Experimental and Investigational Services and Devices

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Related Policies

Utilization Management Overview

Guidelines for Utilization Management Policy Development & Revision

Policy Number	**350**
Original Effective Date:	3/2001
Current Approval Date:	4/23/20
Next Review:	4/2021
Category:	Determination

Policy Statement

Where there is a lack of broadly accepted evidence of the efficacy of a particular intervention, the service will be denied based upon the applicable exclusions recorded in the health plan summary or certificate of coverage.

Purpose

To describe the guidelines for processing submitted cases, where the intervention proposed is determined to be experimental and/or investigational.

Scope

All in and out of network programs, involving all provider types, where Utilization Review (UR) determinations are rendered.

Definitions

Broadly accepted evidence means there is sufficient and consistent empirical evidence that, “A procedure is considered to be valid for a clinical application, when the result is known to represent the actual property/quality desired, when compared to an appropriate standard.” (Hansen)

Experimental or investigational means that the technology or service is:

- not of proven benefit for the particular diagnosis or treatment of a particular condition; or
- not generally recognized by the healthcare community as reflected in the published peer-reviewed clinical/scientific literature as effective or appropriate for the particular diagnosis or treatment of a particular condition

Background

In the absence of a governing health plan policy, Optum* by OptumHealth Care Solutions, LLC has adopted the following criteria in evaluating technologies and services:

- If applicable, the technology must have final approval from the appropriate governmental regulatory bodies
- The scientific evidence must permit conclusions concerning the effect of the technology/service on health outcomes
- The technology/service must improve the net health outcome
- The technology/service must be as beneficial as established alternatives
- The improvement must be attainable outside investigational settings

The assessment workgroups are comprised of clinical peers, who have completed specific training in the critical evaluation of clinical and scientific literature. The process of structured qualitative and quantitative literature review is described in Utilization Management (UM) policy 429.

Clinical and scientific evidence means the following sources:

A. Peer-reviewed scientific studies published in or accepted for publication by healthcare journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
B. Peer-reviewed literature, biomedical compendia, and other healthcare literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in index Medicus, Excerpta Medicus (EMBASE), Medline, or MEDLARS database Health Services Technology Assessment Research (STAR).
C. Healthcare journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act (42U.S.C. 1395x).
D. Peer-reviewed abstracts accepted for presentation at major healthcare association meetings
E. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally or internationally recognized research institutes including the:
    - Agency for Healthcare Research and Quality,
    - National Institutes of Health,
    - National Cancer Institute,
    - National Academy of Sciences,
    - Center for Medicare and Medicaid Services, and
    - Any national board recognized by the National Institutes of Health or designated governmental oversight agency for the purpose of evaluating the medical value of health services.

Peer-reviewed literature shall not include publications or supplements to publications sponsored to a significant extent by a product manufacturing company or by an entrepreneur.

Services currently determined to be <u>experimental and investigational</u> include but are not limited to:

- Interferential muscle stimulation (Aetna Plan Summary)
- Surface electromyography (SEMG) (Aetna Plan Summary)
- Intersegmental traction (IST), anatamotor, spinalator, motorized traction (Aetna Plan Summary)
- Meridian Therapy (Aetna Plan Summary)

References

1. Hansen DT, Mootz RD. Formal Processes in Health Care Technology Assessment: A Primer For The Chiropractic Profession. Topics in Clinical Chiropractic, 1996; 3(1)
2. Article 49 of the Public Health Law – Utilization Review and External Appeal – New York State, July 1999
3. Wiesel SW. How Third-party Payers Evaluate New Treatments. The BackLetter, 2004; 19(8):96
4. Priester R, Vawter DE, Gervais KG. Investigational treatments: Process, payment, and priorities. JAMA. 1997; 278(17):1403-1404.
5. Beebe DB, Rosenfeld AB, Collins N. An approach to decisions about coverage of investigational treatments. HMO Pract. 1997;11(2):65-67.
6. Centers for Medicare and Medicaid (CMS) National Coverage Policy and current Centers for Medicare and Medicaid (CMS) Policy Manual(s) *http://www.cms.hhs.gov*

Policy History/Revision Information

Date	Action/Description
3/07/2001	Original effective date
9/20/2002	Annual review and approval completed
11/11/2003	Annual review and approval completed
10/18/2004	Annual review and approval completed
2/14/2006	Annual review and approval completed
4/10/2008	Annual review and approval completed
1/15/2009	Policy reformatted
4/30/2009	Annual review and approval completed
4/08/2010	Annual review and approval completed
10/26/2010	Policy rebranded to "OptumHealth Care Solutions, Inc. (OptumHealth)"
4/07/2011	Annual review and approval completed
4/19/2012	Annual review and approval completed
4/18/2013	Annual review and approval completed
4/17/2014	Annual review and approval completed; Policy rebranded "Optum* by OptumHealth Care Solutions, Inc."
4/16/2015	Annual review and approval completed
4/21/2016	Annual review and approval completed
4/20/2017	Annual review and approval completed; Legal entity name changed from "OptumHealth Care Solutions, Inc." to "OptumHealth Care Solutions, LLC."
4/26/2018	Annual review and approval completed; no significant changes made to the document
4/25/2019	Annual review and approval completed; no significant changes made to the document
4/23/2020	Annual review and approval completed; no significant changes made to the document

Contact Information

Please forward any commentary or feedback on Optum utilization management policies to: policy.inquiry@optumhealth.com with the word "Policy" in the subject line.