Introduction

Some tumors form within the brain and spinal cord, which are both part of the central nervous system (CNS). Treatment for these tumors may include surgery, chemotherapy, and radiation. High dose chemotherapy may damage the person’s bone marrow, which is important in making different types of blood cells. In order to restore bone marrow function, a hematopoietic stem cell transplant may be done.

Hematopoietic stem cells are cells that form within the bone marrow and can become many different types of blood cells. In a hematopoietic stem cell transplant, stem cells can be taken from a donor’s bone marrow, peripheral blood, or from a newborn baby’s umbilical cord blood or placenta shortly after the baby was delivered. The stem cells can also be harvested from the patient himself before he is given any high dose chemotherapy. In all of these cases, the harvested stem cells are then given to the patient, just like in a transfusion. It is hoped that these new stem cells will then settle into the bone marrow and start producing normal blood cells.

If the hematopoietic stem cells are harvested from another person, it is called an allogeneic transplant. If the cells come from the patient himself before his high dose chemotherapy is given, it is called an autologous stem cell transplant. This policy discusses when different types of hematopoietic stem cell transplants might be medically necessary to treat CNS tumors.
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

<table>
<thead>
<tr>
<th>Transplant</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autologous hematopoietic cell transplantation</td>
<td>Autologous hematopoietic cell transplantation may be considered medically necessary as consolidation therapy for previously untreated embryonal tumors of the central nervous system (CNS) that show partial or complete response to induction chemotherapy, or stable disease after induction therapy (see Additional Information below).</td>
</tr>
</tbody>
</table>

Autologous hematopoietic cell transplantation may be considered medically necessary to treat recurrent embryonal tumors of the CNS.

<table>
<thead>
<tr>
<th>Transplant</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tandem autologous hematopoietic cell transplantation</td>
<td>Tandem autologous hematopoietic cell transplant is investigational to treat embryonal tumors of the CNS.</td>
</tr>
<tr>
<td>Allogeneic hematopoietic cell transplantation</td>
<td>Allogeneic hematopoietic cell transplantation is investigational to treat embryonal tumors of the CNS.</td>
</tr>
<tr>
<td>Autologous, tandem autologous, and allogeneic hematopoietic cell transplant</td>
<td>Autologous, tandem autologous, and allogeneic hematopoietic cell transplant is investigational to treat ependymoma.</td>
</tr>
</tbody>
</table>

### Additional Information

In general, use of autologous hematopoietic cell transplantation for previously untreated medulloblastoma has shown no survival benefit for those patients considered to be at average risk (ie, patients older than 3 years of age, without metastatic disease, and with
Additional Information

Total or near total surgical resection (<1.5 cm² residual tumor) when compared with conventional therapies.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT 38232</td>
<td>Bone marrow harvesting for transplantation; autologous</td>
</tr>
<tr>
<td>CPT 38240</td>
<td>Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor</td>
</tr>
<tr>
<td>CPT 38241</td>
<td>Hematopoietic progenitor cell (HPC); autologous transplantation</td>
</tr>
<tr>
<td>HCPCS S2150</td>
<td>Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre and post transplant care in the global definition</td>
</tr>
</tbody>
</table>

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Related Information

Other CNS tumors include astrocytoma, oligodendroglioma, and glioblastoma multiforme. However, these tumors arise from glial cells and not neuroepithelial cells. These tumors are considered in a separate policy. (See Related Policies)

Due to their neuroepithelial origin, peripheral neuroblastoma and Ewing sarcoma may be considered PNETs. However, these peripheral tumors are considered in a separate policy. (See Related Policies)
Benefit Application

The following considerations may supersede this policy:

- State mandates requiring coverage for autologous hematopoietic bone marrow transplantation offered as part of clinical trials of autologous bone marrow transplantation approved by the National Institutes of Health (NIH).

- Some plans may participate in voluntary programs offering coverage for patients participating in NIH-approved clinical trials of cancer chemotherapies, including autologous hematopoietic bone marrow transplantation.

- Some contracts or certificates of coverage may include specific conditions in which autologous hematopoietic bone marrow transplantation would be considered eligible for coverage.

