MEDICAL POLICY – 8.01.24
Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults

BCBSA Ref. Policy: 8.01.24

Effective Date: April 1, 2019
Last Revised: March 5, 2019
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.50 Placental and Umbilical Cord Blood as a Source of Stem Cells
7.01.95 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
7.01.526 Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors
8.01.21 Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms
8.01.22 Allogeneic Hematopoietic Cell Transplantation for Genetic Diseases and Acquired Anemias
8.01.25 Hematopoietic Cell Transplantation for Autoimmune Diseases
8.01.26 Hematopoietic Cell Transplantation for Acute Myeloid Leukemia
8.01.29 Hematopoietic Cell Transplantation for Hodgkin Lymphoma
8.01.42 Hematopoietic Cell Transplantation for Primary Amyloidosis
8.01.511 Hematopoietic Cell Transplantation for Solid Tumors of Childhood
8.01.529 Hematopoietic Cell Transplantation for Non-Hodgkin Lymphomas
8.01.532 Hematopoietic Cell Transplantation in the Treatment of Germ-Cell Tumors

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING |RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

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. 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.

Hematopoietic stem cell transplants are sometimes given to patients who have cancers that are solid tumors. These transplants are considered investigational when used to treat solid tumors. This policy explains why it is considered to be investigational.

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>Investigational</th>
</tr>
</thead>
</table>
| Autologous or allogeneic hematopoietic cell transplant | Autologous or allogeneic hematopoietic cell transplant is considered investigational for the following malignancies in adults:  
- Cancer of the bile duct  
- Cancer of the fallopian tubes  
- Cervical cancer  
- Colon cancer  
- Esophageal cancer  
- Gall bladder cancer  
- Lung cancer, any histology  
- Malignant melanoma  
- Nasopharyngeal cancer  
- Neuroendocrine tumors  
- Pancreatic cancer  
- Paranasal sinus cancer  
- Prostate cancer  
- Rectal cancer  
- Renal cell cancer  
- Soft tissue sarcomas  
- Stomach cancer |
### Transplant

<table>
<thead>
<tr>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Thyroid tumors</td>
</tr>
<tr>
<td>• Tumors of the thymus</td>
</tr>
<tr>
<td>• Tumors of unknown primary origin</td>
</tr>
<tr>
<td>• Uterine cancer</td>
</tr>
</tbody>
</table>

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>38232</td>
<td>Bone marrow harvesting for transplantation; autologous</td>
</tr>
<tr>
<td>38240</td>
<td>Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor</td>
</tr>
<tr>
<td>38241</td>
<td>Hematopoietic progenitor cell (HPC); autologous transplantation</td>
</tr>
<tr>
<td>38242</td>
<td>Allogeneic lymphocyte infusions</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<tr>
<td>S2140</td>
<td>Cord blood harvesting for transplantation, allogeneic</td>
</tr>
<tr>
<td>S2142</td>
<td>Cord blood-derived stem-cell transplantation, allogeneic</td>
</tr>
<tr>
<td>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>

**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**

The following considerations may supersede this policy:
• State mandates requiring coverage for autologous 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 bone marrow transplantation.

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

Evidence Review

Description

Hematopoietic cell transplantation (HCT) is an established treatment for certain hematologic malignancies and has been investigated for a variety of adult solid tumors. Interest continues in exploring nonmyeloablative allogeneic HCT (allo-HCT) for a graft-versus-tumor effect of donor-derived T cells in metastatic solid tumors.

Background

Hematopoietic Cell Transplantation

HCT refers to a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of cytotoxic drugs with or without whole body radiotherapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HCT) or from a donor (allogeneic HCT [allo-HCT]). They can be harvested from bone marrow, peripheral blood, or from umbilical cord blood shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically “naive” and thus are associated with a lower incidence of rejection or graft-versus-host disease (GVHD). Cord blood is discussed in detail in a separate medical policy (see Related Policies).

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. However, immunologic compatibility between donor and patient is a
critical factor for achieving a good outcome of allo-HCT. Compatibility is established by typing of human leukocyte antigens (HLAs) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the HLA-A, -B, and -DR (antigen-D related) loci on each arm of chromosome 6. Depending on the disease being treated, an acceptable donor will match the patient at all or most of the HLA loci (with the exception of umbilical cord blood).

