ANY** of the following apply:

- The service or supply requires approval of a federal or other governmental body approval for general use, but does not have such final approval for use in treatment of the condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.
- No recognized national professional medical (or dental) society or organization, which has done a formal evaluation, has declared the service to be the appropriate standard of medical or dental practice.
- The service or supply under consideration is not as beneficial as an established alternative.
- The service or supply under consideration is determined by ODS, in consultation with medical or dental advisors, to be in a research status prior to general use in the medical (or dental) community in the state of Oregon.

**Criteria:**

Investigational or experimental services and supplies are not covered by ODS Health Plan, Inc.

Occasionally, requests are submitted for approval of services and/or supplies for patients enrolled in treatment protocols or clinical trials (refer to the ODS Clinical Trial criteria). These requests will be reviewed to ascertain whether they are investigational or experimental, or whether they represent an acceptable modification of treatment that has been established and accepted in the medical community.

**Information to be Submitted with Pre-Authorization Request:**

1. Medical records that indicate the medical necessity of the proposed service and/or supply.
2. Description of the proposed treatment including outcome data reported to date and any medical literature supporting the benefit of the proposed treatment compared to previously established alternatives.
3. A signed Patient Informed Consent Form.
4. Institutional Review Board (IRB) approval.

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5. Estimated cost of the proposed service or supply.

<p><b>References:</b></p> <ul style="list-style-type: none"><li>• HAYES Directory of New Medical Technologies' Status; April 7, 1999.</li><li>• FDA Web site: <a href="http://www.fda.gov/cdrh/d952.html">www.fda.gov/cdrh/d952.html</a>; June 2001.</li><li>• Drug Information for the Health Care Professional (USPDI); Volume I, 15<sup>th</sup> Edition, 1995.</li><li>• The Oregon Health Resources Commission Web site: <a href="http://www.ohppr.state.or.us/hrc/index_hrc.htm">www.ohppr.state.or.us/hrc/index_hrc.htm</a>; June 2001.</li><li>• The United States National Institutes of Health: <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a>; June 2001.</li><li>• National Library of Medicine: <a href="http://www.nlm.nih.gov/services/faqctgov.html">www.nlm.nih.gov/services/faqctgov.html</a>; June 2001.</li><li>• Physician Advisors</li></ul>
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