Revised: December 2022

Healthcare Technology Assessment Program Description

2022

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Appendices

Healthcare Technology Assessment Program Description 2022

I. Introduction

This Technology Assessment applies to Medical Mutual of Ohio and its family of companies (the "Company") including -members in the Commercial, Marketplace and Medicare Advantage-HMO, POS and PPO-products/lines of business.

The Company employs a healthcare technology assessment review process to examine certain healthcare diagnostic and therapeutic technologies, pharmaceuticals, medical devices, and medical/surgical/behavioral health services and procedures. Reviews focus on recently developed technologies and evolving applications of established modalities, particularly those that are most relevant to the clinical care of our members. This process is intended to afford all members with access to safe, high-quality, cost-effective healthcare.

The Healthcare Technology Assessment Program incorporates the development of Corporate Medical Policies (CMP) including the evaluation of new and emerging technology for consideration of future policy inclusion. CMPs address but are not restricted to the following areas:

- Medical necessity.
- Investigational/experimental.
- Cosmetic.

CMPs are designed to facilitate continuity and consistency in how medical criteria are applied for members and ensure that benefit coverage decisions *reflect current scientific data and medical knowledge and are consistent with current accepted standards of clinical practice*.

II. Goals/Objectives

- Provide guidelines to assist with establishing individual coverage determinations pertaining to emerging healthcare diagnostic and therapeutic technologies, pharmaceuticals, medical devices, medical/surgical/behavioral health services and procedures, and other health related services.
- Establish Company-wide policies and procedures to promote delivery of safe, evidence-based clinical care to members.
- Perform ongoing monitoring of available scientific literature to identify, evaluate, and define the roles of novel and emerging technologies and/or new applications of existing technologies.
- Permit judicious allocation of resources by providing coverage for medically necessary, cost-effective services that best reflect current scientific data and accepted standards of clinical practice.
- Periodically review and revise policies to maintain accreditation and governmental compliance related to healthcare access, quality, utilization management, and other Clinical Care Management functions.
- Permit providers and members to remain abreast of Company decisions by making policies available on the Company's Web site (www.MedMutual.com).
- Facilitate ongoing dialogue with providers concerning improvements and changes to coverage of healthcare services.

III. Organizational Structure

Responsibility for Healthcare Technology Assessment is as follows:

- The Chief Medical Officer (CMO) is responsible for providing strategic direction and medical guidance on the overall healthcare technology assessment process.
- The Medical Director for CQHS and Bravo Health, who reports to the Vice President/Sr. Medical Director-Clinical Operations, is responsible for daily operations of the Medical Policy Development department; general oversight of policy development for medical procedures, behavioral health procedures, and medical devices; assuring criteria are developed by appropriate specialists, including that all behavioral healthcare policy decisions are made by appropriate behavioral health providers; and approving all Corporate Medical Policies.
- Vice President/Sr. Medical Director-Clinical Operations is responsible for physician reviewers who apply criteria according to medical policy guidelines.
- The Vice President, Pharmacy Management is responsible for general oversight of pharmacy policy development including oversight of the Pharmacy Benefit Manager. Clinical pharmacists are responsible for pharmacy policy development.
- The Vice President, Clinical, Quality and Health Services is responsible for general oversight of the process by which MCG™ criteria are utilized by the nursing staff.
- Healthcare Analysts and Policy Writers ("Policy Writers") are responsible for medical policy development and report to the Medical Director for

CQHS and Bravo Health, who reports to the Vice President/Sr. Medical Director-Clinical Operations.

Committees and work groups support the healthcare technology assessment process.

- The Medical Policy Work Group, consisting of physicians, registered nurses, pharmacists, policy writers, data scientists, and/or management as needed, is responsible for the ongoing surveillance and review of scientific literature related to new and emerging technology; prioritizing policy development; and approving criteria that are used as guidance in making coverage determinations. Behavioral healthcare professionals are involved in the decision-making process for behavioral healthcare services.
- The Pharmacy & Therapeutics Committee is responsible for prioritizing and approving criteria and policies for pharmaceutical coverage determinations. Behavioral healthcare professionals are involved in the decision-making process for behavioral healthcare services.

