Gray text indicates quoted regulatory, statutory, or other language not subject to change

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<td>Origination Date</td>
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<tr>
<td>Revision Effective Date</td>
<td>May 6, 2021</td>
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<td>Responsible Position</td>
<td>Utilization Management Manager</td>
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<td>Regulatory Requirement(s)</td>
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**Policy**

Pursuant to the above regulatory authorities and accreditation requirements, PrimeWest Health will follow 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 Minn. Rules part 4685.0100, Subp.6a and 4685.0700, Subp.4 F. 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, but may do so at its own discretion.

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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

PrimeWest Health
All new pharmaceuticals will be reviewed by PrimeWest Health’s contracted pharmacy benefit manager (PBM), MedImpact. MedImpact’s Pharmacy & Therapeutics (P&T) Committee will review new pharmaceuticals within 120 days of United States Food and Drug Administration (FDA) approval for possible inclusion into 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. The P&T Committee will base 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.

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.
UM11 Technologies – New and Existing

Procedure

A. In respect to medical treatments, dental treatments, behavioral health practices, medications, diagnostic procedures, technologies, medical devices, or procedures, PrimeWest Health will follow the following procedure.
   1. All such medical treatment, diagnostic procedures, medical devices, procedures, medications, or technologies are decided by the PrimeWest Health Chief Senior Medical Director as outlined in this policy.
   2. All areas of dental treatment are addressed by the PrimeWest Health Dental Director as outlined in this policy.
   3. All areas of behavioral health treatment are addressed by the PrimeWest Health Psychiatric Medical Director as outlined in this policy.
   4. Upon a final State decision for coverage based on the State’s assessment of new technologies and new applications of existing technologies, PrimeWest Health will follow Minnesota Department of Human Services (DHS) guidance. Sources of DHS criteria used include the following:
      a. Criteria developed by Blue Cross Blue Shield (BCBS) of Minnesota and administered on behalf of the State through DHS’s Medical Review Agent. These criteria can be accessed via the Internet at www.bluecrossmnonline.com/pmpint/?context=BCBSMN&content=MEDICALPOLICY&migrated=Y&region=ALL&user=PUBLIC&_ga=1.173597603.1227369425.1442581649.

B. In accordance with Minn. Rule. 4685.0700, subp. 4 F, if there is no final State decision for coverage of a new technology, PrimeWest Health’s Chief Senior Medical Director will make 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 Food and Drug Association (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 local health care providers and applicable specialty or subspecialty societies that typically would employ or apply the technology at issue. The Chief Senior Medical Director will identify the applicable specialty that typically provides the medical care or uses the medical device in question. The Chief Senior Medical Director seeks written or verbal input from the selected specialty within the network or from outside of the network and considers the opinion in making the final determination.

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 determines it is more likely than not that the new technology is, or is not, experimental, investigative, or unproven.

C. Should PrimeWest Health determine a treatment or other technology to be experimental, investigative, or unproven, it will determine whether or not the treatment 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 treatment/technology and new applications of existing treatments/technology or from 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 by the Chief Senior Medical Director after following the steps previously outlined in this procedure. The PrimeWest Health Utilization Committee reviews and discusses aspects of new technology such as the following: new procedures, drug devices, or behavioral treatments presented to the group for additional discussion and input. The approval or denial of the service request does not need Quality and Care Coordination Committee (QCCC) or Joint Powers Board (JPB)
approval. The PrimeWest Health Chief Senior Medical Director makes the decision to approve or deny all requests based on individual member medical necessity. Decisions concerning dental and behavioral health take into account recommendations from the Dental Director and/or Psychiatric Medical Director. The final decision to approve or deny is made by the Chief Senior Medical Director according to one of the following time frames:

1. Requests for covered outpatient drugs are evaluated in time to comply with Title 42 United States Code (USC) Section 1396r-8 (d)(5), including providing a response to a prior authorization request within 24 hours of the request and authorizing a 72 hours supply of a covered prescription drug in emergency situations for Medicaid, within 72 hours for Medicare Part B standard requests, and within 24 hours for Medicare Part B expedited requests.
2. Within 10 business days of receiving a pre-service request or 72 hours for an expedited request.
3. Within 72 hours for urgent concurrent review request or 10 business days for non-urgent concurrent review requests.
4. Within 30 days for retro-service requests. If the Service Authorization request is marked urgent, the decision to treat it as an urgent request is made by the Chief Senior Medical Director. The decision will be made within 72 hours.
5. If additional time is needed to obtain all input and complete research, an extension of time can be requested by PrimeWest Health of up to a maximum of 14 days. This extension needs to be approved by the requestor. (See PrimeWest Health Policy and Procedure CC06: Service Authorization).

E. The addition of new technology/treatment or new applications of existing technology/treatment as a benefit for a group of members or for all members must be approved by QCCC and JPB, which is the next step of the process. PrimeWest Health presents information that has been gathered to QCCC for input and final approval from JPB if the technology at issue is deemed beneficial to PrimeWest Health members. This information may be used to make organizational policy determinations and/or case-based decisions on whether to cover a specifically requested new technology or a specifically requested service as a covered benefit. There must be evidence that case-based decisions result in a review of medical necessity guidelines and procedures for possible revision. If a technology is determined to not be experimental, it will be added as an approved new technology. Subsequent requests for this technology would require individual review, but the technology would not need to be re-evaluated. The time frame for decision making to add new technology/treatment and/or applications of existing technology/treatment as a benefit for a group of members or all members is six months to a year.

F. QCCC will not be informed of each individual determination that a new technology is deemed experimental or investigational. QCCC will receive summary information.

G. Pharmaceutical additions to formulary
   a. The Pharmacy & Therapeutics (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 the desk audit of MedImpact (see Policy and Procedure MedImpact Policy 460-PD-1003). Any drug coverage request made prior to P&T Committee review of the drug for inclusion into the formulary is evaluated through the formulary exception pharmacy determination process, as described in PrimeWest Health Policy and Procedure UM02: 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:  
Susan Paulson, MD  
Chief Senior Medical Director  
Date: 05/06/2021

Board Approval:  
Brent Olson, Chair  
PrimeWest Health Joint Powers Board of Directors  
Date: 05/06/2021