Evidence Review

Description

High-dose chemotherapy (HDC) with hematopoietic cell transplantation (HCT) has been investigated as a possible therapy in pediatric patients with brain tumors, particularly in patients with disease that is considered high risk. In addition, the use of HCT has allowed for a reduction in the dose of radiation needed to treat both average and high-risk disease, with preservation of quality of life and intellectual functioning, without compromising survival.

Background

Hematopoietic cell transplantation (HCT) refers to a procedure in which hematopoietic cells are infused to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of cytotoxic drugs. Bone-marrow stem cells may be obtained from the transplant recipient (ie, autologous HCT) or from a donor (ie, allogeneic HCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood and placenta shortly after delivery of neonates.
**HCT for Brain Tumors**

Autologous HCT allows for escalation of chemotherapy doses above those limited by myeloablation and has been tried in patients with high-risk brain tumors in an attempt to eradicate residual tumor cells and improve cure rates. The use of allogeneic HCT for solid tumors does not rely on escalation of chemotherapy intensity and tumor reduction but rather on a graft-versus-tumor effect. Allogeneic HCT is not commonly used in solid tumors and may be used if an autologous source cannot be cleared of tumor or cannot be harvested.

**CNS Embryonal Tumors**

Classification of brain tumors is based on both histopathologic characteristics of the tumor and location in the brain. CNS embryonal tumors are more common in children and are the most common brain tumor in childhood. CNS embryonal tumors are primarily composed of undifferentiated round cells, with divergent patterns of differentiation. It has been proposed that these tumors be merged under the term primitive neuroectodermal tumor (PNET); however, histologically similar tumors in different locations in the brain demonstrate different molecular genetic alterations. Embryonal tumors of the CNS include medulloblastoma, medulloepithelioma, cerebral neuroblastoma, ganglioneuroblastoma, embryonal tumors with multilayered rosettes (ETMR), and atypical teratoid/rhabdoid tumor (AT/RT).

Medulloblastomas account for 20% of all childhood CNS tumors. The other types of embryonal tumors are rare by comparison. Surgical resection is the mainstay of therapy with the goal being gross total resection with adjuvant radiotherapy, as medulloblastomas are very radiosensitive. Treatment protocols are based on risk stratification as average or high risk. The average-risk group includes children older than 3 years, without metastatic disease, and with tumors that are totally or near totally resected (<1.5 cm² of residual disease). The high-risk group includes children aged 3 years or younger, or with metastatic disease, and/or subtotal resection (>1.5 cm² of residual disease).¹

The current standard treatment regimen for average-risk medulloblastoma is postoperative craniospinal irradiation with boost to the posterior fossa followed by 12 months of chemotherapy. This treatment has resulted in 5-year overall survival (OS) rates of 80% or better.¹ For high-risk medulloblastoma treated with conventional doses of chemotherapy and radiotherapy, the average event-free survival (EFS) at 5 years ranges from 34% to 40% across studies.² Fewer than 55% of children with high-risk disease survive longer than 5 years. The treatment of newly diagnosed medulloblastoma continues to evolve. In children younger than 3 years of age, therapeutic approaches have attempted to delay and sometimes avoid the use of
radiation because of the concern of the deleterious effects of craniospinal radiation on the immature nervous system. Instead, treatment has included trials of higher-dose chemotherapeutic regimens with autologous HCT.

sPNETs (supratentorial primitive neuroectodermal tumors) are most commonly located in the cerebral cortex and pineal region. The prognosis for these tumors is worse than for medulloblastoma, despite identical therapies. After surgery, children with a sPNET are usually treated similarly to children with a high-risk medulloblastoma. Three- to 5-year OS rates of 40% to 50% have been reported, and for patients with disseminated disease, survival rates at 5 years range from 10% to 30%.

It is not uncommon for childhood CNS embryonal tumors to recur, and depending on which type of treatment the patient initially received, autologous HCT may be an option. For patients who receive HDC and autologous HCT for recurrent embryonal tumors, objective response is 50 to 75%; however, long-term disease control is obtained in fewer than 30% of patients and is primarily seen in patients in first relapse with localized disease at the time of relapse.

