Experimental and Investigational Services

Date of Origin: 12/2002 **Last Review Date: 01/22/2025** **Effective Date: 02/01/2025**

Dates Reviewed: 01/2004, 02/2005, 02/2006, 02/2007, 02/2008, 02/2009, 02/2011, 02/2012, 12/2012, 12/2013, 09/2014, 01/2015, 01/2016, 01/2017, 01/2018, 01/2019, 01/2020, 01/2020, 01/2021, 01/2022, 01/2024, 01/2025

Developed By: Medical Necessity Criteria Committee

I. Description

Experimental or investigational or services or supplies are those not recognized by Moda Health as standard medical care for a condition, disease, illness or injury. The drug, device or biological product is experimental or investigational if it cannot be marketed without approval of the U.S. Food and Drug Administration (FDA).

A clinical trial is a research study designed to answer specific questions about new therapies, diagnostic tests, screenings and disease prevention through tests performed on individuals. 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.

II. Policy

A. Moda Health considers a service or supply to be experimental or investigational if one or more of following conditions are met:
   a. The requested services or supplies are not provided by an accredited institution or provider within the United States or are provided by one that has not demonstrated proficiency in the provision of the services or supplies.
   b. The service or supply involves a treatment for which the approval of one or more government agency is required but has not been obtained at the time the services or supplies are provided or are to be provided. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.
   c. The requested services or supplies are not recognized by the medical community in which they are received or 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.

d. Review of evidence-based literature does not support the requested service as safe and efficacious. The consensus among experts is that further studies or clinical trials are necessary to determine the requested services maximum tolerated dose, safety, and/or efficacy.
e. The requested procedure or services are considered investigational if they are requested in a quantity or panel of services that may be individually proven but when performed as a group or panel, the evidence-based literature does not support the requested procedures or services.
f. The requested tests or procedures are not consistent with the member's presenting complaint, injury, or illness and are not considered standard of care.
g. The service or supply under consideration is only available in the United States as part of a clinical trial or determined by Moda Health to be in research status prior to general use in the medical (or dental) community in the United States.

III. Criteria

A. Experimental or investigational services and supplies are not covered by Moda Health

*Requests for approval of services and/or supplies for patients enrolled in treatment protocols or clinical trials are reviewed according to Moda Health Clinical Trial Medical Necessity 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.

IV. Information Submitted with the Prior 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.

V. Annual Review History

Review Date	Revisions	Effective Date
12/2012	Annual Review: Added table with review date, revisions, and effective date.	01/01/2013
11/13	Annual Review: Revised to match standard plan language for experimental and investigational	12/19/2013
09/2014	Annual Review: Removed consent form and IRB required documents for pre-auth	09/30/2014
01/2015	Added additional language to #4 regarding multiple tests, procedures and services performed as a group.	01/28/2015
7/2015	Added Medicare reference	07/2015
01/2016	Annual Review: No change	01/26/2016

01/2017	Annual Review: Updated to new template, no changes	01/25/2017
01/25/2018	Annual Review:	01/25/2017
01/23/2019	Annual Review: No changes	02/01/2019
01/22/2020	Annual Review: Minor grammar updates	02/01/2020
01/27/2021	Annual Review: No changes	02/01/2021
01/26/2022	Annual Review: No changes	02/01/2022
01/25/2023	Annual Review: No changes	02/01/2023
01/24/2024	Annual Review: No changes	02/01/2024
01/22/2025	Annual Review: No changes	02/01/2025

VI. References

- Drug Information for the Health Care Professional (USPDI); Volume I, 15th Edition, 1995.
- The Oregon Health Resources Commission. https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/About.aspx
- The United States National Institutes of Health: www.clinicaltrials.gov;
- National Library of Medicine. https://www.nlm.nih.gov/
- HAYES Directory of New Medical Technologies' Status. https://www.hayesinc.com/
- FDA Web site: www.fda.gov/cdrh/d952.html
- Clinical Trials and IDE Guidance Documents http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIDE/daIDEgd_print.cfm
- Centers for Medicare & Medicaid Services: Local Coverage Determinations (LCD) L35008 Non-Covered Services, L35008 Non-covered Services; Noridian Healthcare Solutions; Revision effective date, 01/02/2020
- Physician Advisors

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): F	**NCD/LCD Document (s): L35008**
https://med.noridianmedicare.com/documents/10546/6990983/Non-Covered+Services+LCD	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC