Medical Necessity Criteria for Compounded Medications

Effective Date: Jan. 1, 2020
Last Revised: Dec. 10, 2019
Replaces: N/A

RELATED GUIDELINES / POLICIES:
5.01.529 Management of Opioid Therapy
5.01.549 Off-Label Use of Drugs and Biologic Agents

Introduction

A compounded medication is a specially mixed prescription drug. A licensed pharmacist makes this kind of medication if a person needs a custom dose or a different way of taking the medication. Compounded drugs can combine two or more drugs. Compounded drugs are sometimes used when other drugs are not available due to drug shortages. They can also be used if a person needs a drug in a dose or form that a drug company doesn't make. For example, if a person is unable to swallow a pill, a liquid form of the drug may be compounded. Another example would be when a person is allergic to a dye in a medication, a compounded medication can be made without that dye. It’s important to note that compounded drugs are not evaluated for safety or effectiveness and are not approved by the Food and Drug Administration. This policy describes when a compounded drug may be considered medically necessary. This policy is not intended to apply to infused admixtures.

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.
<table>
<thead>
<tr>
<th>Medication</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| **Compounded medications** | **Compounded medications may be considered medically necessary when ALL of the following criteria are met:**  
  • The primary active ingredient in the compounded medication must be a legend medication  
  **AND**  
  • The active ingredients must be in therapeutic amounts, based on FDA indication or adequate medical and scientific evidence  
  **AND**  
  • The safety and effectiveness of the compounded medication and its route of administration (including delivery system) is supported by FDA indication or adequate medical and scientific evidence (Such documentation is the responsibility of the prescriber to provide.)  
  **AND**  
  • If a compounded medication is similar to a commercially available product, but differs from the commercially available products in dosage, dosage form, and/or omission of a sweetener, dye, flavoring or preservative, clinical documentation is required from the prescriber supporting the need for the compound  
  **AND**  
  • If any active ingredient in the compound otherwise requires prior authorization, the member must meet criteria established for medical necessity for that ingredient |

<table>
<thead>
<tr>
<th>Medication</th>
<th>Coverage Not Provided</th>
</tr>
</thead>
</table>
| **Compounded medications** | **Coverage for compounded medications will not be provided under the following circumstances:**  
  • Any compound that does not contain a legend drug otherwise covered by the plan  
  **OR**  
  • Compounds used for cosmetic, performance enhancing or experimental/investigational purposes  
  **OR**  
  • Compounds using legend ingredients for non-FDA approved indications or uses that are not compliant with the policy for |
<table>
<thead>
<tr>
<th>Medication</th>
<th>Coverage Not Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>off-label use of drugs and biologic agents (see Related Guidelines/Policies)</td>
</tr>
<tr>
<td>OR</td>
<td>• Compounded formulations that use drugs withdrawn or removed from the market for safety reasons</td>
</tr>
<tr>
<td>OR</td>
<td>• Compounded formulations that use an unproven route of administration to deliver a drug product</td>
</tr>
<tr>
<td>OR</td>
<td>• Prescription ingredients compounded for purposes of convenience only</td>
</tr>
<tr>
<td></td>
<td>▪ Exceptions include:</td>
</tr>
<tr>
<td></td>
<td>▪ Formulation for those members who have difficulty or inability to swallow standard oral dosage forms who require the use oral liquid or non-oral routes of administration. Examples include, but not limited to, patients requiring the use of nasogastric tubes or children who require prescription medication for which no liquid formulation is commercially available</td>
</tr>
<tr>
<td></td>
<td>▪ Formulations for those who have documented allergies or sensitivities to one or more of the following: dyes, preservatives, excipients or other inactive ingredients found in commercial preparations</td>
</tr>
<tr>
<td>Medication</td>
<td>Investigational</td>
</tr>
<tr>
<td><strong>Compounded implantable hormone replacement pellets</strong></td>
<td><strong>Compounded implantable hormone replacement pellets or granules (such as estrogen-based implantable pellets) are considered investigational:</strong></td>
</tr>
<tr>
<td></td>
<td>• Rationale: The FDA’s Fertility and Maternal Health Drugs Advisory Committee unanimously agreed to terminate compassionate investigative new drug (IND) programs for estrogen pellets as a last-resort treatment of menopausal disorder.</td>
</tr>
<tr>
<td></td>
<td>• The Committee noted “the risk of bleeding and infection, the lack of information on release rates, difficulty in reversibility of the drug, increased feasibility of over-dosage of the drug, and</td>
</tr>
</tbody>
</table>
Medication | Investigational
--- | ---
 | increased risk of non-compliance with safety measures [such as] the addition of progestin.”

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>J7999</td>
<td>Compounded drug, not otherwise classified</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**

**Benefit Application**

This guideline applies to all pharmacy benefit contracts that include Point of Sale/Prior Authorization Edits.

This guideline applies to all medical benefit contracts.