**Ependymoma**

Ependymoma is a neuroepithelial tumor that arises from the ependymal lining cells of the ventricles and is, therefore, usually contiguous with the ventricular system. An ependymoma tumor typically arises intracranially in children, while in adults a spinal cord location is more common. Ependymomas have access to the cerebrospinal fluid and may spread throughout the entire neuroaxis. Ependymomas are distinct from ependymoblastomas due to their more mature histologic differentiation. Initial treatment of an ependymoma consists of maximal surgical resection followed by radiotherapy. Chemotherapy usually does not play a role in the initial treatment of an ependymoma. However, disease relapse is common, typically occurring at the site of origin. Treatment of recurrence is problematic, as further surgical resection or radiotherapy is usually not possible. Given the poor response to conventional-dose chemotherapy, HDC with autologous HCT has been investigated as a possible salvage therapy.

**Summary of Evidence**

The evidence for autologous hematopoietic stem cell transplantation (HCT) in individuals who have newly diagnosed central nervous system (CNS) embryonal tumors includes prospective and retrospective single-arm studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. In the case of pediatric CNS embryonal
tumors, an important consideration is whether the use of HCT may allow for a reduction in radiation dose. Data from single-arm studies using high-dose chemotherapy (HDC) with autologous HCT to treat newly diagnosed CNS embryonal tumors have shown comparable or improved survival (both event-free survival and overall survival) compared with historical controls treated with conventional therapy, with or without radiotherapy, particularly in patients with disease that is considered high risk. In a retrospective comparative study, survival in patients receiving HDC with HCT and delayed craniospinal irradiation was comparable to survival in those receiving upfront craniospinal irradiation. Overall, data from these observational studies has suggested HCT may allow reduced doses of craniospinal irradiation without worsening survival outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have recurrent/relapsed CNS embryonal tumors who receive autologous HCT, the evidence includes prospective and retrospective single-arm studies and a systematic review of these studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. For recurrent/relapsed CNS embryonal tumors, survival outcomes after HCT are more variable, and survival is generally very poor for tumors other than medulloblastoma. Data from some single-arm studies using autologous HCT to treat recurrent CNS embryonal tumors have shown comparable or improved survival compared with historical controls treated with conventional therapy for certain patients. The results of a 2012 systematic review of observational studies in patients with relapsed supratentorial primitive neuroectodermal tumors suggest that a subgroup of infants with chemosensitive disease might benefit from autologous HCT, achieving survival without the use of radiotherapy, whereas the outcome in older children and/or in pineal location is poor with this modality. However, a relatively large prospective multicenter study reported that HCT was not associated with improved survival outcomes in patients who had had a good response to therapy. Overall, data from these single-arm studies suggests HCT may be associated with improved survival outcomes, although data for some tumor types is limited (eg, atypical teratoid/rhabdoid tumors). HCT may allow reduced doses of craniospinal irradiation without worsening survival outcomes.

The evidence for tandem autologous HCT in individuals who have CNS embryonal tumors includes prospective and retrospective single-arm studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. Less evidence specifically addresses the use of tandem autologous HCT for CNS embryonal tumors. The available single-arm studies appear to report overall survival and event-free survival rates comparable to single autologous HCT. Tandem transplants may allow reduced doses of craniospinal irradiation, with the goal of avoiding long-term radiation damage. However, most studies used standard-dose irradiation, making the relative benefit of tandem autologous HCT
uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for allogeneic HCT in individuals who have CNS embryonal tumors includes case reports. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. The available evidence is limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for autologous HCT in individuals who have ependymomas includes relatively small case series. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. The available case series do not report higher survival rates for patients with ependymomas treated with HCT than with standard therapies. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td>NCT00653068</td>
<td>Treatment of Atypical Teratoid/Rhabdoid Tumors (AT/RT) of the Central Nervous System With Surgery, Intensive Chemotherapy, and 3-D Conformal Radiation</td>
<td>70</td>
<td>Apr 2015 (ongoing)</td>
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<tr>
<td>NCT00336024</td>
<td>A Phase III Randomized Trial for the Treatment of Newly Diagnosed Supratentorial PNET and High Risk Medulloblastoma in Children &lt; 36 Months Old With Intensive Induction Chemotherapy With Methotrexate Followed by Consolidation With Stem Cell Rescue Versus the Same Therapy Without Methotrexate</td>
<td>96</td>
<td>Dec 2016 (ongoing)</td>
</tr>
<tr>
<td>NCT00085202</td>
<td>Treatment of Patients With Newly Diagnosed Medulloblastoma, Supratentorial Primitive Neuroectodermal Tumor, or Atypical Teratoid Rhabdoid Tumor</td>
<td>416</td>
<td>Sep 2018</td>
</tr>
<tr>
<td>NCT02653196</td>
<td>A Multi-Institutional Phase II Feasibility Study of Allogeneic Hematopoietic Stem Cell Transplantation for Patients With</td>
<td>30</td>
<td>Jul 2019</td>
</tr>
</tbody>
</table>
### Practice Guidelines and Position Statements