IV. Healthcare Technology Assessment Program

A. Scope

The Clinical Care Management division relies heavily on the Medical Policy department to ensure the Company's medical necessity and other benefit determinations are consistent with accepted standards of clinical practice and are supported by current scientific data. The Vice President/Sr. Medical Director-Clinical Operations is responsible for ensuring that the Medical Policy department adequately supports Company needs pertaining to the Healthcare Technology Assessment Program and CMP development, revisions, and maintenance.

Company CMPs largely focus on emerging, complex healthcare technologies, but also address selected pharmaceuticals, medical devices, and medical/surgical/behavioral health services and procedures. In some instances, utilization of established technologies, services, or procedures may also be addressed (e.g., modified surgical techniques or expanded indications for medical devices).

Each CMP is designed to serve as a guideline or reference point. The information is intended to guide medical necessity determinations and benefit coverage decisions made by the Company's professional staff and physician reviewers. Each such determination or decision is necessarily dependent upon the unique facts of each situation presented.

The Medical Director for CQHS and Bravo Health, who reports to the Vice President/Sr. Medical Director-Clinical Operations, oversees the CMP development and revision process. Although most requests for policy development are generated within the Clinical Care Management division, requests for development or revision may be submitted from any department within the organization.

B. Initiation of Policy Development and Revision

The development or revision of a CMP most commonly occurs because of the following:

- Emerging and/or availability of new healthcare diagnostic and therapeutic technologies, pharmaceuticals, medical devices, and medical/surgical/behavioral health services and procedures.
- New indications or contraindications pertaining to existing healthcare diagnostic and therapeutic technologies, pharmaceuticals, medical devices, and medical/surgical/behavioral health services and procedures.

The CMP development and revision process may be initiated as follows:

Internal Sources:

- CMP development or revision requests may be generated by Company employees or consultants from any department within the organization. Requests and supporting documentation may be submitted to a Healthcare Analyst & Policy Writer.

External Sources:

- The Medical Policy department regularly reviews national and local communications and coverage determinations established by the Centers for Medicare & Medicaid Services (CMS.gov).
- Current scientific literature is frequently used to initiate CMP development or revision; this includes periodic surveillance and review by the Vice President/Sr. Medical Director-Clinical Operations, Medical Director for CQHS and Bravo Health,

Healthcare Analyst & Policy Writer(s), and nurse reviewers. Sources include but are not limited to:

  - *Hayes Inc.*, a national independent review organization of medical technology.
  - Medical and behavioral health peer-reviewed literature sources.
  - Nationally recognized government agencies (e.g., National Institutes of Health, Centers for Disease Control and Prevention), expert panel, and specialty society reports and recommendations.

- Company physician reviewers are encouraged to notify the Vice President/Sr. Medical Director-Clinical Operations, Medical Director for CQHS and Bravo Health, or Company staff when a new or evolving technology is encountered during medical review, individual clinical practice, or literature review. A Physician Reviewer may detect unusual or irregular provider utilization patterns in the course of review, which could lead to the initiation of policy development or revision. The Physician Reviewer is instructed to notify the Nurse Reviewer, who will inform the Director or a Healthcare Analyst & Policy Writer of the request.
- Specific requests or concerns raised by network practitioners, professional medical organizations, contracting groups, medical facilities, and members may trigger development or revision of a CMP.
- Following the release of new or revised codes by the American Medical Association (AMA) and Health Care Procedure Coding System National Level II Medicare Codes, changes are evaluated by the Healthcare Analyst & Policy Writer(s) for possible integration of these codes into existing CMPs. When necessary, recommendations are requested from appropriate specialty physician reviewers to ensure proper handling of these codes.
- Policy re-evaluation occurs annually or as new developments in technology arise that may significantly alter the Company's position regarding the service or device. The following factors indicate the necessity to initiate the review process:

  - Identification of new scientific literature significantly altering current practices regarding efficacy and health outcomes relevant to the service.
  - Increased prior approval requests for the service.
  - Increased provider utilization of the service.

