MEDICAL POLICY – 8.01.531
Hematopoietic Cell Transplantation for Waldenström Macroglobulinemia

BCBSA Ref. Policy: 8.01.54

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>April 1, 2019</th>
<th>RELATED MEDICAL POLICIES:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Revised:</td>
<td>March 5, 2019</td>
<td>7.01.50 Placental and Umbilical Cord Blood as a Source of Stem Cells</td>
</tr>
<tr>
<td>Replaces:</td>
<td>8.01.54</td>
<td>8.01.21 Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms</td>
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<tr>
<td></td>
<td></td>
<td>8.01.29 Hematopoietic Cell Transplantation for Hodgkin Lymphoma</td>
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<td></td>
<td>8.01.42 Hematopoietic Cell Transplantation for Primary Amyloidosis</td>
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<td>10.01.518 Clinical Trials</td>
</tr>
</tbody>
</table>

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Introduction

Waldenström macroglobulinemia (WM) is a type of non-Hodgkin lymphoma, which is a cancer that starts in a type of white blood cells called lymphocytes. WM causes the body to create a lot of an abnormal protein called macroglobulin. A stem cell transplant using the patient’s own cells may be one treatment option. Stem cells are collected from the patient and stored. After the patient receives high-dose chemotherapy, the stem cells are given back to the patient. Using a person’s own stem cells is known as an autologous stem cell transplant. Using stem cells from a donor is called an allogeneic transplant. Using donor stem cells to treat WM is investigational (unproven). There is not enough scientific evidence to show that it works in this situation.

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>Service</th>
<th>Medical Necessity</th>
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<tr>
<td>Autologous hematopoietic cell transplantation</td>
<td>Autologous hematopoietic cell transplantation may be considered medically necessary as salvage therapy of chemosensitive Waldenström macroglobulinemia.</td>
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</table>

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allogeneic hematopoietic cell transplantation</td>
<td>Allogeneic hematopoietic cell transplantation is considered investigational to treat Waldenström macroglobulinemia.</td>
</tr>
</tbody>
</table>

Documentation Requirements

The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Prior treatment (if any) patient has received

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<td>CPT</td>
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<tr>
<td>38230</td>
<td>Bone marrow harvesting for transplantation; allogeneic</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>
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</tbody>
</table>

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Description

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 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). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically “naïve” and thus are associated with a lower incidence of rejection or graft-versus-host disease. Cord blood is discussed in greater detail in a separate medical policy (see Related Policies).

Background

Waldenström Macroglobulinemia

Waldenström macroglobulinemia (WM) is a clonal disorder of B lymphocytes that accounts for 1% to 2% of hematologic malignancies, with an estimated 1500 new cases annually in the United States. Symptoms include weakness, headaches, stroke-like symptoms (confusion, loss of coordination), vision problems, excessive bleeding, unexplained weight loss, and frequent infections. The median age of WM patients is 63 to 68 years, with men comprising 55% to 70% of cases. Median survival of WM ranges from 5 to 10 years, with age, hemoglobin concentration, serum albumin level, and \( \beta_2 \)-microglobulin level as predictors of outcome.

The Revised European American Lymphoma and World Health Organization classification and a consensus group formed at the Second International Workshop on Waldenström’s macroglobulinemia recognize WM primarily as a lymphoplasmacytic lymphoma with an
associated immunoglobulin M (IgM) monoclonal gammopathy. The definition also requires the presence of a characteristic pattern of bone marrow infiltration with small lymphocytes demonstrating plasmacytic differentiation with variable cell surface antigen expression. The Second International Workshop indicated that no minimum serum concentration of IgM is necessary for a diagnosis of WM.

**Treatment**

The goal of therapy for patients with WM is to achieve symptomatic relief and reduce organ damage without compromising quality of life. Treatment of WM is indicated only in symptomatic patients and should not be initiated solely on the basis of serum IgM concentration. Clinical and laboratory findings that indicate the need for therapy of diagnosed WM include a hemoglobin concentration less than 10 g/dL; platelet count less than 100,000/mL; significant adenopathy or organomegaly; symptomatic Ig-related hyperviscosity (>50 g/L); severe neuropathy; amyloidosis; cryoglobulinemia; cold-agglutinin disease; or evidence of disease transformation.

Primary chemotherapeutic options in patients that may undergo autologous hematopoietic cell transplantation (HCT) often combine rituximab with other agents (eg, dexamethasone, cyclophosphamide, bortezomib, bendamustine), but other agents may also be used including purine analogues (cladribine, fludarabine). Plasma exchange is indicated for acute treatment of symptomatic hyperviscosity.

**Conventional Preparative Conditioning for HCT**

The conventional (“classical”) 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 effect that develops after engraftment of allogeneic stem cells within patients’ bone marrow space. While the slower graft-versus-malignancy effect is considered the potentially curative component, 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 to tolerate substantial adverse events that include preengraftment 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 graft-versus-host disease, 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 radiotherapy 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 prior to engraftment, but not graft-versus-host disease.

**Reduced-Intensity Conditioning for Allogeneic HCT**

Reduced-intensity conditioning (RIC) refers to the pretransplant use of lower doses or less intense regimens of cytotoxic drugs or radiotherapy 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 and non-relapse mortality in the period during which the beneficial graft-versus-malignancy 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 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 this policy, the term reduced-intensity conditioning will refer to all conditioning regimens intended to be nonmyeloablative, as opposed to fully myeloablative (conventional) regimens.

