Department:	Medical Management	**Original Approval:**	04/30/2010
Policy & Procedure #:	MM161	**Last Approval:**	06/26/2018
Title:	New Technology Evaluation		
Approved By:	UM Medical Sub Committee; MMLT; UM Committee		
Dependencies:	*Drug Formulary Development and Distribution* policy (PM500) *HCA HTA New Technology Evaluation Process for Operations* procedure (OP622)		

Purpose

CHPW ensures that covered members have access to new technologies as appropriate. This policy and procedure documents how Community Health Plan of Washington (CHPW) assesses new technology and new applications of existing technologies, including medical, surgical and behavioral health procedures and devices, pharmaceuticals, diagnostic tests, and medical equipment and other emerging technologies for the treatment of medical and behavioral health conditions. For State Programs, the purpose of this policy is also to ensure that CHPW reviews and follows the determinations of the Health Technology Assessment (HTA) program promulgated by HCA (Chapter 182-55 WAC with the inclusion of medications and other emerging technologies). For Medicare Programs, this procedure also ensures that CHPW reviews and follows the determination in CMS National and Local Coverage Determinations. New technology and new applications of current technology (hereafter referred to as "new technology") are evaluated for inclusion in benefits packages on an ongoing basis. This procedure is used when CHPW usual criteria --CHPW internal policies and procedures, determinations made by the Washington State HTA program (for State programs), and CMS National and Local Coverage Decisions (for Medicare programs) -- have not yet addressed the proposed topic or update of CHPW internal policy is indicated.

Policy and Procedure

Requests for evaluation of a new technology or a new application of an existing technology may come from multiple sources, including but not limited to:

A. Providers via a request to the CHPW Chief Medical Officer, Medical Director, Behavioral Health Medical Director or their designees
B. Providers or members as a request for authorization of a medical, surgical and behavioral health procedures and devices, pharmaceuticals, diagnostic tests, and medical equipment and other emerging technologies for the treatment of medical and behavioral health conditions for a specific member
C. CHPW staff, including Physicians, Pharmacists, Behavioral health specialists, Nurses and other staff members based on new information learned through professional activities and reading of peer reviewed literature from authoritative sources

Requests for new technology evaluation are forwarded to a Medical Director, Behavioral Health Medical Director or Pharmacist who then:

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A. Uses the CHPW coverage criteria hierarchy (see *Background* above) and assures that no existing applicable coverage determinations have been made
B. Reviews any applicable internally developed CHPW criteria in possible need of update
C. Reviews guidelines, and other sources including Hayes, Inc. and other scientific and medical literature
D. Initiates the full New Technology Evaluation process for either new technology or technology evaluation update requests when appropriate

DECISION PROCESS

Recommendations regarding new technologies and new applications of existing technologies are made to the appropriate UM Subcommittee (Medical, Behavioral Health or Pharmacy) which each meet at least quarterly and more frequently if the need should arise. The UM Subcommittees report up to the UM Committee. The UM Subcommittee (Medical, Behavioral Health or Pharmacy) may appoint a workgroup to assist with the technology assessment.

A. At least one member of the UM Subcommittee (Medical, Behavioral Health or Pharmacy) or workgroup will be a professional who has expertise in the technology being reviewed.
B. A board certified psychiatrist chairs the UM Behavioral Health Subcommittee for behavioral health technologies that may require review.
C. If a specialist or professional who has expertise in the technology is not available for the UM Subcommittee, or for appointment to the workgroup, the UM Subcommittee will have access to such a professional or specialist in its decision-making process if needed

The UM Subcommittee or workgroup will review relevant information from:

A. Governmental regulatory bodies.
B. The published medical and scientific literature.
C. Published guidelines including MCG and Hayes, Inc.
D. Evidence based Behavioral Health guidelines and scientific literature.

The members of the appropriate UM Subcommittee (Medical, Behavioral Health or Pharmacy), and workgroup if appointed, will use their discretion and professional judgment to select relevant information for review. The reviewers will have access to experts if needed.
The appropriate UM Subcommittee (Medical, Behavioral Health or Pharmacy) will make a recommendation regarding acceptance of the new technology. The UM Committee will make the final decision regarding adaptation of the new technology.

TECHNOLOGY ASSESSMENT CRITERIA

The technology is assessed using the following five technology assessment criteria:

A. The technology must have final approval from the appropriate governmental regulatory bodies.
    1. This criterion applies to medical, surgical and behavioral health procedures and

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devices, pharmaceuticals, diagnostic tests, and medical equipment and other emerging technologies for the treatment of medical and behavioral health conditions, humanitarian devices, and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration, local institutional review board (IRB) 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 CHPW is evaluating. The technology or indication for the technology may not be considered experimental or investigational as defined below.

B. 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 evaluation of 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.
C. 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.
D. 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.
E. The improvement must be attainable outside the investigational settings.
F. When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy criteria C and D.

DOCUMENTATION OF TECHNOLOGY ASSESSMENT PROCESS AND DECISION

The recommendation to the appropriate UM Subcommittee (Medical, Behavioral Health or Pharmacy) regarding the new technology will be documented using the following format:

A. Assessment Objective and Background. This section includes descriptive information needed to understand the clinical context for evaluating the technology. It includes:
    1. Description of the technology;
    2. Proposed clinical coverage criteria for the technology;
    3. Comparative or alternative treatments or interventions; and
    4. U.S. Food and Drug Administration (FDA) approval status.