C. Assessment of Healthcare Technologies

The Vice President/Sr. Medical Director-Clinical Operations or Medical Director for CQHS and Bravo Health carefully reviews and evaluates requests submitted for consideration of policy development or those related to existing or potential behavioral health policies. A CMP is not developed for every healthcare technology (therapeutic and diagnostic), pharmaceutical, medical device, procedure, or service. The decision to proceed with CMP development is directed by the Vice President/Sr. Medical Director-Clinical Operations or Medical Director for CQHS and Bravo Health, with input from Care Authorization Nurses.

When a drug, medical device, treatment, or procedure has been identified for possible policy development or revision, factors including but not limited to the following are considered:

- Requests for reimbursement and review of appeals from providers.
- Submission of information regarding new technologies to the Company from external sources (e.g., companies, hospitals).
- Quantity and quality of relevant clinical scientific data.
- Presence of expert panel or nationally recognized authority recommendations.
- Availability of cost-effectiveness data.
- Presence of data establishing equivalent or superior health outcomes when compared with currently accepted standard means of treatment.

When necessary, findings will be presented to the Medical Policy Work Group and/or Pharmacy & Therapeutics Committee to decide whether a CMP should be developed for the service as outlined in the Healthcare Technology Assessment Program Description.

D. Development Process

Healthcare Analyst and Policy Writers are responsible for CMP development and updating and follow a staged process that is tracked and documented.

Prior to developing a new CMP or updating an existing CMP, the Policy Writer first checks MCG™ Care Guidelines® to verify if medical criteria are available. If criteria are available, the Policy Writer will:

- Evaluate criteria for suitability to the need for a policy; and
- Evaluate medical codes for completeness; and
- Make a recommendation to adopt all or some MCG™ Care Guidelines®; and
- Collaborate with Clinical Operations in customizing and/or implementing the criteria; and
- Assure input from relevant specialists and professionals who have expertise in the technology; and
- Determine necessity for customization of criteria based on physician review; and
- Collaborate with Clinical Operations and other internal stakeholders in customizing and/or implementing the criteria.

Absent MCG™ Care Guidelines® the Policy Writer will:

- Conduct research and compose a summary report of research findings; and
- Draft a CMP along with appropriate source references; and
- Determine ICD-10, CPT, and HCPCS codes as appropriate to the policy; and
- Obtain claims and appeal data to determine impact to the Company (when necessary); and
- Prepare the policy for physician review in the appropriate specialty (when necessary); and
- Select system edits for medical necessity, investigational, or cosmetic.

A proposed CMP is developed by the Healthcare Analyst & Policy Writer based upon the clinical data accumulated. A resource packet or online folder is compiled to include:

- Data analysis indicating utilization patterns, financial impact and claims experience.
- Relevant internal and external medical policies.
- Pertinent peer-reviewed scientific literature, materials, and all available technology evaluations.

Policy Writers collaborate with physician reviewers as needed during the healthcare technology assessment process to provide input on specific factors related to the drafted CMP. Physicians must have the education, training, and/or professional experience in managing the care of patients in the service, procedure, or device under review, and must be board-certified. Provider input includes insight on whether the healthcare technology or procedure…

- Consistently and reliably demonstrates an improved patient outcome as a direct result of this technology or procedure; and/or
- Is equal or superior to current standards of care; and/or
- Is safe, without history of adverse reactions disproportionate to its benefits or disproportionate to existing, standard modalities.

The Physician Reviewer provides a conclusive determination with suggestions, revisions and detailed supportive rationale to the Healthcare Analyst & Policy Writer. A final draft of the proposed CMP is presented to the Vice President/Sr. Medical Director-Clinical Operations and the Medical Director for CQHS and Bravo Health for review and if necessary, to resolve any conflicts of medical opinion or recommendations presented by the specialty matched, board certified physician reviewer(s), and/or Medical Policy Work Group members.

