Experimental and Investigational Technologies

Optum Health Solutions Musculoskeletal (MSK) Utilization Management Policy
Policy Number: 350

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Policy Statement

A technology (service, procedure, device, supply, or drug) that is deemed investigational or experimental will be denied based upon the applicable exclusions recorded in the member's benefit coverage document or medical policy; or as not medically necessary in accordance with the criteria established by Optum.

The following criteria when determining if a technology is investigational or experimental:

- Does the technology have final approval from the appropriate governmental regulatory bodies (if applicable)?
- Does the scientific evidence permit confident conclusions concerning the effect of the technology on health outcomes?
- Does the technology improve the net health outcome (the balance between benefit and harms)?
- Is the technology at least as beneficial and safe as any established alternatives?
- Is the expected health improvement attainable in the clinical practice setting (i.e., not restricted to investigational settings)?

Purpose

This policy outlines the general criteria and guidelines used in determining the medical necessity of experimental/investigational or potentially experimental/investigational healthcare technologies.

Scope

All in and out of network programs, involving all provider types, where Utilization Review (UR) determinations are rendered. This policy is applicable only when there is no other policy, criteria, or coverage statement available. This policy does not apply to healthcare technologies employed within clinical trials.

Definitions

Experimental or investigational means the technology 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.
- There is uncertainty about the risks associated with the proposed use of the technology, including the risk of not receiving established and effective intervention.
- The technology is generally provided or performed in special settings for research purposes or under a controlled environment or clinical protocol.

Peer-review: The peer-review process subjects research studies to the scrutiny of others, who are experts in the same field (peers) and is considered necessary to ensure scientific quality.

Background

Historically, experimental, and investigational technologies (i.e., services, procedures, devices, supplies, or drugs) are standard benefit exclusions defined in the member's certificate of coverage or health plan summary. Additionally, benefit coverage documents may exclude specific technologies as experimental or investigational.

Judgments about which technologies are safe and effective, and which remain of uncertain value, must be made by health care plans and their delegates. The criteria used to distinguish experimental/investigational from standard/established technologies relate to:

- The populations and conditions for which use is expected to be helpful (i.e., indications for use)
- The known/unknown risks and ethical considerations (safety)
- The degree of certainty regarding anticipated clinical outcomes (clinical effectiveness)
- The skills, personnel, and site requirements for appropriate application (practitioner expertise, the facilities necessary for proper use)

Standard technologies are characterized by broadly established indications for use; empirical knowledge of the risk of adverse events and contraindications to use; a precise understanding of the type, duration, and magnitude of benefits to be gained; and specification of the conditions required for successful use of the technology. In contrast, a technology is considered experimental and investigational when any of the following conditions are met:

- The technology is not of proven benefit for a specific diagnosis or treatment of a particular condition.
- The technology is not generally recognized by the medical community as effective or appropriate for the diagnosis or treatment of a particular condition.
- There is uncertainty about the risks associated with the proposed use of the technology, including the risk of not receiving established and effective intervention.
- The technology is generally provided or performed in special settings for research purposes or under a controlled environment or clinical protocol.

The basis for determining the experimental or investigational status of a technology is explicitly derived from information obtained using transparent and evidence-informed processes. These include descriptions of the methods used to identify evidence, critical appraisal of research evidence, considered judgments and contextual factors. The findings are then translated into terminology that is consistent with the member’s benefit documents.

References

Article 49 of the Public Health Law – Utilization Review and External Appeal – New York State, July 1999

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*

Priester R, Vawter DE, Gervais KG. Investigational treatments: Process, payment, and priorities. JAMA. 1997; 278(17):1403-1404.

Reiser SJ. Criteria for standard versus experimental therapy. Health Aff (Millwood) 1994;13(3):127-136.

Steinberg EP, Tunis S, Shapiro D. Insurance coverage for experimental technologies. Health Aff (Millwood) 1995;14(4):143-158.

Review and Approval History

Date	Description
3/7/2001	Original effective date
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11/11/2003	Annual review and approval completed
10/18/2004	Annual review and approval completed
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4/8/2010	Annual review and approval completed
10/26/2010	Policy rebranded to “OptumHealth Care Solutions, Inc. (OptumHealth)”
4/7/2011	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
4/22/2021	Annual review and approval completed; no significant changes made to the document
5/3/2022	Annual review and approval completed; Incorporated OrthoNet content; Revised Policy Statement, Purpose, Scope, Definitions, Background, and References. Added Appendix – OrthoNet Guidelines
6/29/2022	Updated legal entity name “OptumHealth Care Solutions, LLC.” to *Optum™ Physical Health (“Optum”) includes OptumHealth Care Solutions, LLC; ACN Group IPA of New York, Inc.; ACN Group IPA of California, Inc. d/b/a OptumHealth Physical Health of California; Managed Physical Network, Inc.; and OrthoNet Holdings, Inc. which includes OrthoNet New York IPA, Inc., OrthoNet West, Inc., OrthoNet, LLC, OrthoNet of the South, Inc.
4/27/23	Annual review and approval completed; no significant changes made to the document. Updated contact email from policy.inquiry@optumhealth.com to phpolicy_inquiry@optum.com.

3/6/2024	Annual review; no substantive changes. Approved by Optum Clinical Guideline Advisory Committee.
4/25/2024	Annual review and approval completed. Document content transitioned to new policy template. Appendix – OrthoNet Guidelines removed.