**National Comprehensive Cancer Network Practice Guidelines 2014**

Current National Comprehensive Cancer Network guidelines on treating central nervous system (CNS) tumors (v.1.2016) make the following recommendations about hematopoietic cell transplant (HCT)\(^\text{36}\):

- The guidelines do not address the use of autologous HCT in treating ependymomas.
- For medulloblastoma and supratentorial primitive neuroectodermal tumor, autologous HCT for localized recurrent disease with maximum safe resection is a category 2A recommendation.

**U.S. Preventive Services Task Force Recommendations**

Hematopoietic stem-cell transplant is not a preventive service.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
Regulatory Status

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation (CFR) title 21, parts 1270 and 1271. Hematopoietic stem cells are included in these regulations.

References


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### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/01/00</td>
<td>Add to Therapy Section - New Policy — replaces 8.01.15, original master policy on high-dose chemotherapy for miscellaneous malignancies. However, policy statement is unchanged.</td>
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<tr>
<td>12/11/01</td>
<td>Replace Policy - Policy references updated.</td>
</tr>
<tr>
<td>03/11/03</td>
<td>Replace Policy - Policy updated and references added; no change in policy statement.</td>
</tr>
<tr>
<td>10/12/04</td>
<td>Replace Policy - Policy updated with literature review; policy statement unchanged (text updated for clarification only). Approved by OAP 10/29/04, no need to go back to MPC.</td>
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<tr>
<td>01/10/06</td>
<td>Replace Policy - Policy updated with literature review; no change to policy statement. Reviewed by OAP 10/27/05.</td>
</tr>
<tr>
<td>06/02/06</td>
<td>Disclaimer and Scope update - No other changes</td>
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<tr>
<td>11/14/06</td>
<td>Replace Policy - Policy reviewed and recommended by OAP October 26, 2006; no changes to policy statement.</td>
</tr>
<tr>
<td>12/11/07</td>
<td>Replace Policy - Policy updated with literature review. Policy statement added to indicate that multi-cycle high-dose chemotherapy (with or without associated radiotherapy) and autologous stem-cell support (ie, tandem transplants) as investigational. Policy reviewed and recommended by OAP November 15, 2007.</td>
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<tr>
<td>05/13/08</td>
<td>Cross Reference Update - No other changes</td>
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<td>12/16/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy</td>
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<td>01/13/09</td>
<td>Code Updates - Code added, J8705; effective 1/1/09.</td>
</tr>
<tr>
<td>01/12/10</td>
<td>Replace Policy - Policy extensively revised with literature search; policy title changed to remove “high-dose chemotherapy” and to change PNET to embryonal tumors. Policy statement changed regarding autologous consolidation therapy in patients with previously untreated embryonal tumors showing complete or partial response to, or stable disease after, induction therapy; now considered medically necessary. Other policy statements reworded and separated to address ependymoma and embryonal CNS tumors specifically; however, the intent of the statements remains the same. References added.</td>
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<tr>
<td>02/09/10</td>
<td>Code Update - New 2010 codes added.</td>
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<tr>
<td>03/08/11</td>
<td>Replace Policy - Policy updated with literature search through October 2010; references 7, 12-14 added. No change to policy statements.</td>
</tr>
<tr>
<td>05/12/11</td>
<td>Reviewed by OAP - No changes recommended to the policy.</td>
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<tr>
<td>01/06/12</td>
<td>Replace Policy – Policy updated with literature search. No references added; no change in policy statements. ICD-10 codes added.</td>