The following criteria are used to determine if a drug, medical device, treatment, or procedure is medically necessary:

- Appropriate regarding the standards of good medical practice, and not experimental or investigational; and
- Not primarily for member or provider convenience; and
- Most appropriate supply or level of service which can be safely provided to the member.

The following criteria are generally used to determine if a drug, medical device, treatment, or procedure is considered investigational/experimental:

- The drug or medical device cannot be lawfully marketed without clearance or approval of the U.S. Food and Drug Administration, and clearance or approval for marketing has not been given at the time the drug or device is furnished.
- Reliable evidence shows that the drug, medical device, treatment, or procedure is not considered standard of care, the subject of an on-going phase I, II or III clinical trial, or is under study to determine maximum tolerated dose, toxicity, safety, or efficacy as compared with the standard means of treatment or diagnosis.
- The consensus of opinion among experts regarding the drug, medical device, treatment, or procedure is that further studies or clinical trials are required to determine its maximum tolerated dose, toxicity,

safety, or efficacy, as compared with the standard means of treatment or diagnosis.
- *Note:* Any services determined to be investigational/experimental are not eligible for reimbursement, except as specified in member specific certificate language or as may be required by applicable law.

See **Appendix A**: Hierarchy of Medical Case Review, 2017.003
See **Appendix B**: Corporate Medical Policy Process Flow

E. Implementation

When the CMP has been completed, the document is presented to the Vice President/Sr. Medical Director-Clinical Operations for review and signature. Upon approval and signature, an effective date is established, and the next review date is scheduled.

Each CMP is posted on the division's SharePoint site, providing access to all Clinical Care Management division staff members. The policy is also posted on Company Web site and validated for accuracy by a Healthcare Analyst & Policy Writer(s) and/or Technical Support Specialist. The CMP is accessible to Company employees, providers and members.

When a CMP is implemented, the policy and all associated file updates are forwarded to the Benefit Services department to ensure integration into existing Company benefit packages.

A CMP is applied to all Company products except where not applicable, which ensures consistency, uniformity and equality across the entire Medical Review process.

Healthcare Analyst & Policy Writers work collaboratively with the Medical Policy Systems department and/or the Benefit Services department on determining and applying medical and/or benefit coding edits for appropriate claims and/or case adjudication.

F. Case Review Process

Coverage determinations are based upon member specific benefit language pertinent to the requested services.

The Company has established an appeal process to examine determinations that initially deny coverage because the drug, medical device, treatment, or procedure at issue is considered either not medically necessary or investigational/experimental.

Members may be eligible for an external, independent review as outlined in their certificate of coverage or benefit booklet.

G. Absence of Corporate Medical Policy

This document provides a process used in situations where the Company does not have a Medical Policy or Clinical Utilization Management (UM) Guideline that addresses the specific service or product for which benefits are requested. If a relevant Medical Policy or Clinical UM Guideline is available, it is to be used as the basis for decision making, and this process (Absence of Corporate Medical Policy) is not to be followed.

If no CMP or Clinical UM Guideline is directly applicable to the description of the service and the decision to be made, the physician reviewer may rely on peer-reviewed scientific literature, materials, technology evaluations published by either independent and/or vendor sources and their professional expertise as appropriate for the requested services and the clinical circumstances of the member.

The physician reviewer will consider the following as applicable:

- Whether the proposed treatment or procedure is the subject of on-going phase I, II, or III trials or is under study to determine maximum tolerated dose, toxicity, safety, or efficacy as compared with the standard means of treatment or diagnosis.
- Whether the consensus of opinion of experts in the field regarding the proposed treatment or procedure is that further studies or clinical trials are necessary to determine maximum tolerated dose toxicity, safety, or efficacy as compared with the standard means of treatment or diagnosis.
- If the proposed procedure or testing is investigational in nature.
- If the procedure is not investigational, is it medically necessary.
- If the diagnostic or screening testing is not investigational, will the testing results lead to a marked change in the course of treatment and management other than standard established testing.

