Product Lines Affected

F&C	X	PHC (HMO SNP)[4]	X
MSC+[1]	X	MnCare	X
PWSHC (HMO SNP)[2]	X	Part D	X
SNBC[3]	X	Other	

Policy Name	**Technologies – New and Existing**
Policy Number	**UM11**
Origination Date	August 2005
Revision Effective Date	March 5, 2026
Responsible Position	Utilization Management Manager
Regulatory Requirement(s)	2026 Minnesota Department of Human Services (DHS) Families and Children contract, article 6 2026 DHS Minnesota Senior Health Options (MSHO)/Minnesota Senior Care Plus (MSC+) contract, article 6 2026 DHS Special Needs BasicCare (SNBC) contract, article 6 MN Rules parts 4685.0100, subp. 6a, 4685.0700, subp. 4.F, and 9505.5005, subp. 9.B Title 42 Code of Federal Regulations (CFR) Parts 422.101, 422.138, and 423.120 Title 42 United States Code (USC) Section 1396r-8 (d)(5) Medicare Managed Care Manual, chapter 4, Benefits and Beneficiary Protections, section 10.7 Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance Medicare Prescription Drug Benefit Manual, chapter 6, Part D Drugs and Formulary Requirements, sections 30.1 – 30.2 Minnesota Health Care Programs (MHCP) Provider Manual, Provider Basics – Authorization PrimeWest Health ***Provider Manual***, *Authorization Criteria* and *Authorization Standards*
Cross-References	CC06: Service Authorization UM01: Utilization Management Structure/Plan PM04: Pharmacy Determinations MedImpact Policy 460-PD-1003 Pharmacy & Therapeutics Committee
Attachments	

Policy

Pursuant to the above regulatory authorities and accreditation requirements, PrimeWest Health follows a formal mechanism to evaluate and address new developments in technology and new applications of existing technology for evaluating coverage for experimental, investigative, or unproven treatments made possible through new and emerging technologies. This process is defined by MN Rules parts 4685.0100, subp. 6a, and 4685.0700, subp.4F. It includes an evaluation of medical and dental procedures, behavioral health procedures, pharmaceuticals, and devices.

PrimeWest Health is not obligated to cover any emerging or experimental procedures and technologies absent established coverage criteria, but may do so at its own discretion.

[1]PrimeWest Health's Minnesota Senior Care Plus (MSC+) program for members who have only Medicaid coverage through PrimeWest Health
[2]PrimeWest Health's Minnesota Senior Health Options (MSHO) program for members who have both Medicaid and Medicare coverage through PrimeWest Health
[3]PrimeWest Health's Special Needs BasicCare (SNBC) program for members who have only Medicaid coverage through PrimeWest Health
[4]PrimeWest Health's Special Needs BasicCare (SNBC) program for members who have both Medicaid and Medicare coverage through PrimeWest Health

Definitions

"Experimental, investigative, or unproven" means a drug, device, medical treatment, diagnostic procedure, technology, or procedure for which reliable evidence does not permit conclusions concerning its safety, effectiveness, or effect on health outcomes.

"Formulary" means a current list of covered outpatient prescription drug products that is subject to periodic review and update.

Procedure

A. In respect to medical treatments, dental treatments, behavioral health practices, medications, diagnostic procedures, technologies, medical devices, and procedures, PrimeWest Health adheres to the following:
   1. All areas of medical treatment, diagnostic procedures, medical devices, technologies, or other procedures are addressed by the PrimeWest Health Chief Senior Medical Director and/or Assistant Chief Senior Medical Director as outlined in this policy.
   2. All areas of dental treatment are addressed by the PrimeWest Health Dental Medical Director as outlined in this policy.
   3. All areas of behavioral health treatment are addressed by the PrimeWest Health Behavioral Health Medical Director as outlined in this policy.
   4. All areas of medication are addressed by PrimeWest Health's contracted pharmacy benefit manager (PBM), MedImpact.
      a. MedImpact's Pharmacy & Therapeutics (P&T) Committee reviews new pharmaceuticals within 120 days of United States Food and Drug Administration (FDA) approval for possible inclusion in the Medical Assistance (Medicaid) and MinnesotaCare formularies, and within 90 days of FDA approval for the Medicare Part D formularies, per State and Federal regulations.
      b. The P&T Committee bases all clinical decisions on the strength of scientific evidence, standards of practice, peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other appropriate materials as needed.
   5. PrimeWest Health follows final decisions for coverage based on applicable Medicare statutes, regulations, national coverage determinations (NCDs), and local coverage determinations (LCDs).
   6. PrimeWest Health follows final decisions for coverage based on Minnesota Department of Human Services (DHS) assessment of new technologies and new applications of existing technologies. PrimeWest Health follows declarations by the FDA that a drug or device has been declared safe and effective for the use prescribed.

