Healthcare Technology Assessment Program
Description

2016
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I. Introduction

This Technology Assessment applies to Medical Mutual of Ohio (MMO), Medical Health Insuring Corporation of Ohio (MHICO) and Consumers Life Insurance Company (CLIC). Hereafter, the term Company refers to all three legal entities.

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; ensures that benefit coverage decisions reflect current scientific data and medical knowledge; and are consistent with current, accepted standards of clinical practice.

II. Goals/Objectives

- 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 role 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 Pharmacy and Care Management functions.
- Permit providers and members to remain abreast of Company decisions by making policies available on the Company’s Web site (MedMutual.com).
- Facilitate ongoing dialogue with providers concerning improvements and changes to coverage of healthcare services.

III. Organizational Structure

Eight committees support the Pharmacy and Care Management division. The structure of each committee has been developed to reflect national accreditation standards and to enable the division to efficiently and effectively operate within the Company.

The supporting committees include:

- Clinical Quality Improvement Committee
- Credentialing Committee
- Behavioral Health Committee
- Medical Policy Committee
- Care Management Committee
- Pharmacy Quality Management Committee
- Service Quality Improvement Committee
- Disease Management, Wellness & Health Promotion Committee

The Medical Policy Committee is responsible for the Healthcare Technology Assessment Program. Pharmacy Quality Management Committee is included in this document because the Company strives to synchronize medical utilization
policy with the policy of our Pharmacy Benefit Manager(s). This synchrony is facilitated via the Pharmacy Quality Management Committee.

The role, responsibilities, meeting times and membership of the Medical Policy Committee and the Pharmacy Quality Management Committee are outlined below. Each committee may call special meetings on an Ad Hoc (as needed) basis. A chairperson has been identified for each committee.

A. Medical Policy Committee

Role: The Medical Policy Committee provides ongoing oversight and direction of the Healthcare Technology Assessment Program, including policies guiding coverage assessments pertaining to healthcare diagnostic and therapeutic technologies, pharmaceuticals, medical devices, and medical/surgical/behavioral health services and procedures.

Committee responsibilities include the following:

- Provide input on which healthcare diagnostic and therapeutic technologies, pharmaceuticals, medical devices and medical/surgical/behavioral health services and procedures require medical policy development;
- Identify novel or modified applications of established healthcare diagnostic and therapeutic technologies, pharmaceuticals, medical devices, medical/surgical/behavioral health services and procedures requiring revision of existing medical policy;
- Approve changes to medical criteria included in medical policies;
- Provide recommendations, when requested, regarding inclusion of specific services in Company benefit packages;
- Review, revise (as needed) and approve the Healthcare Technology Assessment Program Description annually.

Members

- Director, Medical Policy, Chairperson
- Chief Medical Officer
- Sr. Medical Director
- Vice President, Clinical Care Management
- Vice President, Pharmacy and Strategic Initiatives
- Director, Clinical Care Management
- Manager, Clinical Care Management
- Manager, Financial Investigations
- Liaison, Benefit Services
- Coordinator, Medical Policy Systems
- Healthcare Analyst & Policy Writer(s)
- Provider Contracting Representative (Ad Hoc)
- Technical Support Specialist, Recording Secretary

The Medical Policy Committee meets two times per year. Additional meetings are scheduled as needed.

B. Pharmacy Quality Management Committee

Role: The Pharmacy Quality Management (PQM) Committee provides ongoing oversight and direction to the Company’s prescription drug program and drug management initiatives as it relates to clinical and quality issues.

Committee responsibilities include the following:

- Identify opportunities to improve clinical quality and healthcare outcomes;
- Assist in the development, evaluation and support of drug maintenance initiatives such as drug utilization review, disease management and quality initiatives;
• Provide delegated oversight, monitoring, and clinical/quality direction over all pharmacy benefit and drug utilization review initiatives;
• Review and approve the delegated Pharmacy Benefit Manager’s (PBM) prescription drug formulary;
• Review external vendor(s) Pharmacy & Therapeutic Committee to ensure that formulary updates occurring throughout the year are communicated to appropriate Company personnel, members and providers;
• Review reports on drug utilization in accordance with acceptable medical guidelines;
• Oversee delegation of prior approvals for pharmacy and medical drugs including member/physician appeals;
• Review and advise on communications with providers and members regarding pharmacy benefit and drug utilization management;
• Monitor member and provider complaints regarding pharmacy benefit and drug utilization management

The Pharmacy Quality Management Committee meets at least five (5) times annually.