**Conditioning for HCT**

**Conventional Conditioning**

The conventional ("classical") practice of allo-HCT involves administration of cytotoxic agents (eg, cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to destroy endogenous hematopoietic capability in the recipient. The beneficial treatment effect in this procedure is a result of a combination of initial eradication of malignant cells and subsequent graft-versus-malignancy (GVM) effect mediated by non-self-immunologic effector cells that develop after engraftment of allogeneic stem cells within the patient’s bone marrow space. While the slower GVM effect is considered to be the potentially curative component, it may be overwhelmed by extant disease without the use of pre-transplant conditioning. However, intense conditioning regimens are limited to patients who are sufficiently fit medically to tolerate substantial adverse effects that include pre-engraftment opportunistic infections secondary to loss of endogenous bone marrow function and organ damage and failure caused by the cytotoxic drugs. Furthermore, in any allo-HCT, immune suppressant drugs are required to minimize graft rejection and GVHD, which also increases susceptibility of the patient to opportunistic infections. The immune reactivity between donor T cells and malignant cells that is responsible for the GVM effect also leads to acute and chronic GVHD.

The success of autologous HCT is predicated on the ability of cytotoxic chemotherapy with or without radiation to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of bone marrow space with presumably normal hematopoietic stem cells obtained from the patient before undergoing bone marrow ablation. As a consequence, autologous HCT is typically performed as consolidation therapy when the patient’s disease is in complete remission. Patients who undergo autologous HCT are susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not GVHD.
Reduced-Intensity Conditioning for Allo-HCT

Reduced-intensity conditioning (RIC) refers to the pre-transplant use of lower doses or less intense regimens of cytotoxic drugs or radiation than are used in traditional full-dose myeloablative conditioning treatments. The goal of RIC is to reduce disease burden but also to minimize as much as possible associated treatment-related morbidity and non-relapse mortality in the period during which the beneficial GVM effect of allogeneic transplantation develops. Although the definition of RIC remains arbitrary, with numerous versions employed, all seek to balance the competing effects of nonrelapse mortality and relapse due to residual disease. RIC regimens can be viewed as a continuum in effects, from nearly totally myeloablative, to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and the patient condition. Patients who undergo RIC with allo-HCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism, which may be supplemented with donor lymphocyte infusions to eradicate residual malignant cells. For the purposes of this policy, RIC will refer to all conditioning regimens intended to be nonmyeloablative, as opposed to fully myeloablative (conventional) regimens.

HCT in Solid Tumors in Adults

HCT is an established treatment for certain hematologic malignancies. Its use in solid tumors is less well established, although it has been investigated for a variety of solid tumors. With the advent of nonmyeloablative allogeneic transplant, interest has shifted to exploring the generation of alloreactivity to metastatic solid tumors via a graft-versus-tumor effect of donor-derived T cells.¹

HCT as a treatment of ovarian cancer, germ cell tumors, ependymoma, or malignant glioma is addressed in separate policies (see Related Policies). This policy collectively addresses other solid tumors of adults for which HCT has been investigated, including lung cancer; malignant melanoma; tumors of the gastrointestinal tract (affecting the colon, rectum, pancreas, stomach, esophagus, gallbladder, or bile duct); male and female genitourinary systems (eg, renal cell carcinoma, prostate cancer, cervical cancer, uterine cancer, fallopian tube cancer); tumors of the head and neck; soft tissue sarcoma; thyroid tumors; tumors of the thymus; and tumors of unknown primary origin.
Summary of Evidence

**Autologous HCT**

For individuals who have adult soft tissue sarcomas who receive autologous HCT, the evidence includes two TEC Assessments, a randomized controlled trial (RCT), and a number of phase 2 single-arm studies, some of which have been summarized in a systematic review. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The 1995 and 1999 TEC Assessments, focusing on autologous HCT as primary and salvage therapy for a variety of solid tumors, found that the available evidence did not permit conclusions about the effect of HCT on patient survival. Although a small phase 2 RCT reported longer survival for patients treated with autologous HCT than with standard chemotherapy, this trial did not show a survival benefit with HCT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have small cell lung cancer (SCLC) who receive autologous HCT, the evidence includes two TEC Assessments, several RCTs, and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The 1995 and 1999 TEC Assessments, focusing on autologous HCT as primary and salvage therapy for a variety of solid tumors, found that the available evidence did not permit conclusions about the effect of HCT on patient survival. Studies published since the TEC Assessments have not reported increased overall survival for patients with small cell lung cancer treated with autologous HCT. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Allo-HCT**