H. Category III CPT Codes

The AMA developed a set of temporary codes to track the utilization of emerging technologies, services, and procedures referenced as Category III codes. The Category III code description does not establish a service or procedure as safe, effective, or applicable to the clinical practice of medicine.

Because of the specific purpose these Category III codes serve, the Company considers the item, service, or procedure represented by these codes to be not proven effective; therefore, the codes will be denied as investigational, unless a Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD), Local Coverage Determination (LCD), or coverage article specifically extending coverage to a particular Category III code has been published. The AMA indicates that a Category III code will typically be archived in 5 years and the technology or service description is either converted to a specific Category I code or should be reported with a Category I unlisted code.

V. Practitioner Communication and Education

If formal practitioner notification about a CMP is necessary, the Vice President/Sr. Medical Director-Clinical Operations or designee will consult with the CMO and the Legal department as to process and content. The Company follows Ohio *Revised Code 3963.01 Healthcare Contracts Definitions* in deciding how to proceed as a material amendment.

A change in policy is considered a material amendment if the CMP *decreases the participating provider's payment or compensation, changes the administrative procedures in a way that may reasonably be expected to significantly increase the provider's administrative expenses, or adds a new product*.

In the event a material amendment must be issued, the Company must:

- Provide to the participating provider the material amendment in writing; and
- Provide notice of the material amendment not later than ninety days prior to the effective date of the material amendment; and
- Make the notice conspicuously entitled "Notice of Material Amendment to Contract."

If formal notification is deemed not necessary, the new or amended CMP will be published in the normal course and in the traditional formats as other existing policies. CMPs are posted on www.MedMutual.com for access by Company employees, members, providers, and the public. Access to MCG™ Care Guidelines® is only through the provider portal.

Input from the practitioner community regarding the Company's CMPs is strongly encouraged. The Company will provide the current Healthcare Technology Assessment Program Description to any practitioner, provider, or member upon written request.

VI. Pharmaceutical Technology Assessment

New pharmaceutical products are reviewed quarterly by the Pharmacy Benefit Manager's Pharmacy & Therapeutics Committee. The Pharmacy Benefit Manager's Pharmacy & Therapeutics Committee reviews scientific and clinical information and recommends that a drug should be added, not added, or removed from the formulary. The Pharmacy Benefit Manager's Pharmacy & Therapeutics Committee also determines the formulary tier on which a drug is placed.

Recommendations from the Pharmacy Benefit Manager's Pharmacy & Therapeutics Committee are reviewed by the Company's Pharmacy & Therapeutics Committee, which accepts, modifies, or rejects the recommendations. The Company's Pharmacy & Therapeutics Committee is also responsible for:

- Evaluating new or existing medical benefit drugs and developing coverage criteria and parameters for these drugs; and
- Evaluating new or existing pharmacy benefit drugs for utilization management and developing coverage criteria and parameters including but not limited to prior authorization, step therapy, and quantity limits.

VII. Review and Approval Signatures

David Muzina, MD, MBA

12/31/2022

David Muzina, MD, MBA
Vice President, Sr. Medical Director-Clinical Operations

Date

Tere Koenig, MD, MBA

12/31/2022

Tere Koenig, MD, MBA
Executive Vice President, Chief Medical Officer

Date

Appendix A: Hierarchy of Medical Case Review

MEDICAL MUTUAL® CORPORATE POLICY		*Medical Policy: Hierarchy of Medical Case Review*
Policy No. 2017.003	**Responsible Area:** Clinical Quality Health Services (CQHS)- Medical Policy Development	
Date Approved: 03/31/2017 01/18/2019 12/08/2020 03/02/2022 12/31/2022	**Approved by:** David Muzina, MD, MBA Vice President/Sr. Medical Director-Clinical Operations	**Date Reviewed/Revised:** 03/31/2017 01/18/2019 12/08/2020 03/02/2022 12/31/2022

Scope:
This policy applies to Medical Mutual of Ohio and its family of companies (the "Company") including members in the Commercial, Marketplace (ACA) and Medicare Advantage-HMO, POS and PPO-products/lines of business.

