Introduction

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are two types of cancer that affect the white blood cells and the bone marrow. Many patients initially do not have any obvious symptoms of these diseases, and they may be discovered during an annual physical exam or by doing routine blood tests. Other patients may have symptoms and go to their doctor because they are worried and don’t feel well. A variety of medications can be used to treat these cancers, and the choice of treatment may depend on how bad a person’s symptoms are and how aggressive their cancer is. In some cases, a hematopoietic cell transplant may be used to treat these diseases. This policy discusses when a hematopoietic cell transplant may be medically necessary to treat CLL and SLL.

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

Transplant Medical Necessity

**Allogeneic hematopoietic cell transplantation**

Allogeneic hematopoietic cell transplantation is considered medically necessary to treat chronic lymphocytic leukemia or small lymphocytic lymphoma in patients with markers of poor-risk disease (see Table 2 below). Use of a myeloablative or reduced-intensity pretransplant conditioning regimen should be individualized based on factors that include patient age, the presence of comorbidities, and disease burden.

Transplant Investigational

**Autologous hematopoietic cell transplantation**

Autologous hematopoietic cell transplantation is considered investigational to treat chronic lymphocytic leukemia or small lymphocytic lymphoma.

Staging and Prognosis of Chronic Lymphocytic Leukemia or Small Lymphocytic Leukemia

Two scoring systems are used to determine stage and prognosis of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL). As outlined in Table 1, the Rai and Binet staging systems classify patients into 3 risk groups with different prognoses and are used to make therapeutic decisions.

**Table 1. Rai and Binet Classification for CLL or SLL**

<table>
<thead>
<tr>
<th>Rai Stage</th>
<th>Risk</th>
<th>Description</th>
<th>Median Survival, y</th>
<th>Binet Stage</th>
<th>Description</th>
<th>Median Survival, y</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Low</td>
<td>Lymphocytosis</td>
<td>&gt;10</td>
<td>A</td>
<td>≤3 lymphoid areas, normal hemoglobin and platelets</td>
<td>&gt;10</td>
</tr>
<tr>
<td>I</td>
<td>Int</td>
<td>Lymphocytosis + lymphadenopathy</td>
<td>7-9</td>
<td>B</td>
<td>≥3 lymphoid areas, normal hemoglobin and platelets</td>
<td>7</td>
</tr>
<tr>
<td>Rai Stage</td>
<td>Risk</td>
<td>Description</td>
<td>Median Survival, y</td>
<td>Binet Stage</td>
<td>Description</td>
<td>Median Survival, y</td>
</tr>
<tr>
<td>-----------</td>
<td>------</td>
<td>--------------------------------------------------</td>
<td>--------------------</td>
<td>-------------</td>
<td>--------------------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>II</td>
<td>Int</td>
<td>Lymphocytosis + splenomegaly ± lymphadenopathy</td>
<td>7-9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>High</td>
<td>Lymphocytosis + anemia ± lymphadenopathy or splenomegaly</td>
<td>1.5-5</td>
<td>C</td>
<td>Any number of lymphoid areas, anemia, thrombocytopenia</td>
<td>5</td>
</tr>
<tr>
<td>IV</td>
<td>High</td>
<td>Lymphocytosis + thrombocytopenia ± anemia, splenomegaly, or lymphadenopathy</td>
<td>1.5-5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Because prognosis of patients varies within the different Rai and Binet classifications, other prognostic markers are used in conjunction with staging to determine clinical management. These are summarized in Table 2, according to availability in clinical centers.

Table 2. Markers of Poor Prognosis in CLL or SLL

<table>
<thead>
<tr>
<th>Community Center</th>
<th>Specialized Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Advanced Rai or Binet stage</td>
<td>• IgVh wild type</td>
</tr>
<tr>
<td>• Male sex</td>
<td>• Expression of ZAP-70 protein</td>
</tr>
<tr>
<td>• Atypical morphology or CLL or SLL</td>
<td>• Del(11q22-q23) (loss of ATM gene)</td>
</tr>
<tr>
<td>• Peripheral lymphocyte doubling time &lt;12 mo</td>
<td>• del(17p13)/variant TP53</td>
</tr>
<tr>
<td>• CD38-positive</td>
<td>• Trisomy 12</td>
</tr>
<tr>
<td>• Elevated β2-microglobulin level</td>
<td>• Elevated serum CD23</td>
</tr>
<tr>
<td>• Diffuse marrow histology</td>
<td>• Elevated serum tumor necrosis factor-α</td>
</tr>
<tr>
<td>• Elevated serum lactate dehydrogenase level</td>
<td>• Elevated serum thymidine kinase</td>
</tr>
<tr>
<td>• Fludarabine resistance</td>
<td></td>
</tr>
</tbody>
</table>