</tr>
<tr>
<td>01/24/12</td>
<td>Code 38232 added.</td>
</tr>
<tr>
<td>02/10/12</td>
<td>The CPT code 38204 was removed from the policy.</td>
</tr>
<tr>
<td>06/20/12</td>
<td>Minor update: Related Policies updated; 8.01.17 replaced 8.01.507 effective June 12, 2012.</td>
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<tr>
<td>07/30/12</td>
<td>Related Policy title updates to: 8.01.17, 8.01.22, 8.01.31, 8.01.35 and 8.01.520. Deleted 8.01.38 as it was archived.</td>
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<tr>
<td>10/08/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>01/29/13</td>
<td>Replace policy. Policy updated with literature search. References 7, 8, 13 and 18 added; no change in policy statements. Removed CPT codes 38220 and 38221; they do not apply to this policy. Change title to Related Policy 8.01.21.</td>
</tr>
<tr>
<td>03/20/13</td>
<td>The following codes were removed from the policy, as they were not suspending and just informational: HCPCS J9000-J9999 and Q0083 – Q0085.</td>
</tr>
<tr>
<td>09/30/13</td>
<td>Update Related Policies. Change policy title to 8.01.31.</td>
</tr>
<tr>
<td>10/18/13</td>
<td>Update Related Policies. Change title to policy 8.01.17.</td>
</tr>
<tr>
<td>01/21/14</td>
<td>Replace policy. Policy updated with literature search through October 8, 2013. References 13 and 14 added, references 3 and 24 updated; no change in policy statements. Remove CPT code 38230; it does not apply to this policy.</td>
</tr>
<tr>
<td>03/21/14</td>
<td>Update Related Policies. Remove 801.514 as it was deleted.</td>
</tr>
<tr>
<td>04/18/14</td>
<td>Update Related Policies. Remove 8.01.20 and replace with 8.01.529.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>----------</td>
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<tr>
<td>06/24/14</td>
<td>Update Related Policies. Remove 8.01.35, 8.01.42 and 8.01.54, then add 8.01.530, 8.01.531 and 8.01.532.</td>
</tr>
<tr>
<td>12/03/14</td>
<td>Update Related Policies. Remove 8.01.17 and 8.01.26.</td>
</tr>
<tr>
<td>01/28/15</td>
<td>Annual Review. Policy updated with literature review through September 30, 2014. References 5-6, 9, 15, and 17-19 added. Policy statements unchanged. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in policy adjudication.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, approved April 12, 2016. Policy updated with literature review through October 27, 2015; references 4-6 and 9 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>11/04/16</td>
<td>Coding update. Removed codes that are transplant benefit related.</td>
</tr>
<tr>
<td>04/01/17</td>
<td>Annual Review, approved March 14, 2017. Policy updated with literature review through November 7, 2016; references 6, and 22-23 added. Changed “hematopoietic stem cell transplantation” to “hematopoietic cell transplantation” per NCCN terminology change. Policy statements unchanged.</td>
</tr>
<tr>
<td>11/10/17</td>
<td>Policy moved to new format, no changes to policy statement.</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). ©2017 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.
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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

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Français (French):


Kreyòl ayisyen (Creole):

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Deutsche (German):


Hmoob (Hmong):


Ilokano (Ilocano):

Daytoy a Pakdaa ket naglaon iti Napateg nga Impomarn. Daytoy a pakdaa mabalin nga adda ket naglaon iti napateg nga impomarn maipanggep iti aplikasyonowyen no coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelsa iti daytoy a pakdaar. Mabalin nga adda rumbang nga aramidenyo nga addang sakbay dagiti particular a naiutding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-ayowo ti tulog kadayit gastos. Adda karbenganyo a mangala iti daytoy nga impomarn ken tulog iti bukodo a pagasasao nga awan ti bayadanyo. Tumawg iti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