Purpose:
This policy provides the order in which the Company utilizes regulations, various guidelines, medical policies, and medical criteria to make organizational determinations on medical review cases.

Policy:
When making a medical determination on a medical review case the Company follows the hierarchy of sources as listed below in order. Alternative sources may be utilized at the direction of the Chief Medical Officer (CMO) or Vice President/Sr. Medical Directors.

1. Federal and State of Ohio regulations (or the state in which an employer group is domiciled).
2. An employer group's contract that may specify benefit additions, exclusions, or limitations which are systematically hard-coded and/or recognized with a system alert in Focus Manager.
3. Medical Mutual's Corporate Medical Policies for all Commercial and Marketplace members, plus Medicare Advantage members where no National Coverage Determination (NCD), Local Coverage Determination (LCD) for the appropriate jurisdiction, or other guideline applies (see below for Medicare Advantage members).
4. MCG™ Care Guidelines®.
5. Professional judgment in the absence of evidence-based methodology.

In the absence of evidence-based methodology the reviewer will use appropriate resources or other clinical best practice guidelines applicable to the unique circumstances of the member. Resources include but are not limited to:

- Clinical Practice Guidelines published by consortiums of medical organizations and generally accepted as industry standard.
- National panels and consortiums such as National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), National Comprehensive Cancer Network (NCCN), and Substance Abuse and Mental Health Services Administration (SAMHSA); for persons less than 18 years of age studies must be approved by a United States (US) institutional review board (IRB) accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) to protect vulnerable minors;
- Evidence from **two** published studies from major scientific or medical peer-reviewed journals that are < 5 years old is preferred (< 10 years is required) to support the proposed use for the specific medical condition as safe and effective in persons aged 18 and over.

Appendix A: Hierarchy of Medical Case Review

- Commercial External Review Organizations such as *Hayes, Inc.*
- Specialty and sub-specialty societies.
- UpToDate®.

