Assessment of New Healthcare Technology

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Related Policies

Utilization Management Overview

Experimental and Investigational Services and Devices

Guidelines for Utilization Management Policy Development & Revision

Policy Number	**488**
Original Effective Date:	2/2020
Current Approval Date:	4/27/2023
Next Review:	4/2024
Category:	Compliance

Policy Statement

Optum* by OptumHealth Care Solutions, LLC evaluates new technology and the new application of existing technology, when determining benefits coverage for healthcare (medical) procedures (services) and devices within its utilization management (UM) program.

Optum employs a systematic healthcare technology assessment (HTA) methodology that includes:

1. The process and decision variables used to make determinations.
2. A review of information from appropriate government regulatory bodies.
3. A review of information from published scientific evidence.
4. A process for seeking input from relevant specialists and professionals who have expertise in the technology.
5. A process to translate evidence ratings into benefit coverage terminology

The results of the HTA are used to inform utilization review case-based medical necessity determinations and/or UM policy for benefit coverage decisions.

Purpose

This policy describes the process used by Optum for the evaluation of new technology and the new application of existing technology, when determining benefits coverage for healthcare (medical) procedures (services) and devices within its UM program.

*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.

Scope

In-scope: All in and out of network programs, involving all provider types, where utilization review (UR) determinations are rendered; all healthcare procedures and devices that are applied within the scope of professional licensure by chiropractors, physical, speech and occupational therapists.

Out-of-scope: Technologies outside the scope of professional licensure.

Background

Optum evaluates new technology and the new application of existing technology, when determining benefits coverage for healthcare (medical) procedures (services) and devices within its utilization management (UM) program. For the purpose of this policy, healthcare technology can be defined as all medical procedures and devices used within the regulated scopes of practice by chiropractors, physical, speech and occupational therapists.

Healthcare technology assessment (HTA) is defined in this policy as the systematic and comprehensive evaluation of healthcare technologies with regard to efficacy, safety, feasibility, comparative effectiveness and indications for use. A complete HTA should take into consideration the overall quality of healthcare including how the technology will influence gaps in currently recommended care, the prevalence of use, patient preferences, and the net risk/benefit trade-offs.

Optum employs a systematic HTA process that provides full transparency including:

- The process and decision variables used to make determinations.
- A review of information from appropriate government regulatory bodies.
- A review of information from published scientific evidence.
- A process for seeking input from relevant specialists and professionals who have expertise in the technology.
- A process to translate evidence ratings into benefit coverage terminology

The results of the HTA will be used to inform utilization review case-based medical necessity determinations and/or UM policy for benefit coverage decisions.

Healthcare Technology Assessment Process

1. Optum receives a request for a procedure or device that is ***not***:
    a. Excluded in the member's benefits coverage contract
    b. Identified by the health plan as investigational and/or unproven
    c. Excluded from the healthcare provider's licensed scope of practice
    d. Applicable to a current UM policy

2. The request is forwarded to the appropriate clinical director or designated clinical researcher who will conduct a focused HTA that includes, as available, the following components:
    a. Potential clinical indications and uses of the technology
    b. Alternative technologies that address these same indications
    c. Critical patient-important outcomes expected with the use of the technology
    d. A comprehensive literature search [see UM policy 429: Guidelines for Utilization Management Policy Development and Revision]
    e. Review of governmental HTA databases e.g., Agency for Health Care Research and Quality (AHRQ)
    f. If applicable, the legal regulatory status of the technology e.g., device approval by the FDA
    g. Review of any national coverage determinations issued by CMS
    h. Identification of applicable legislated Federal or State benefit coverage mandates
    i. Designated current procedural terminology (CPT) codes for claims reporting (if available)
    j. Review of the technology website for unpublished research, prevalence of use, protocols, etc.
    k. Input (when appropriate) from relevant specialists and professionals, who have expertise in the technology
    l. Qualitative review of the body of evidence on the technology, employing the systematic steps described in UM policy 429 (Guidelines for Utilization Management Policy Development and Revision).
    m. Conclusions about the net benefits/risks of the technology, using standardized evidence ratings and analogous benefit coverage terminology [Tables 1 and 2 Evidence to decision framework]
    n. Recommendations for case-based medical necessity determinations and/or UM policy for benefit coverage decisions.

3. The information used to complete the HTA is stored in a secure electronic folder

4. The HTA will be forwarded to the applicable clinical director, who will make a case-based medical necessity determination to approve or deny the technology in accordance with the procedures detailed in UM policies 350 (Experimental and Investigational Service and Devices) and 429 (Guidelines for Utilization Management Policy Development and Revision).

5. A UM policy recommendation, based on the HTA, may be forwarded to the Utilization Management and Quality Improvement Committees for review and approval. This process follows the guidance in UM policy 429 and the UM Program.