Medical Mutual Committee Management Members

Vice President, Pharmacy & Strategic Initiatives
Chief Medical Officer
Senior Medical Director
Clinical Pharmacist
Healthcare Analyst & Policy Writer
Pharmacy Director, Chairperson

Director, Medical Policy (Ad Hoc)
Manager, Pharmacy Management (Ad Hoc)
Sr. Specialist, Clinical Compliance (Ad Hoc)
Recording Secretary

Pharmacy Benefit Management Committee Members

Clinical Account Executive
National Account Executive (Ad Hoc)

Director, Account Management (Ad Hoc)
Senior Account Manager (Ad Hoc)

Drug Utilization Management Members

Account Executive, Medical Benefit Management
Clinical Account Executive, Medical Benefit Management

NOTE: Medical Mutual’s partner PBM vendor is Express Scripts Holding Company (Express Scripts).

IV. Healthcare Technology Assessment Program

A. Scope

The Pharmacy and 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 Chief Medical Officer and Director, Medical Policy are responsible for ensuring that the Medical Policy department adequately supports Company needs pertaining to the Healthcare Technology Assessment Program and Corporate Medical Policy development, revisions and maintenance.

Company Corporate Medical Policies 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 Corporate Medical Policy is designed to serve as a guideline or reference point. The information is intended to be utilized to guide, but not dictate the medical necessity determinations and benefit coverage decisions that are 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 Chief Medical Officer oversees the Corporate Medical Policy development and revision process. Although most requests for policy development are generated within the Pharmacy and 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 Corporate Medical Policy most commonly occurs as a result 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 Corporate Medical Policy development and revision process may be initiated as follows:

**Internal Sources:**

- Corporate Medical Policy 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 (e.g., Cigna Government Services Administrators, LLC) and coverage determinations established by the Centers for Medicare & Medicaid Services (CMS.hhs.gov).
- Current scientific literature is frequently used to initiate Corporate Medical Policy development or revision; this includes periodic surveillance and review by the Chief Medical Officer; Director, Medical Policy, Healthcare Analyst & Policy Writer(s) and nurse reviewers. Sources include but are not limited to:
  1. *Hayes Inc.*, a national independent review organization of medical technology;
  2. Blue Cross Blue Shield Technology Evaluation Center Assessments (BCBS.com);
  3. Medical and behavioral health peer-reviewed literature sources (emerging technologies, newer treatments and modified therapeutic approaches);
  4. Nationally recognized government agencies (e.g., National Institute of Health and Centers for Disease Control and Prevention), expert panel and specialty society reports and recommendations.
- Company physician reviewers are encouraged to notify the Chief Medical Officer or Company staff when a new or evolving technology is encountered in the course of 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 Corporate Medical Policy.
- Following the release of new or revised codes by the American Medical Association 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 Corporate Medical Policies. When necessary, recommendations are requested from appropriate specialty physician reviewers to ensure proper handling of these codes.
Corporate Medical Policy re-evaluation occurs at periodic intervals. Reassessment may occur at any time if new developments arise that may significantly alter the Company’s position regarding the service or if revision is requested by the Medical Policy Committee. The following factors indicate the necessity to initiate the review process:

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

C. Assessment of Healthcare Technologies

When a drug, medical device, treatment or procedure has been identified for possible policy development or revision, the Chief Medical Officer reviews the current scientific literature and other pertinent documentation including, but not limited to, the following:

- Requests for reimbursement and review of appeals from providers, determined by the Pharmacy and Care Management department;
- 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.

The Chief Medical Officer, and Director, Medical Policy carefully review and evaluate requests submitted for consideration of policy development. The Senior Medical Director, evaluates requests related to existing or potential behavioral health policies. A Corporate Medical Policy is not developed for every healthcare technology (therapeutic and diagnostic), pharmaceutical, medical device, procedure or service. The decision to proceed with Corporate Medical Policy development is directed by the Chief Medical Officer, and Director, Medical Policy, with input from Care Authorization Nurses. When necessary, findings will be presented to the Medical Policy Committee and/or Pharmacy Management Quality Committee to decide whether a Corporate Medical Policy should be developed for the service as outlined in the Healthcare Technology Assessment Program Description.