B. In accordance with MN Rule 4685.0700, subp. 4 F, and Title 42 Code of Federal Regulations (CFR) 422.101(b)(6), if coverage criteria of a new technology is not fully established by the State or applicable Medicare statutes, regulations, NCDs, and LCDs, PrimeWest Health makes the determination of whether a new technology is experimental, investigative, or unproven based on a preponderance of the evidence after the examination of reliable evidence such as the following, none of which shall be determinative in and of itself:
   1. Review of documented approval from an appropriate government regulatory agency such as the FDA or Centers for Medicare & Medicaid Services (CMS), if approval is required.
   2. Review of consensus opinions and recommendations reported in relevant scientific and medical literature, peer-reviewed journals, or the reports of clinical trial committees and other technology assessment bodies.
   3. Review of published guidelines or consensus opinions from national and local health care providers and applicable specialty or subspecialty societies that typically manage the condition that the drug, device, medical treatment, diagnostic procedure, technology, or other procedure at issue is designed to treat. The Chief Senior Medical Director, Assistant Chief Senior Medical Director, or Assistant Medical Director identifies the applicable specialty or subspecialty, and the Chief Senior Medical Director seeks written or verbal input from a selected specialty or subspecialty provider within the network or from outside of the network and considers the opinion when making the final determination.
   4. Large, randomized controlled trials or prospective cohort studies with clear results published in a peer-reviewed journal and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.

   For purposes of this procedure, "preponderance of the evidence" means that based on consideration of the evidence described above, PrimeWest Health's Chief Senior Medical Director, PrimeWest Health's Dental Medical Director, and/or PrimeWest Health's Behavioral Medical Director determines it is more likely than not that the new technology is or is not experimental, investigative, or unproven.

C. Should PrimeWest Health determine that medical treatments, dental treatments, behavioral health practices, diagnostic procedures, technologies, medical devices, or procedures are experimental, investigative, or unproven, it will determine whether or not the treatment, practice, procedure, technology, or device will be covered on a case-by-case basis based on medical necessity.

D. PrimeWest Health implements a coverage decision based on its assessment of the new treatments, practices, procedures, technologies, or devices based on new applications of existing treatments, practices, procedures, technologies, or devices, or based on review of special cases. If there is a specific request from a member, the decision to approve or deny coverage for the individual member is made in accordance with PrimeWest Health Policy and Procedure CC06: Service Authorization after following the steps previously outlined in this procedure.

E. Adding coverage of new treatments, practices, procedures, technologies, or devices or new applications of existing treatments, practices, procedures, technologies, or devices as a benefit for a group of members or for all members must be approved by the P&T Committee (acting as PrimeWest Health's Utilization Management Committee), the Quality and Care Coordination Committee (QCCC), and the Joint Powers Board (JPB). PrimeWest Health presents information that has been gathered to the P&T Committee and QCCC for input and to the JPB for final approval if the treatments, practices, procedures, technologies, or devices at issue are deemed beneficial to PrimeWest Health members, as required by PrimeWest Health Policy and Procedure CC06: Service Authorization. This information may be used to make organizational policy determinations and/or case-based decisions on whether to cover a specifically requested new treatment, practice, procedure, technology, or device as a covered benefit. Case-based decisions include review of medical necessity guidelines and procedures for possible revision. If a treatment, practice, procedure, technology, or device is determined to not be experimental, it is added as an approved new treatment, practice, procedure, technology, or device. Subsequent requests for this treatment, practice, procedure, technology, or device require individual review, but the treatment, practice, procedure, technology, or device does not need to be re-evaluated. The time frame for decision making to add new treatments, practices, procedures, technologies, or devices and/or applications of existing treatments, practices, procedures, technologies, or devices as a benefit for a group of members or all members is six months to a year, unless an earlier time frame is required per PrimeWest Health Policy and Procedure CC06: Service Authorization.

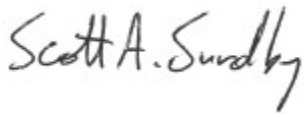
F. QCCC need not be informed of each individual determination that a new treatment, practice, procedure, technology, or device is deemed experimental or investigational for a particular member.

G. Pharmaceutical Additions to Formulary
   a. The P&T Committee reviews new drugs for formulary inclusion following State and Federal time frames. The P&T Committee's policy and criteria for approval are reviewed annually during a desk audit of MedImpact (see MedImpact Policy 460-PD-1003). Any drug coverage request made prior to P&T Committee review of the drug for inclusion in the formulary is evaluated through the formulary exception pharmacy determination process, as described in PrimeWest Health Policy and Procedure PM04: Pharmacy Determinations.

Violation of this Policy or Procedure

No or only partial adherence to this policy or procedure may result in noncompliance with current regulatory requirements and subsequent penalties to PrimeWest Health. Remediation for violators includes, but is not limited to, disciplinary action up to and including termination depending on the circumstances of the situation at the time.

Signatures



Medical Director Approval: **Date:** 03/05/2026

Scott Sundby, MD
Chief Senior Medical Director

Board Approval: **Date:** 03/05/2026

Gary Hendrickx, Chair
PrimeWest Health Joint Powers Board of Directors