6. The approved UM policy is then posted on the provider web portal

7. A designated researcher maintains regular monitoring of emerging evidence and regulatory status of the technology

Evidence to Decision Framework

Table 1. Evidence rating scheme

Rating	Descriptor	Definition
A	Established Benefit	Use of the technology is supported by a high level of positive published evidence regarding safety and efficacy for the cited application(s)
B	Some Proven Benefit	Use of the technology is supported by a moderate level of positive published evidence regarding safety and efficacy for the cited application(s). Further research is required to fully clarify clinical indications, contraindications, treatment parameters, comparison with other technologies, and/or impact on health outcomes.
C	Potential but Unproven Benefit	Use of the technology is supported by some positive published data regarding safety and/or efficacy for the cited application(s), but a beneficial impact on health outcomes has not been proven for one of two reasons: (1) Data are imprecise and the level of evidence is low, or (2) Data are inconsistent or conflicting.
D	No Proven Benefit and/or Not Safe	This rating conveys one of two conclusions: (1) Use of the technology has been shown to be unsafe and/or there is no evidence in the current scientific literature that its use improves health outcomes; or (2) The research regarding use of the technology is so limited that an appraisal of safety and efficacy cannot be made.

Evidence rating: summarizes the evidence using terminology consistent with guidance for systematic literature reviews

Table 2. Translation of evidence ratings

<table>
<tr><th>Rating</th><th>Descriptor</th><th colspan="2">Benefit Terminology</th></tr>
<tr><td>A</td><td>Established Benefit</td><td colspan="2">Proven/Medically Necessary</td></tr>
<tr><td>B</td><td>Some Proven Benefit</td><td colspan="2">Proven/Medically Necessary
(with conditions)</td></tr>
<tr><td rowspan="2">C</td><td rowspan="2">Potential but Unproven Benefit</td><td>An effective alternative is available</td><td>Unproven/Not Medically Necessary</td></tr>
<tr><td>A treatment option in the absence of other effective treatment</td><td>Clinically Appropriate
(for trial of care)</td></tr>
<tr><td>D</td><td>No Proven Benefit and/or Not Safe</td><td colspan="2">Unproven/Not Medically Necessary</td></tr>
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Translation of ratings: application of a standardized methodology that is intended to serve as a 'bridge' between formal evidence appraisal terminology and health plan benefit document language

Resources

- Beebe DB, Rosenfeld AB, Collins N. An approach to decisions about coverage of investigational treatments. HMO Pract. 1997;11(2):65-67.
- 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*
- Furlan AD, Malmivaara A, Chou R, et al. 2015 updated method guideline for systematic reviews in the Cochrane Back and Neck Group. Spine 2015;40(21):1660-73.
- Guyatt G, Rennie D, editors. Users' guides to the medical literature: a manual for evidence-based clinical practice. 3rd ed. Chicago, IL: AMA press; 2015.
- Hayes WS. What to do when there is no evidence: a framework for technology decision-making under uncertainty. Winifred S. Hayes, Inc. Nov. 17, 2009.
- Herndon JH, Hwang R, Bozic KH. Healthcare technology and technology assessment. European Spine Journal 2007;16(8):1293-1302.
- IJzerman MJ. Evaluation of new technology in health care: in need of guidance for relevant evidence. Koninklijke Nederlandse Academie van Wetenschappen (KNAW) 2014; Amsterdam, KNAW.
- Koster MA. Evaluating new medical technologies: FDA, Medicare and private payers. MFT Evidence-Based Medicine Services Unit Kaiser Permanente Southern California 2014.
- Oxman AD, Grading the quality of evidence and strength of recommendations. British Medical Journal 2004; 328:1490-1497.
- Priester R, Vawter DE, Gervais KG. Investigational treatments: Process, payment, and priorities. JAMA. 1997; 278(17):1403-1404.
- NCQA. 2019 UM-CR-PN standards and guidelines; UM 10 A/B. National Committee for Quality Assurance (NCQA); https://www.ncqa.org/programs/health-plans/utilization-management/benefits-support/standards/
- Tricco AC, Langlois E, Straus SE, World Health Organization. Rapid reviews to strengthen health policy and systems: a practical guide. World Health Organization; 2017. https://apps.who.int/iris/bitstream/handle/10665/258698/9789241512763-eng.pdf
- Wiesel SW. How Third-party Payers Evaluate New Treatments. The BackLetter, 2004; 19(8):96.

Policy History/Revision Information

Date	Action/Description
02/13/2020	Original effective date
4/22/2021	Annual review and approval completed
5/03/2022	Annual review and approval completed; Updated References
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

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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.

Contact Information

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

The services described in Optum* by OptumHealth Care Solutions, LLC policies are subject to the terms, conditions and limitations of the Member's contract or certificate. Optum reserves the right, in its sole discretion, to modify policies as necessary without prior written notice unless otherwise required by Optum's administrative procedures.

Certain internal policies may not be applicable to self-funded members and certain insured products. Refer to the member's Summary Plan Description (SPD) or Certificate of Coverage (COC) 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 SPD or COC, the member's SPD or COC will govern.