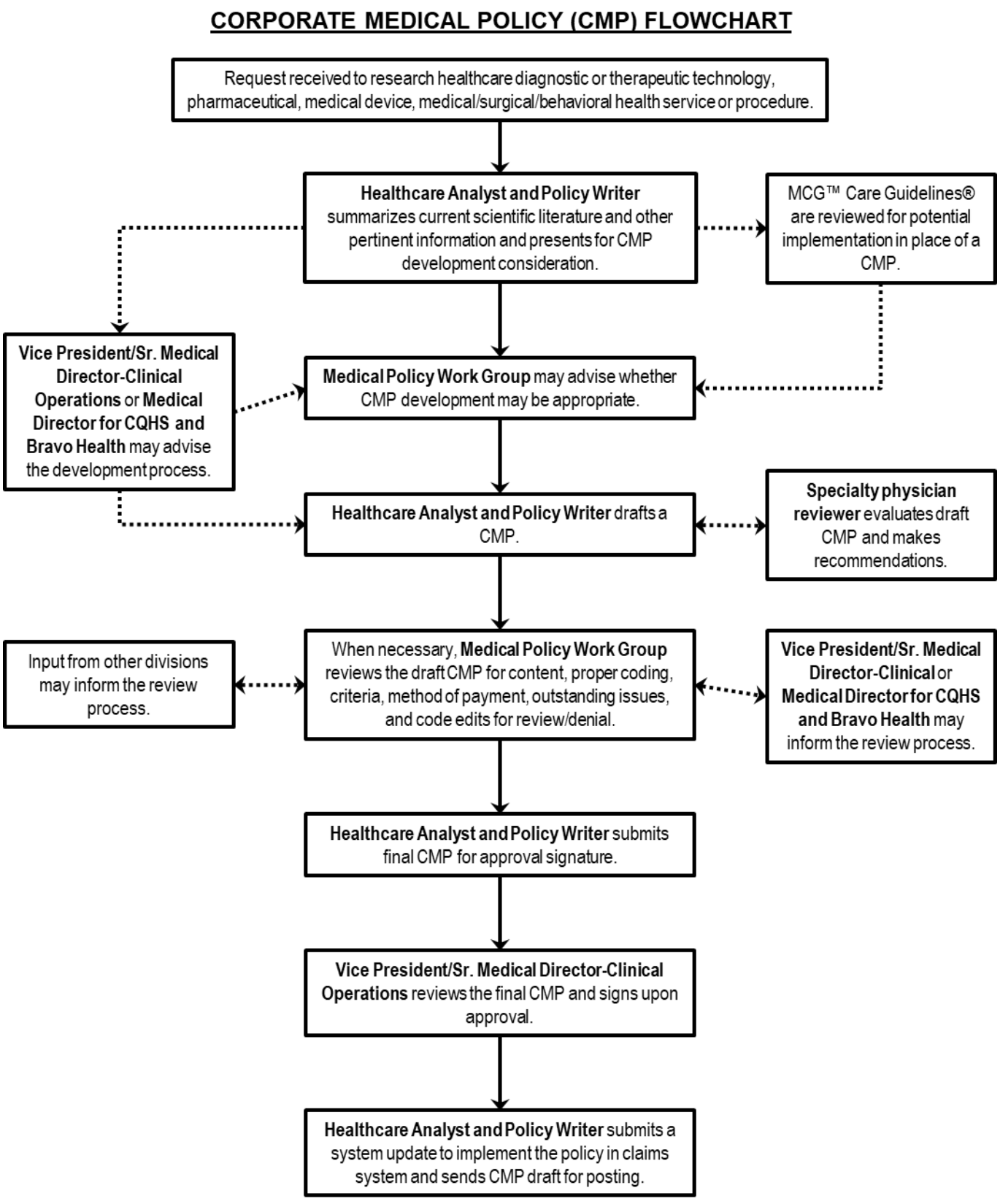
In the absence of evidence-based methodology the physician reviewer will consider the following as applicable:

- Whether the proposed treatment or procedure is the subject of on-going phase I, II, or III trials or is under study to determine maximum tolerated dose, toxicity, safety, or efficacy as compared with the standard means of treatment or diagnosis.
- Whether the consensus of opinion of experts in the field regarding the proposed treatment or procedure is that further studies or clinical trials are necessary to determine maximum tolerated dose toxicity, safety, or efficacy as compared with the standard means of treatment or diagnosis.
- If the proposed procedure or testing is investigational in nature.
- If the procedure is not investigational, is it medically necessary.
- If the diagnostic or screening testing is not investigational, will the testing results lead to a marked change in the course of treatment and management other than standard established testing.

When making medical determinations specifically for members of a Medicare Advantage plan, Medical Mutual follows the hierarchy of sources as listed below in order.

1. NCD(s)
2. LCD(s) for Ohio, Local Coverage Articles (LCAs), and other contractor-based bulletins (e.g., Medicare Administrative Contractor (MAC) for Medical Mutual's service area)
3. LCD(s) for other regions when special rules apply such as qualified chains, DME providers, and out of network labs
4. CMS guidance, including but not limited to:
    - Medicare benefit policy manual
    - Medicare Program Integrity Manual
    - Medicare Managed Care Manual
    - Other CMS-based Resource such as Medicare Learning Network (MLN) and Federal Register (FR) publications
    - Social Security Title XVIII Social Security Act, Sec. 1862
    - CMS approved Compendia
5. Medical Mutual's Corporate Medical Policies
6. MCG™ Care Guidelines®

Appendix B: Medical Policy Flowchart



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