Introduction

To determine if a new technology may be covered, teams of doctors, pharmacists, and nurses review new drugs and medical services. The Medical Policy Committee reviews new technology and other medical or surgery services. The Pharmacy and Therapeutics Committee reviews new drugs and some therapies. These committees decide if a new drug or service will be covered. Their decisions are based on sound studies. Their decisions help protect against the use of treatments that are not proven or not safe. This policy describes how new technologies are reviewed and the resources used to determine coverage criteria.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

The Medical Policy Committee (MPC) members and Medical Directors evaluate new technology, including medical and behavioral health procedures, pharmaceuticals, and devices, to determine
whether the service(s) meet contractually defined coverage criteria. Behavioral Health, Dental, and Pharmacy Professionals are included in the Medical Policy Committee membership.

<table>
<thead>
<tr>
<th>Review</th>
<th>Resources</th>
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| Technology reviews occur in the context of Medical Policy Committee or in determinations when an individual member or provider requests coverage of:  
  • A new technology  
  • A change to an existing technology | The technology review process may include, but is not limited to, the following resources:  
  • Agency for Healthcare Research and Quality (AHRQ)  
  • BCBSA Technology Evaluation Center (TEC) Assessments and other national sources of technology assessments such as:  
    • Clinical trial data  
    • Company Medical Policy Manual  
    • Consultation with local physicians with expertise in the relevant field or specialty, including behavioral health and chemical dependency.  
    • Applicable medical scientific data or information found by an Internet search, including manufacturer’s website if available.  
    • Hayes, Inc. Knowledge Center and Technology Assessment Services (©1996-2017 Winifred S. Hayes, Inc.)  
    • Independent external advisory group or medical specialty association recommendations  
    • Institute for Clinical Systems Improvement (ICSI)  
    • MEDLINE or other scientific literature databases, with an emphasis on credible scientific evidence in peer-reviewed medical literature generally recognized by the relevant medical community.  
    • National physician specialty society guidelines and recommendations  
    • Regulatory rulings and publications, (eg, FDA status and State specific office of insurance commissioner (OIC) regulations)  
    • Up-To-Date® (Wolters Kluwer Health, ©2017, UpToDate, Inc.) |

**Coding**

N/A
Related Information

Description

The Company regularly evaluates new and developing medical, behavioral health, dental, and pharmacy applications of technologies, drugs, and services to determine if published scientific evidence supports the safety, efficacy and appropriate use of the proposed services. Using the general principles of research methodology as a consistent approach to evaluating new technologies promotes adherence to the standards of the National Committee for Quality Assurance (NCQA), a private, not-for-profit agency that maintains accreditation standards for health plans.

The Medical Policy Committee and Medical Directors use the five BCBSA TEC criteria listed below to assess new and evolving technology:

1. The technology must have final approval from the appropriate governmental regulatory bodies.
   - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology.
   - 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.
   - The indications for which the technology is approved need not be the same as those which Blue Cross and Blue Shield Association’s Technology Evaluation Center is evaluating.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   - 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 evaluating the evidence.
o 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.

o 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.

3. The technology must improve the net health outcome.

   o The technology’s beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

4. The technology must be as beneficial as any established alternatives.

   o The technology should improve the net health outcome as much as, or more than, established alternatives.

5. The improvement must be attainable outside the investigational settings.

   o When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy TEC criteria in numbers 3 and 4 above.

The above criteria are listed in the majority of member contracts as the threshold to define services that are investigational. A given technology, drug or service must meet all of the criteria listed above. Failure of a technology, drug or service to meet any one of the criteria results in a designation of that service as investigational (or experimental and investigational) and therefore excluded by the member’s contract.

Note: A small number of member contracts may contain differing definitions of investigational or medically necessary services. The member benefit booklet should be consulted for the definition of investigational and/or medically necessary for that group.