D. Development Process

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

- Extensive 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, published by either independent and/or vendor sources.

The proposed Corporate Medical Policy and resource packet/on-line folder are forwarded to an actively-practicing, board-certified physician reviewer(s) working in specialties related to the topic under evaluation for review, including a determination whether the service, procedure, treatment or technology meets the following criteria:

- Approved for use in the United States by the appropriate government regulating body;
- Consistently and reliably demonstrate an improved patient outcome as a direct result of this technology or procedure;
• Equal or superior to current standards of care;
• 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 Chief Medical Officer, and/or Healthcare Analyst & Policy Writer. A final draft of the proposed Corporate Medical Policy is presented to the Chief Medical Officer and Director, Medical Policy for review and if necessary, resolve any conflicts of medical opinion or recommendations presented by the specialty matched, board certified physician reviewer(s) and/or Medical Policy Committee members.

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

• Appropriate with regard to the standards of good medical practice and not experimental or investigational;
• Not primarily for member or provider convenience;
• 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:

• Drug or medical device cannot be lawfully marketed without approval of the U.S. Food and Drug Administration and 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;
• Reliable evidence shows that 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: Physician Review of New Technology, CM0137
See Appendix B: Corporate Medical Policy Process Flow

E. Implementation

When the Corporate Medical Policy has been completed, the document is presented to the Chief Medical Officer and Director, Medical Policy and/or Vice President, Pharmacy and Strategic Initiatives for review and signature. Upon approval and signature, an effective date is established and the next review date is scheduled.

Each Corporate Medical Policy is posted on the division’s SharePoint site, providing access to all Pharmacy and 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 Corporate Medical Policy is accessible to Company employees, providers and members.

When a Corporate Medical Policy 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 Corporate Medical Policy 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 Corporate Medical Policy 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 American Medical Association (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, Medical Mutual will consider 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) or 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

The Chief Medical Officer and Director, Medical Policy determines whether formal practitioner notification is necessary following completion of the formal Corporate Medical Policy process. The Legal department is consulted as necessary. If formal notification is to occur, practitioners are informed via various Company publications. These publications contain recent update(s) and information on new and existing Corporate Medical Policies. The publications also include helpful tips on topics such as claims submission, prior approval requirements, Current Procedural Terminology coding information and International Classification of Diseases 10th Revision Clinical Modification diagnosis coding pertaining to specific Corporate Medical Policies.

If formal notification is deemed not necessary, the new or amended Corporate Medical Policy will be published in the normal course and in the traditional formats as other existing policies.

Input from the practitioner community regarding the Company’s Corporate Medical Policies is strongly encouraged by the Pharmacy and Care Management department. 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. Using current clinical and scientific information, Pharmacy Benefit Manager’s Pharmacy & Therapeutics Committee, which is composed of practicing physicians and pharmacists in varying specialties and practice settings, reviews information and arrives at one of the following recommendations:

- The drug offers superior clinical benefits over existing products and must be added;
- The drug shows no obvious clinical superiority over existing products but may be added;
- The drug shows no superiority and may not be clinically effective, or presents safety issues and should not be added.

The recommendations of the Pharmacy Benefit Manager’s Pharmacy & Therapeutics Committee are reviewed by the Company’s Pharmacy Quality Management Committee, which either accepts, modifies or rejects the recommendations (refer to Appendix E).

VII. Review and Approval Signatures

______________________________  _______________________
Robert E. Rzewnicki, MD        Date
Chief Medical Officer

______________________________  _______________________
Nancy Ross Bell, MBA, RN, FACHE  Date
Director, Medical Policy
PHARMACY AND CARE MANAGEMENT
POLICY AND PROCEDURES

TITLE: Physician Review of New Technology

PURPOSE: Provide standard criteria for the review of new technology, new applications of existing technology or the review of special cases for medical policy physician reviewers, independent practitioners and external advisors assisting in the development of the Company's corporate medical policies. The details of these standard criteria are defined in the Company's healthcare technology assessment program description.