For individuals who have renal cell carcinoma (RCC), colorectal cancer (CRC), pancreatic cancer, or nasopharyngeal cancer who receive allo-HCT, the evidence includes a TEC Assessment and small single-arm series. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The 1995 and 1999 TEC Assessments, focusing on allo-HCT as primary and salvage therapy for a variety of solid tumors, found the available evidence did not permit conclusions about the effect of allo-HCT on patient survival. Since the publication of the TEC Assessments, the evidence for allo-HCT to treat renal cell carcinoma, colorectal cancer, pancreatic cancer, and nasopharyngeal cancer has been limited to small case series. 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>
</tr>
</thead>
<tbody>
<tr>
<td>NCT03236883</td>
<td>Phase I Study of Nonmyeloablative Allogeneic Hematopoietic Stem Cell Transplantation in the Treatment of Pancreatic Cancer</td>
<td>30</td>
<td>April 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network Guidelines

Current National Comprehensive Cancer Network guidelines (2017-2018) on the tumors addressed in this policy do not discuss hematopoietic cell transplantation (HCT) as a treatment option.\(^{31}\)

American Society for Blood and Marrow Transplantation

The American Society for Blood and Marrow Transplantation (2015) issued guidelines related to indications for autologous and allogeneic HCT.\(^{32}\) The tumors addressed herein for which the Society has provided recommendations are as listed in Table 2.
Table 2. Recommendations for Use of Autologous and Allogeneic HCT

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treatment Option</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ewing sarcoma, high risk</td>
<td>Allogeneic HCT</td>
<td>Not generally recommended</td>
</tr>
<tr>
<td></td>
<td>Autologous HCT</td>
<td>Standard of care, clinical evidence available</td>
</tr>
<tr>
<td>Renal cancer, metastatic</td>
<td>Allogeneic HCT</td>
<td>Developmental</td>
</tr>
<tr>
<td></td>
<td>Autologous HCT</td>
<td>Not generally recommended</td>
</tr>
</tbody>
</table>

U.S. Preventive Services Task Force Recommendations

Hematopoietic cell transplantation is not a preventive service.

Medicare National Coverage

The Centers for Medicare & Medicaid Services currently have the following national noncoverage decision on autologous stem cell transplantation: “Insufficient data exist to establish definite conclusions regarding the efficacy of AuSCT [autologous stem cell transplantation] for the following condition[s]: Solid tumors (other than neuroblastoma).”