**Summary of Evidence**

For individuals who have WM who receive HCT, the evidence includes case series. Relevant outcomes are overall survival, change in disease status, quality of life, and treatment-related mortality and morbidity. Several retrospective series have evaluated HCT for WM. Analyses of registry data have found 5-year overall survival rates of 52% after allogeneic HCT and 68.5%
after autologous HCT. The total number of patients studied is small and there is a lack of published controlled studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2011 and national and international clinical guidelines support the use of autologous HCT as salvage therapy for patients with chemosensitive Waldenström macroglobulinemia. Allogeneic HCT is recommended in the context of clinical trials. Thus, autologous HCT may be considered medically necessary as salvage therapy for patients with chemosensitive Waldenström macroglobulinemia. Allogeneic HCT for patients with Waldenström macroglobulinemia is considered investigational.

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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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT01251575</td>
<td>Sirolimus, Cyclosporine, and Mycophenolate Mofetil in Preventing Graft-versus-Host Disease in Treating Patients with Blood Cancer Undergoing Peripheral Blood Stem Cell Transplant</td>
<td>80</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT02844361</td>
<td>Comparison of ASCT and Conventional Chemotherapy in High Risk Waldenström Macroglobulinemia (BDH-WM03)</td>
<td>70</td>
<td>May 2020</td>
</tr>
</tbody>
</table>

NCT: National clinical trial

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, 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 5 academic medical centers, including 3 transplant centers, while this policy was under review in 2011. The input indicated that autologous hematopoietic cell transplantation may be considered medically necessary as salvage therapy for Waldenström macroglobulinemia that is chemosensitive. Input was mixed on use of allogeneic hematopoietic cell transplantation, with comments suggesting the procedure be performed as part of a clinical trial.

**Practice Guidelines and Position Statements**

*National Comprehensive Cancer Network*

National Comprehensive Cancer Network guidelines on Waldenström macroglobulinemia (WM) and lymphoplasmacytic lymphoma (v.2.2019) indicate that, for patients with previously treated WM, stem cell transplantation may be appropriate in selected cases with either: high-dose therapy with autologous stem cell rescue or allogeneic cell transplant (myeloablative or nonmyeloablative). The Network noted that allogeneic cell transplantation “should ideally be undertaken in the context of a clinical trial.” For potential autologous cell transplantation candidates, the guidelines also provide suggested treatment regimens considered non-stem-cell toxic.

*Mayo Clinic Cancer Center*

In 2017, the Mayo Clinic Cancer Center updated its guidelines on the diagnosis and management of WM. The guidelines noted that patients who are potentially eligible for autologous hematopoietic cell transplantation (HCT; <70 years of age and with chemosensitive disease), should consider harvesting stem cells during first remission after a low tumor burden has been achieved. The guidelines recommended: “Autologous HCT should be considered for first or second relapse in transplant-eligible patients with chemosensitive disease, especially if the first remission duration is short (<2 years). Patients with refractory WM should not be offered [autologous HCT] (level 3, grade B).”

*Eighth International Workshop on Waldenström’s Macroglobulinemia*

In 2016, consensus recommendations from the Eighth International Workshop on Waldenström’s Macroglobulinemia were published. The panel concluded that autologous HCT
is a treatment option for high-risk WM patients who are eligible for transplant. It further stated that autologous HCT should be offered at early relapses and is not as beneficial once patients have been exposed to more than 3 lines of therapy or in those with chemotherapy refractory disease. Regarding allogeneic HCT, it stated that this treatment, “when appropriate, should preferably be considered in the context of clinical trials.”

**Myeloma Foundation of Australian**

In 2017, the Myeloma Foundation of Australia published practice guidelines on the treatment of patients with WM. The guidelines provided the following treatment recommendation for HCT: “Younger patients with good physical fitness should be considered for autologous and allogeneic stem cell transplantation at first or second relapse and should avoid stem cell-toxic therapies such as fludarabine (Level III, grade C).”

**Medicare National Coverage**

There is no national coverage determination.

**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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<tbody>
<tr>
<td>05/12/14</td>
<td>New PR policy replacing 8.01.54. Autologous hematopoietic stem-cell transplantation may be considered medically necessary as salvage therapy of chemosensitive Waldenstrom macroglobulinemia in select patients when criteria are met (qualifying criteria added to policy), considered investigational outside of qualifying criteria unless enrolled in a clinical trial.</td>
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<tr>
<td>02/03/15</td>
<td>Update Related Policies. Remove 8.01.23 and 8.01.28.</td>
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<td>Annual Review. Policy updated with literature review; no change in policy statements.</td>
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<td>11/04/16</td>
<td>Coding Update. Transplant benefit-related codes removed.</td>
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<td>Annual review, approved November 8, 2016. No changes to the policy statement.</td>
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<td>Annual review, approved February 14, 2017. Policy updated with literature review through October 26, 2016; references 2 and 5 added. Policy statements unchanged.</td>
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<td>06/09/17</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7867 (TDD)

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አማርኛ (Amharic):

አማርኛ (Amharic):

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