CLL: chronic lymphocytic leukemia; IgVH: immunoglobulin heavy-chain variable-region; SLL: small lymphocytic lymphoma.
An expert panel convened by the American Society for Blood and Marrow Transplantation was queried about criteria used to define high-risk CLL, as part of the process for developing 2016 guidelines. Panelists responded that the criteria are the presence of del17P and/or TP53 variants (100%) and presence of complex karyotype (67%).

Reduced-Intensity Conditioning for Allogeneic HCT

Some patients for whom a conventional myeloablative allotransplant could be curative may be considered candidates for reduced-intensity conditioning (RIC) allogeneic hematopoietic cell transplantation (allo-HCT). They include those patients whose age (typically >60 years) or comorbidities (eg, liver or kidney dysfunction, generalized debilitation, prior intensive chemotherapy, low Karnofsky Performance Status) preclude use of a standard myeloablative conditioning regimen. A patient who relapses following a conventional myeloablative allogeneic HCT could undergo a second myeloablative procedure if a suitable donor is available and his or her medical status would permit it. However, this type of patient would likely undergo RIC before a second allo-HCT if complete remission could be reinduced with chemotherapy.

The ideal allogeneic donors are human leukocyte antigen (HLA)-identical siblings, matched at the HLA-A, -B, and -DR loci on each arm of chromosome 6. Related donors mismatched at a single locus are also considered suitable donors. A matched, unrelated donor identified through the National Marrow Donor Registry is typically the next option considered. Recently, haploidentical donors—typically a parent or a child of the patient—with whom there is usually sharing of only 3 of the 6 major histocompatibility antigens, have been under investigation as a stem cell source. Most patients will have such a donor; however, the risk of graft-versus-host disease (GVHD) and overall morbidity of the procedure may be severe, and experience with these donors is not as extensive as that with matched donors.

### Coding

<table>
<thead>
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<td>Bone marrow harvesting for transplantation; allogeneic</td>
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<tr>
<td>38232</td>
<td>Bone marrow harvesting for transplantation; autologous</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<td>-----------------------------------------------------------------------------</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>
</tbody>
</table>

**HCPCS**

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<td>S2140</td>
<td>Cord blood harvesting for transplantation, allogeneic</td>
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<tr>
<td>S2142</td>
<td>Cord blood-derived stem cell transplantation, allogeneic</td>
</tr>
<tr>
<td>S2150</td>
<td>Bone marrow or blood-derived peripheral stem-cell harvesting and transplantation, allogeneic or autologous, including pheresis, high-dose chemotherapy, and the number of days of post-transplant care in the global definition (including drugs; hospitalization; medical, surgical, diagnostic, and emergency services)</td>
</tr>
</tbody>
</table>

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**Related Information**

**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.

**Evidence Review**
Description

Risk stratification of patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) guides therapy decisions, which may include hematopoietic cell transplantation (HCT) for those with poor-risk features.

Background

Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are neoplasms of hematopoietic origin characterized by the accumulation of lymphocytes with a mature, generally well-differentiated morphology. In CLL, these cells accumulate in blood, bone marrow, lymph nodes, and spleen; in SLL they are generally confined to lymph nodes. The Revised European-American/World Health Organization Classification of Lymphoid Neoplasms considers B-cell CLL and SLL a single disease entity.

CLL and SLL share many common features and are often referred to as blood and tissue counterparts of each other, respectively. Both tend to present as asymptomatic enlargement of the lymph nodes, tend to be indolent, but can undergo transformation to a more aggressive form of disease (e.g., Richter transformation). The median age at diagnosis of CLL is approximately 72 years, but it may present in younger individuals, often as poor-risk disease with significantly reduced life expectancy.

Treatment regimens used for CLL are generally the same as those used for SLL, and treatment outcomes are comparable for both diseases. Both low- and intermediate-risk CLL and SLL demonstrate relatively good prognoses, with median survivals of 6 to 10 years; however, the median survival of high-risk CLL or SLL may only be 2 years. Although typically responsive to initial therapy, CLL and SLL are rarely cured by conventional therapy, and nearly all patients ultimately die of their disease. This natural disease history prompted investigation of HCT as a possible curative regimen.