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, title 21, parts 1270 and 1271. Hematopoietic stem cells are included in these regulations.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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</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>03/11/03</td>
<td>Replace policy - Policy updated; new references; no change in policy statement.</td>
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<tr>
<td>05/13/03</td>
<td>Replace policy - Update CPT codes only.</td>
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<tr>
<td>08/12/03</td>
<td>Replace policy - Reviewed by OAP on 7/22/03. Recommended that investigational statement be more inclusive.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>10/12/04</td>
<td>Replace policy - Policy updated with literature review; no change to policy statement. Approved by OAP 10/29/04, no need to back to MPC.</td>
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<tr>
<td>10/11/05</td>
<td>Replace policy - Policy updated with literature review; no clinical trial publications found. No change to policy statement.</td>
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<td>06/02/06</td>
<td>Disclaimer and Scope updates - No other changes.</td>
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<tr>
<td>11/14/06</td>
<td>Replace policy - Policy updated with literature review; policy statement unchanged.</td>
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<tr>
<td>02/22/07</td>
<td>Update References - Policy reviewed and recommended by OAP on February 22, 2007.</td>
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<tr>
<td>11/13/07</td>
<td>Replace policy - Policy updated with literature review; policy statement unchanged. References added.</td>
</tr>
<tr>
<td>11/11/08</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. Description and rationale updated. Title changed to delete “HDC” and added “Transplant” after “Stem Cell”. References and codes added. Policy reviewed and recommended by OAP on May 22, 2008.</td>
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<td>12/08/09</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. References added. Policy reviewed and recommended by OAP on November 19, 2009.</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>12/14/10</td>
<td>Replace policy - Policy updated with literature review using MEDLINE through July 2010; reference number 22 added and number 23 updated. Policy statements remain unchanged. Reviewed and recommended by OAP in November 2010.</td>
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<tr>
<td>10/11/11</td>
<td>Replace policy – Policy updated with literature review using MEDLINE through July 2011; reference numbers 9 and 22 added; reference 6 removed; references renumbered. Policy statements unchanged. ICD-10 codes added. Codes 38220 and 38221 removed from policy.</td>
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<tr>
<td>01/24/12</td>
<td>Code 38232 added.</td>
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<tr>
<td>02/10/12</td>
<td>The CPT code 38204 was removed from the policy.</td>
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<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>07/31/12</td>
<td>Update Related Policy titles: 8.01.17, 8.01.21, 8.01.26, 8.01.27, 8.01.29, 8.01.30, 8.01.31, and 8.01.35. Removed Policy 8.01.507 as it was renamed to 8.01.17.</td>
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<tr>
<td>12/19/12</td>
<td>Replace policy. Policy updated with literature review using MEDLINE through September 2012; no references added. Policy statement unchanged. Updated Related Policy 7.01.540, now replaced with 7.01.95.</td>
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<td>02/01/13</td>
<td>Update Related Policies, change title of policy 8.01.21.</td>
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<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>
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<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
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<td>09/30/13</td>
<td>Update Related Policies. Change title to policy 8.01.31.</td>
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<tr>
<td>10/18/13</td>
<td>Update Related Policies. Change title to policy 8.01.17.</td>
</tr>
<tr>
<td>01/20/14</td>
<td>Update Related Policies. Change title to 8.01.21.</td>
</tr>
<tr>
<td>03/21/14</td>
<td>Update Related Policies. Delete 8.01.514.</td>
</tr>
<tr>
<td>04/18/14</td>
<td>Update Related Policies. Remove 8.01.20 and add 8.01.529.</td>
</tr>
<tr>
<td>06/24/14</td>
<td>Update Related Policies. Remove 8.01.35 and 8.01.42, then add 8.01.530 and 8.01.532.</td>
</tr>
<tr>
<td>12/17/14</td>
<td>Annual Review. Policy updated with literature review through September 30, 2014. References 9-10, 12, and 26 added. Policy statement unchanged. ICD-9 and ICD-10 diagnosis and procedure codes removed; these do not relate to policy adjudication.</td>
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<tr>
<td>02/03/15</td>
<td>Update Related Policies. Remove 8.01.23, 8.01.28 and 8.01.30.</td>
</tr>
<tr>
<td>12/08/15</td>
<td>Annual Review. Literature review performed; no change to policy statements.</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 2, 6, 18, and 22 added. Policy statement unchanged.</td>
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<tr>
<td>09/01/16</td>
<td>Update Related Policies. Remove 8.01.27 as it was archived.</td>
</tr>
<tr>
<td>11/04/16</td>
<td>Coding update. Removed codes that are transplant benefit related.</td>
</tr>
<tr>
<td>08/01/17</td>
<td>Updated title of Related Policy 8.01.511.</td>
</tr>
<tr>
<td>11/10/17</td>
<td>Policy moved to new format, no changes to policy statement.</td>
</tr>
<tr>
<td>04/01/19</td>
<td>Annual Review, approved March 5, 2019. Policy updated with literature review through November 2018; no references added. Policy statement unchanged.</td>
</tr>
</tbody>
</table>

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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

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Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplanisyowan w lan oswa konsènan kouvèti asirans lan atravé Premera Blue Cross. Kapab genyen dat ki enpòtan nan avsil a. Ou ka gu gen pou pran kék aksyon avan sèten dat limit pou ka enfòmasyon asirans aplanisyowan w la oswa pou yo ka ede w avek derans yo. Se dwa w pou resweva enfòmasyon sa a ak asistans nan lang ou pa pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmong (Hmong):

Iloko (Ilocano):
Daytoy a Pakdaa ket naglaon iti Napateg nga Impormasnon. Daytoy a pakdaa mabalin nga adda ket naglaon iti napateg nga impormasion maiyangge i aplanisyowan wone coverag babenan i Premera Blue Cross. Daytoy ket mabalin dagiti important a pelsa iit daytoy a pakdaa. Mabalin nga adda ranbeng nga aramideny nga adda sambay dagiti particular a naitudging nga adda tapo napan mapagatalaineay ti coverag ti salun-atyo wone tulung kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulung iti bukdoay a pagasaao nga awan ti bayadayan. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):