POLICY: The Company ensures that members have access to safe and effective care through the evaluation of new and existing healthcare diagnostic and therapeutic technologies, pharmaceuticals, medical devices, medical/surgical/behavioral health services and procedures. Requests for the initiation, development and/or revision of an existing corporate medical policy may be generated internally from any department within the organization.

[Healthcare Analyst and Policy Writer]

Draft a proposed Corporate Medical Policy based upon the clinical data accumulated.

Compile a resource packet and on-line folder to include the following information:

Extensive 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, published by either independent and/or vendor sources

InterQual® criteria, if available

Identify specific issues that must be addressed by a specialty-matched, board certified physician reviewer in the proposed Corporate Medical Policy.

Forward the packet/on-line folder to an actively practicing, board certified physician reviewer working in the specialty related to the topic under evaluation for review. Behavioral healthcare professionals are used in the decision making process for all behavioral health procedures under consideration.

Revise the proposed Corporate Medical Policy based upon the specialty-matched, board certified physician reviewers’ recommendations if necessary.

Present a final draft of the proposed Corporate Medical Policy to the Chief Medical Officer and Director.

[Specialty-Matched, Board-Certified Physician Reviewer]

Pursue the following steps in their review effort:

Review the resource packet provided by the Company carefully and completely.

Conduct a literature review supported by a library science search.

Determine whether the service, procedure, treatment or technology under scrutiny meets the following criteria:

- Approved for use in the United States by the appropriate government regulating body
- Consistently and reliably demonstrate an improved patient outcome as a direct result of this technology or procedure
- Equal or superior to current standards of care
- Safe and does not have a history of adverse reactions disproportionate to its benefits or disproportionate to existing, standard modalities

Review the CPT, ICD and HCPCS codes contained with the policy for appropriateness.

Provide a conclusive determination with suggestions, revisions and detailed supportive rationale to the healthcare analyst and policy writer within 14 days of initial distribution.

[Chief Medical Officer]

Review the final draft of the proposed Corporate Medical Policy and resolve any conflicts of medical opinion or recommendations presented by the specialty-matched, board certified physician reviewer and/or Medical Policy Committee members.

Recommend final approval of a proposed medical policy and its signature into Corporate Medical Policy.
Appendix B: Medical Policy Flowchart

Request received to research healthcare diagnostic or therapeutic technology, pharmaceutical, medical device, medical/surgical/behavioral health service or procedure.

Healthcare Analyst and Policy Writer collects current scientific literature and pertinent documents (e.g., reports and recommendations from nationally recognized professional societies and government agencies and InterQual® criteria if available) and presents the information for policy development consideration.

Medical Policy Work Group

Specialty Physician Reviewer

Medical Policy Committee

If a decision is made to proceed with policy development, Healthcare Analyst and Policy Writer drafts a Corporate Medical Policy to include content, coding, criteria and method of payment.

Healthcare Analyst and Policy Writer reviews the draft Corporate Medical Policy and determines what specialty review is required.

Specialty physician reviewer(s) evaluate(s) the draft policy and provide(s) recommendations.

Director, Medical Policy reviews the draft policy for content, proper coding, criteria, method of payment, outstanding issues and possible code edits for review/denial. Input from other divisions is obtained when applicable.

Healthcare Analyst and Policy Writer prepares the final Corporate Medical Policy and submits policy for approval signature.

Chief Medical Officer reviews draft policy, gives recommendations for final version and signs the Corporate Medical Policy upon approval.

Director, Medical Policy reviews the final Corporate Medical Policy and signs upon approval.
Appendix C: Pharmaceutical Coverage Status Process Flow

Pharmaceutical Coverage Status Process Flow

Quarterly
Pharmacy Benefit Manager,
Pharmacy & Therapeutics Committee (P & T)

Recommendation options
1) Must Add
2) May Add
3) Must Not Add

Quarterly
Health Plan
Pharmacy Quality Management Committee

Disposition options
1) Accept
2) Modify
3) Reject

Quarterly
Health Plan
Clinical Quality Improvement Committee