**Background**

Pharmacy compounding is the practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient. Pharmacy compounding, if done properly, can serve an important public health need if a patient cannot be treated with an FDA-approved medication. The end product of the compounding practice is referred to as a compounded medication or compounded formulation.

Compounded medications may replace those that are temporarily unavailable due to drug shortages, or those that are not commercially available in terms of dosage forms or combinations of medications. These forms may serve a useful function for patients who are
unable to swallow standard oral dosage forms and may require liquid forms to continue their therapy.

Unlike FDA-approved medications, compounded medications are not clinically evaluated for safety or efficacy. Compounding pharmacies are not subject to statutes governing good manufacturing practices. They are may be required to comply with United States Pharmacopeia Chapters 795 and 797 which specifies conditions for safe compounding practices for non-sterile and sterile compounded medications. The FDA generally defers to state boards of pharmacy to enforce these guidelines.

Coverage is subject to the coverage limitations and exclusions of the member’s contract. Medical necessity of covered medications is governed by approved FDA indications as well as related guidelines and policies (see Related Guidelines / Policies).

2018 Update

Annual review – no changes required.

2019 Update

Reviewed Food and Drug Administration information on Human Drug Compounding and no changes were made to medical necessity criteria. Updated references.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/09/12</td>
<td>New policy added to Prescription Drug section. Policy approved with 90-day provide notification hold. The policy is effective February 11, 2013.</td>
</tr>
<tr>
<td>01/22/13</td>
<td>Policy effective date delayed and is now April 1, 2013.</td>
</tr>
<tr>
<td>03/11/13</td>
<td>Replace policy. Policy updated within the Policy Guidelines, clarifying criteria added, removed and rearranged; Description section removed; Rationale section significantly updated; references added, removed, renumbered and updated. Policy effective date remains 4/1/13.</td>
</tr>
<tr>
<td>07/08/13</td>
<td>Minor Update – Clarification was added to the policy that it is managed through the member’s pharmacy benefit; this is now listed in the header and within the coding section.</td>
</tr>
<tr>
<td>11/10/14</td>
<td>Annual review. Covered to Benefit Coverage Guideline template. Coverage information added to address hormone pellets; considered investigational. Notation in header section removed indicating coverage is managed by the pharmacy benefit.</td>
</tr>
<tr>
<td>10/13/15</td>
<td>Annual Review. Policy reviewed; no change in policy statements.</td>
</tr>
<tr>
<td>01/19/16</td>
<td>Coding update. New CPT code J7999, effective 1/1/16, added to policy.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Annual Review, approved December 13, 2016. Policy reviewed; no change in policy statements.</td>
</tr>
<tr>
<td>09/01/17</td>
<td>Annual Review, approved August 22, 2017. No changes to policy statements. Statement added to intro “This policy is not intended to apply to infused admixtures.”</td>
</tr>
<tr>
<td>11/01/18</td>
<td>Annual Review, approved October 26, 2018. No changes to policy statements.</td>
</tr>
<tr>
<td>01/01/20</td>
<td>Annual Review, approved December 10, 2019. No changes to policy statements.</td>
</tr>
</tbody>
</table>

**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). ©2020 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 does not apply to 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 with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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)

Writing a Complaint

You can also file a complaint with the Washington State Human Rights Commission at 1750 5th Ave., Suite 650, Seattle, WA 98101, 1-800-537-3900, TTY 800-632-6793, or through their website at www.wschr.org.

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 by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

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

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保單的重要訊息。本通知可能有重要日期，您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):


Français (French):


Hmoob (Hmong):


Italiano (Italian):

Japanese (Japanese):
この通じに重要な情報が含まれています。この通じに、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれている場合があります。

한국어 (Korean):
본 통지는 중요한 정보가 들어 있습니다. 즉 이 통지는 귀하의 신청에
관하여 Premera Blue Cross를 통한 커버리지를 위한 정보를 포함하고 있을 수 있습니다. 귀하의 신청은 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다.

Román (Romanian):

Russian (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении о страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами.

Español (Spanish):
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 clave en este aviso.

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maging nagagalagan ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaring may mga mahalagang petsa dito sa paunawa.

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญเกี่ยวกับการ declarations importantes de Premera Blue Cross และสามารถใช้ในการติดต่อกับ Premera Blue Cross ที่มีข้อมูลเกี่ยวกับสิทธิ์ของคุณอยู่ในประกาศนี้.

Polskie (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso.

Tiếng Việt (Vietnamese):

Farsi (Persian):
این اعلامیه جزء اطلاعات مهمی است که افراد می‌توانند از آن استفاده کنند. با رایگاness و رایگان به این اطلاعات می‌توانید به مدت طولانی بهره‌مندی کنید. به‌طور کلی این اطلاعات جزء اطلاعات مهمی هستند که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاعات مهمی است که شما می‌توانید به آنها در ارتباط با مشکلات بهره‌مندی‌های متقابل بنظیری محیط تهیه کنید. این یکی از اطلاу