Hematopoietic Cell Transplantation

Hematopoietic cell transplantation (HCT) is a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer patients who receive bone-marrow–toxic doses of 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 umbilical cord blood shortly after the 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 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 critical for achieving a good outcome of allo-HCT. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the HLA-A, -B, and -DR 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.

**Conditioning for HCT**

**Conventional Conditioning for HCT**

The conventional practice of allogeneic 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 due to a combination of initial eradication of malignant cells and subsequent graft-versus-malignancy (GVM) effect that develops after engraftment of allogeneic stem cells within the patient’s bone marrow space. The slower GVM effect is considered the potentially curative component, but it may be overwhelmed by extant disease without the use of pretransplant conditioning. However, intense conditioning regimens are limited to patients who are sufficiently fit medically and can 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 allogeneic HCT, immune suppressant drugs are required to minimize graft rejection and GVHD, which also increases susceptibility of the patient to opportunistic infections.

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 (CR). 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 pretransplant use of lower doses or less intense regimens of cytotoxic drugs or radiation than are used in conventional 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 (TRM) and non-relapse mortality (NRM) 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 NRM 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 patient condition. Patients who undergo RIC with allogeneic 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, the term “reduced-intensity conditioning” will refer to all conditioning regimens intended to be non-myeloablative, as opposed to fully myeloablative (conventional) regimens.

**Summary of Evidence**

For individuals who have chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and markers of poor-risk disease who receive allogeneic hematopoietic cell transplantation (allo-HCT), the evidence includes single-arm prospective and registry-based studies as well as a TEC Assessment. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related mortality and morbidity. Data have suggested that allo-HCT can provide long-term disease control and overall survival in patients with poor-risk CLL/SLL. High rates of treatment-related morbidity discourage this approach in lower risk disease, particularly among older patients whose health status typically precludes the use of myeloablative conditioning. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have CLL/SLL who receive autologous HCT, the evidence includes randomized controlled trials (RCTs), systematic reviews, and a TEC Assessment. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-
related mortality and morbidity. Autologous HCT is feasible in younger patients but is not curative, particularly in those with poor-risk CLL. Studies of autologous HCT published to date have not shown improvement in overall survival in patients with CLL/SLL, and results must furthermore be considered in the context of improved outcomes with the use of newer chemo-immunotherapy agents. Additionally, evidence from the European Intergroup RCT has suggested quality-of-life issues are important in selecting patients for autologous HCT and may dictate the management course for patients who are otherwise candidates for this approach. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in November 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 specialty medical center reviewer, 1 academic medical center reviewer, and 2 Blue Distinction Center reviewers while this policy was under review in 2010. Three of 4 reviewers agreed that allogeneic hematopoietic cell transplantation (HCT) was of value to patients with poor-risk chronic lymphocytic leukemia and that this procedure should be medically necessary for this setting. However, the reviewers indicate that the specific approach (eg, reduced-intensity conditioning vs myeloablative conditioning) should be individualized based on criteria such as age and health status. All reviewers concurred with the policy statement that autologous HCT is investigational.
Practice Guidelines and Position Statements

*American Society for Blood and Marrow Transplantation*

In 2015, the American Society for Blood and Marrow Transplantation (ASBMT) published guidelines on indications for allogeneic (allo-) and autologous hematopoietic cell transplantation (HCT) for chronic lymphocytic leukemia (CLL). Recommendations described the current consensus on use of HCT in and out of the clinical trial setting. Treatment recommendations are shown in Table 3.

Table 3: 2015 Recommendations for Allogeneic and Autologous HCT for CLL

<table>
<thead>
<tr>
<th>Adult Indications</th>
<th>Allogeneic HCT</th>
<th>Autologous HCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>High risk, first or greater remission</td>
<td>C</td>
<td>N</td>
</tr>
<tr>
<td>T cell, prolymphocytic leukemia</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>B cell, prolymphocytic leukemia</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Transformation to high-grade lymphoma</td>
<td>C</td>
<td>C</td>
</tr>
</tbody>
</table>

C: standard of care, clinical evidence available; CLL: chronic lymphocytic leukemia; HCT: hematopoietic cell transplantation; N: Not generally recommended; R: standard of care, rare indication.

In 2016, ASBMT published clinical practice recommendations with additional detail on allo-HCT for CLL. Recommendations are shown in Table 4. Note that allo-HCT is no longer recommended for high-risk CLL as consolidation in first remission or immune-chemotherapy sensitive first relapse.