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B. Review of the Evidence. This section provides a comprehensive summary of the body of clinical evidence on the effectiveness of the technology, analyzing the quality of the evidence and synthesizing the study results.
C. Discussion and Conclusion. The discussion section synthesizes the body of evidence to answer the key questions and issues regarding the technology as posed by the Assessment. The conclusion presents a judgment with supporting rationale on the effectiveness of the technology according to the 5 technology assessment criteria. Included are conclusions of:
    1. Whether the quality of the body of evidence permits conclusions to be drawn regarding the effectiveness of the technology;
    2. Whether the technology improves clinically significant outcomes; and
    3. Whether the benefits of the technology outweigh the risks.
D. References. This section provides complete citations for all information reviewed in the Assessment.

RECOMMENDATIONS AND CRITERIA FOR INCLUDED TECHNOLOGY

When the appropriate UM Subcommittee (Medical, Behavioral Health or Pharmacy) has made a decision to recommend acceptance of a new technology or new application of an existing technology in the benefit package, Clinical Coverage Criteria will be prepared and submitted for approval to the UM Committee.

If approved by the UM Committee, the Clinical Coverage Criteria are then handed off to appropriate departments to operationalize, including provider/member notification, updating of benefits lists and websites, claims/payment updating, and notification of appropriate CHPW staff, including UM and CM teams.

EXPERIMENTAL AND INVESTIGATIONAL DEFINED

A service (including medical or behavioral health treatments, diagnostics, medications, and devices) is experimental or investigational if ANY of the following criteria apply to it at the time the service was, or would be, provided to an enrollee:

A. The service cannot be legally marketed in the United States without the approval of the Food and Drug Administration (FDA) and such approval has not been granted;
B. The service is the subject of a current new drug/new device application on file with the FDA;
C. The service is provided as part of a Phase I or Phase II clinical trial, or provided in any other manner that is intended to evaluate the safety, toxicity, or efficacy of the service;
D. The service is provided pursuant to a written protocol or other document that lists an evaluation of the service's safety, toxicity, or efficacy as among its objectives;
E. The service is subject to the approval or review of the Institutional Review Board (IRB) or other body that approves or reviews research concerning the safety, toxicity, or efficacy of services;
F. The service is provided pursuant to informed consent documents that describes the service as experimental or investigational, or in other terms that indicate that the service is being evaluated for its safety, toxicity, or efficacy;

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G. The prevailing opinion among experts as expressed in the published authoritative medical or scientific literature is that further research is necessary to determine the safety, toxicity, or efficacy of the service; or
H. When researched, Hayes, Inc. assigns a 'C' or 'D' rating to the intervention.

List of Appendices

None.

Citations & References

CFR		
WAC	Chapter 182-55	
RCW		
Contract Citation	☒ WAH	2017 Managed Care Contract amended, Section 11.1.9
	☒ IMC	
	☐ MA	
Other Requirements		
NCQA Elements	Health Plan Standard UM 10 Evaluation of New Technology	

Revision History

Revision Date	Revision Description	Revision Made By
02/26/2010	Original	Lucy Sutphen, MD, FACP
03/01/2010	Review and edit	Rachel Koh, AVP of Pharmacy
03/04/2010	Edit for formatting, style, and clarity	Jennifer Carlisle
04/26/2010	Review and edit	Lucy Sutphen, MD, FACP
04/30/2010	Approval	MMLT
03/30/2011	Review and edit	Lucy Sutphen, MD, FACP
04/27/2011	Approval	MMLT
07/26/2012	Minor editing	Lucy Sutphen, MD, FACP
08/08/2012	Approval	MMLT
06/10/2013	Minor editing	Victor Collymore, MD
06/28/2013	Approval	MMLT
03/11/2014	Edit for clarity & concurrence with new titles	MMLT
03/11/2014	Approval	MMLT
05/06/2014	Revised to share between UM and Operations; added Assessing and Communicating Impacts procedure; renumbered as UO219	Kris Shopin
05/06/2014	Approval	Donna Arcieri
04/27/2015	Annual review	J. Hovey / K. Brostoff / A. Kaneko /R. Lillie

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05/06/2015	Approval	MMLT / Donna Arcieri
10/12/2015	Specifically called out Behavioral Health to clarify that PRO meets NCQA and FIMC contract requirements.	Clayton Thompson
11/06/2015	Approval	Donna Arcieri
11/11/2015	Approval	MMLT
12/21/2015	Added FIMC and Wraparound contract citations	Renée Lillie
12/21/2015	Approval	Donna Arcieri
12/24/2015	Approval	MMLT
11/01/2016	Approval	Melissa Shilipetar
11/03/2016	Updated Operations dept. name, tracker location	Renée Lillie
11/03/2016	Approval	Donna Arcieri
02/05/2018	Removed operational section for inclusion in Operations Claims Support procedure; moved to current P&P template	Kimber Bishop
06/01/2018	Renumbered	Cindy Bush
06/19/2018	Removed reference to the Technology Assessment Committee and clarified the role of the UM Medical, Behavioral Health and Pharmacy Subcommittees in evaluating new technology and the role of the UM Committee in the final approval of new technology. Clarified the option of a workgroup being appointed by the UM Subcommittee to evaluate the new technology.	LuAnn Chen, MD
06/22/2018	Review and approval	UM Medical Subcommittee
06/22/2018	Approval	MMLT
06/26/2018	Approval	UM Committee

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