



POLICY AND PROCEDURE MANUAL

Policy Title: Evaluation of New Technology		Policy Number: I.21
Primary Department: Medical Management		NCQA Standard: N/A
Affiliated Department(s): Utilization Management		URAC Standard: N/A
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Applicable Lines of Business: <input type="checkbox"/> MeridianCare <input checked="" type="checkbox"/> MeridianHealth <input type="checkbox"/> MeridianComplete <input checked="" type="checkbox"/> MeridianChoice		
Applicable States: <input type="checkbox"/> All <input checked="" type="checkbox"/> MI <input checked="" type="checkbox"/> IL <input type="checkbox"/> OH <input type="checkbox"/> _____ <input type="checkbox"/> _____		
Applicable Programs: <input checked="" type="checkbox"/> All <input type="checkbox"/> Other _____		
Policy is to be published: Internally Only <input checked="" type="checkbox"/> Internally & Externally <input type="checkbox"/>		

Policy: Meridian Health Plan (MHP) will provide a systematic, scientifically based assessment of new technologies and new applications of existing technologies. This includes medical and behavioral procedures, pharmaceuticals and devices. The plan may not approve new technologies or new applications of existing technologies when it has been determined after appropriate State review, that the service is experimental and/or not standard of care.

This document provides a process to be followed when Meridian Health Plan does not have a medical policy or Clinical Guideline directly applicable to a particular determination of whether a service provided, or proposed to be provided, is medically necessary, not medically necessary, or investigational/experimental Behavioral healthcare professionals are involved in the decision-making process for behavioral healthcare services.

The list of resources included below is not meant to be exhaustive and reviewers should use those resources relevant to the decision at hand. Reviewers do not need and are not expected to use every resource in every case. Reviewers should however, use more than one resource when more than one resource is relevant to their decision. Reviewers should exercise their professional judgment in selecting appropriate resources and in rendering their determination. If a relevant Medical Policy or Clinical UM Guideline is available, it is to be used as the basis for decision making, and the technology assessment process defined in this document is not to be followed.

Procedure:

- a. Requests for assessment of new technologies, new applications of existing technologies, and reassessment of current technologies can originate from either internal or external sources based on new developments, new utilization or new application of existing technology.

- b. Meridian’s physicians, Case Managers, and Utilization Review Staff may recommend a new or existing technology for review based on new developments with pharmaceuticals, medical devices, medical procedures, or behavioral health procedures.
- c. Meridian members, contracted practitioners, or facilities may request coverage of a new technology or new application of an existing technology.
- d. When Meridian receives a request for authorization of a new technology or new application of an existing technology, a Medical Director will review the request to verify that there is no relevant Medical Policy Clinical Guideline, or HAYES review pertaining to the technology.
 - i. If a relevant Medical Policy, Clinical Guideline, or HAYES review is available, it will be used as the basis for decision making.
- e. If no Medical Policy, Clinical Guideline, or HAYES review is directly applicable to the decision to be made, the Medical Director will contact HAYES to perform a review.
- f. Once the HAYES review has been completed, the medical director, Chief Medical Officer (CMO) or designee will review material to determine if additional sources need to be consulted
 - i. Additional sources may include specialists or professional who has expertise in the technology, medication, or device.
- g. Upon completion of the investigation a written report with recommendation to either approve or not include the technology will be presented to the Physician Advisory Committee (PAC).
- h. The PAC reviews the proposed policy and makes recommendations as clinically indicated.
- i. The technology is assessed using the following technology assessment criteria. In order to be approved, all relevant criteria must be met.
 - i. The technology must have final approval from the appropriate governmental regulatory bodies.
 1. This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology.
 2. Any approval that is granted as an interim step in the U.S. Food and Drug Administration's or any other federal governmental body's regulatory process is not sufficient.
 3. The indications for which the technology is approved need not be the same as those which Meridian is evaluating.
 4. The technology or indication for the technology may not be considered experimental or investigational
 - ii. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
 1. The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
 2. The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.
 3. Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.
 - iii. The technology must improve the net health outcome.
 1. The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
 - iv. The technology must be as beneficial as any established alternatives.
 1. The technology should improve the net health outcome as much as, or more than, established alternatives.
 - v. The improvement must be attainable outside the investigational settings.

1. When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy criteria as referenced above.

State specific special instructions:

None:

MI:

IL:

OH:

References: This section provides complete citations for all information reviewed in the Assessment

- i. Agency for Healthcare Research and Quality (AHRQ)
- ii. Agency for Healthcare Research and Quality (AHRQ) Clinical Practice Guidelines
- iii. American Hospital Formulary Service (AHFS) Drug Information
- iv. Centers for Disease Control and Prevention (CDC): <http://www.cdc.gov>
- v. Centers for Medicare and Medicaid Services (CMS): <http://www.cms.hhs.gov/center/coverage.asp>
- vi. The Hayes Directory of Analytics for Payers and Medical Technology Assessment
- vii. Blue Cross Blue Shield Association Technology Evaluation Center
- viii. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (electronic version): <http://www.nccn.org>
- ix. National Library of Medicine – PUBMED: <http://www.ncbi.nlm.nih.gov/sites/entrez>
- x. U.S. Food and Drug Administration (FDA): <http://www.fda.gov>
- xi.

Medicare Managed Care Manual:			
Medicaid CFR:			
State Administrative Codes:			
Contract Requirements:			
Related Policies:			
Related Desk Level Procedures/ Job Aids/Template Letters:			
Related Algorithms/Flowcharts/ Attachments			