Table 4: 2016 Recommendations for Allogeneic HCT for CLL

<table>
<thead>
<tr>
<th>Indications</th>
<th>Allogeneic HCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk CLL</td>
<td>Not recommended in the first-line consolidation setting</td>
</tr>
<tr>
<td></td>
<td>Not recommended for patients who relapse after first-line therapy and demonstrate sensitive disease after second line therapy (not BCR inhibitors)</td>
</tr>
<tr>
<td></td>
<td>Recommended for patients who relapse after first-line therapy, have refractory disease after second-line therapy (not BCR inhibitors) and show an objective response to BCR</td>
</tr>
</tbody>
</table>
Indications | Allogeneic HCT
--- | ---
 | inhibitors or to a clinical trial
Recommended for patients who relapse after first-line therapy, have refractory disease after second-line therapy (including BCR inhibitors but not BCL-2 inhibitors) and show an objective response to BCL-2 inhibitors or to a clinical trial
Recommended when there is a lack of response or there is progression after BCL-2 inhibitors
Recommended after achieving an objective response to anthracycline-based chemotherapy
Not recommended

Richter transformation
Purine analogue relapsed and/or refractory disease

BCR: B cell receptor; BCL-2: B cell lymphoma 2; CLL: chronic lymphocytic leukemia; HCT: hematopoietic cell transplantation.

**National Comprehensive Cancer Network Guidelines**

Current National Comprehensive Cancer Network (NCCN) guidelines (v.2.2018) for CLL and small lymphocytic lymphoma (SLL) state that allogeneic HCT may be considered for patients

- Without significant comorbidities and CLL refractory to small molecule inhibitor therapy
- With relapsed CLL or SLL and without a17p deletion or TP53 mutation
- With CLL or SLL, a response to treatment and with a complex karyotype
- With CLL (Rai stages 0-IV) or SLL (Lugano stages II-IV), after histologic transformation to diffuse large B-cell/Hodgkin lymphoma.

**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 the Code of Federal Regulation title 21, parts 1270 and 1271. Hematopoietic cells are included in these regulations.

References

2. Blue Cross and Blue Shield Association (TEC). High-dose chemotherapy plus allogeneic stem cells to treat chronic lymphocytic leukemia or small lymphocytic lymphoma. TEC Assessments. 2002;Volume 17:Tab 4.


### History

<table>
<thead>
<tr>
<th>Date</th>
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<td>03/10/14</td>
<td>New Policy. Policy replaces 8.01.514. Policy updated with literature review through December, 2013; reference 11 added. In new policy, policy statement regarding autologous HCT changed from medically necessary to investigational. Policy statement regarding allogeneic HCT changed to medically necessary only in patients with</td>
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<td>04/18/14</td>
<td>Update Related Policies. Delete 8.01.20 and replace with 8.01.529.</td>
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<tr>
<td>06/27/14</td>
<td>Update Related Policies. Remove 8.01.35 and add 8.01.532.</td>
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<tr>
<td>12/03/14</td>
<td>Update Related Policies. Remove 8.01.17.</td>
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<td>Coding update. Removed codes that are transplant benefit related.</td>
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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
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Français (French):


Kreyòl ayisyen (Creole):


Deutsche (German):


Hmoob (Hmong):

Tsab ntawv tshaj koj no muaj cov ntsiab lus tseem ceeb. Tej zaum tsab ntawv tshaj koj no muaj cov ntsiab lus tseem ceeb baoj koj daim ntawv thov kev pab los yog koj qhov kev pab cuam los ntawm Premera Blue Cross. Tej zaum muaj cov hnb tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj koy jyuav ta uu qeem yam uas peb koj uas tis puub dhuu cov cajj yuoy uas teev tseeg rau hauv daim ntawv no mas koj thaj jyuav ta baiv kev pab cuam kho mob los yog kev pab them tej jir khow mob ntawv. Koj muaj cai kom lawv muab cov ntsiab lus no uas tau muab sau koj hom luus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Ilokano (Ilocano):

Daytoy a Pakdaak ket naglaon iti Napateg nga Impormacion. Daytoy a pakdaak mabalbin nga adda ket naglaon iti napateg nga impormasun imahibigan iti aplikasyon o nga coverage babaen Premera Blue Cross. Daytoy koj mabalin dagiti importante a pelsa iti daytoy a pakdaak. Mabalbin nga adda rumbeng nga aramidben nga adda sakaay dagiti partikular a niuluding nga adda ilawo tapo mapagatindayed nga coverage ti salay-ayo nga tulog kadaygii gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulog iti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