Evidence Review

N/A
## References

N/A

## History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>03/12/96</td>
<td>Add to Managed Care Policy Manual - Initial documentation of process</td>
</tr>
<tr>
<td>10/06/98</td>
<td>Revise and Update - Transfer to Premera Medical Policy Manual Introduction Section</td>
</tr>
<tr>
<td>10/05/99</td>
<td>Add to Administrative Section - Formatted as a Policy and removed from Introduction Section of Manual</td>
</tr>
<tr>
<td>07/10/01</td>
<td>Replace Policy - Scheduled review; revised for clarity.</td>
</tr>
<tr>
<td>12/10/02</td>
<td>Replace Policy - Policy reviewed; no criteria changes.</td>
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<tr>
<td>12/09/03</td>
<td>Replace Policy - Scheduled review; no criteria changes.</td>
</tr>
<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.10.01.104. No date changes.</td>
</tr>
<tr>
<td>12/14/04</td>
<td>Replace Policy - Scheduled review; no criteria changes.</td>
</tr>
<tr>
<td>11/11/05</td>
<td>Replace Policy - Scheduled review; no criteria changes.</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Scope and Disclaimer language update only. No other changes.</td>
</tr>
<tr>
<td>12/12/06</td>
<td>Replace Policy - Scheduled review, revised for clarity. No change to the policy statement.</td>
</tr>
<tr>
<td>07/10/07</td>
<td>Replace Policy - Policy updated with BCBSA TEC criteria added to Description section and inclusion of information on Physician Specialty Society review board.</td>
</tr>
<tr>
<td>06/10/08</td>
<td>Replace Policy - Scheduled review; no criteria changes.</td>
</tr>
<tr>
<td>12/16/08</td>
<td>Replace Policy - Policy updated to include BCBSA and Premera policies to description section.</td>
</tr>
<tr>
<td>11/10/09</td>
<td>Replace Policy - Scheduled review; no criteria changes.</td>
</tr>
<tr>
<td>12/14/10</td>
<td>Replace Policy - Scheduled review; no criteria changes.</td>
</tr>
<tr>
<td>12/13/11</td>
<td>Replace Policy – Scheduled review. Policy updated with language to include behavioral health procedures, pharmaceuticals and devices, to address whether the services meet contractually defined coverage criteria.</td>
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<tr>
<td>09/11/12</td>
<td>Replace policy. Scheduled review; no criteria changes.</td>
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<tr>
<td>07/08/13</td>
<td>Replace policy. MCG™ and Up-To-Date® added as resources. Guideline description of review process reformatted. Clarification added regarding differing member contract definitions of investigational service.</td>
</tr>
<tr>
<td>06/13/14</td>
<td>Annual Review. Added the full name for the acronym &quot;ICSI&quot; to Policy Guidelines. Moved resources from Description to Policy Guidelines. Reformatted list of resources in Policy Guidelines to alphabetical order. Expanded Description section to include NCQA reference as a health plan accreditation provider.</td>
</tr>
<tr>
<td>09/08/14</td>
<td>Interim review. Notation added within Policy section to indicate that MPC membership includes Behavioral Health Professionals; Policy Guidelines updated in support of this change.</td>
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<tr>
<td>12/22/14</td>
<td>Interim update. MCG™ removed from the list of possible technology sources used in policy development.</td>
</tr>
<tr>
<td>07/14/15</td>
<td>Annual Review. Added dental and pharmacy professionals as members of the Medical Policy Committee (MPC) to the Policy section. Added the full name for the acronym &quot;BCBSA&quot;. Minor edits for readability. Policy section revised as noted.</td>
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<tr>
<td>02/09/16</td>
<td>Annual Review. No changes.</td>
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<tr>
<td>02/01/17</td>
<td>Annual Review, approved January 10, 2017. Policy moved into the new format. Current copyright dates now reflected; no other changes.</td>
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**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy applies to all Company lines of business except Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-537-7697 (TDD)
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

Civil Rights Coordinator - Complaints and Appeals
200 Independence Avenue SW, Room 509F, HHH Building
U.S. Department of Health and Human Services
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action.

Call 800-722-1471 (TTY: 800-842-5357).

오로모오 (Oromo):
Premera Blue Cross gaanaa daytooy nagaa tseet koj daita nthaw koj hauv. Tej zaum daytooy nga kouvèti ase daytooy nga nthaw koj hauv. Tej zaum daytooy nga nthaw koj hauv daim nthaw koj hauv daim nthaw koj hauv. Tej zaum daytooy nga kouvèti ase daytooy nga nthaw koj hauv. Tej zaum daytooy nga kouvèti ase daytooy nga nthaw koj hauv. Tej zaum daytooy nga kouvèti ase daytooy nga nthaw koj hauv.

Francais (French):
Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyol ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan ladann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lан oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. O uns ou pa gen pou pran kék aksyon avan sûten dat limit pou ka kante kouvèti asiransante w l’a oswa pou yo ka ede w avèk depans yo. Se dwa w ou pola enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaar kat naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalini nga adda kat naglaon iti napateg nga impormasion maipanggpe iti aplikasyonwo yeno coverage babaen iti Premera Blue Cross. Daytoy kel mabalini dagiti importante a pelsa ita daytoy a pakdaar. Mabalini nga adda rumbeng nga aramideng nga adda sakyb dagiti partikular a nauluting nga adda aldaw tapno mapagtalaineyo a progres tangan saulo-sawo yeno coverage nga tulag yendo catalyst gastos. Adda karbengano a mangala ita daytoy nga impormasion ken tulag yendo bukodayo a pagasasad nga awan ti bayadayo. Tumawag ki numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero essere necessari un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiama 800-722-1471 (TTY: 800-842-5357).
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

ไทย (Thai):
ประกาศนี้มีข้อความสำคัญที่เกี่ยวกับการขอรับชดเชยสุทธิหรือการขยายผลการสำเร็จของสิทธิประโยชน์ของ Premera Blue Cross และสิทธิ์ในการรับบริการในกรณีที่คุณต้องการดูแลตนเองในสถานการณ์ที่เป็นจำเป็นเพื่อให้สามารถขอรับชดเชยสุทธิหรือการขยายผลการสำเร็จของสิทธิประโยชน์ได้ โปรดติดต่อ Premera Blue Cross ที่ 800-722-1471 (TTY: 800-842-5357).