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Hematopoietic Cell Transplantation for Waldenstrom Macroglobulinemia

Table of Contents

Related Policies (if applicable)
SUR703.002: Hematopoietic Cell Transplantation (HCT) or Additional Infusion Following Preparative Regimens (General Donor and Recipient Information)

Disclaimer

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Coverage

Autologous hematopoietic cell transplantation (HCT) **may be considered medically necessary** as salvage therapy of chemosensitive Waldenström macroglobulinemia (WM).

Allogeneic hematopoietic cell transplantation **is considered experimental, investigational and/or unproven** to treat WM.

NOTE: See Medical Policy SUR703.002 for detailed, descriptive information on HCT-related services.

Policy Guidelines

None.

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 cytotoxic drugs with or without whole body radiation therapy. 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 (GVHD).

Waldenström Macroglobulinemia

Waldenström macroglobulinemia (WM) is a type of cancer that begins in the white blood cells. It is considered a type of non-Hodgkin's lymphoma. In WM, some white blood cells undergo changes that turn them into cancer cells. The cancer cells can build up in the bone marrow (where blood cells are made). The cancer cells crowd healthy blood cells out of the bone marrow. Cancer cells also may build up in other parts of the body, such as the lymph nodes and the spleen. WM cells make a protein that the body can't use. The protein is immunoglobulin M, which is also called IgM. IgM can build up in the blood. This may reduce blood flow in the body and cause other problems. (1) 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 ß2-microglobulin level as predictors of outcome.

The Revised European American Lymphoma (REAL) and World Health Organization (WHO) classification and a consensus group formed at the Second International Workshop on WM recognized 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 no minimum serum concentration of IgM is necessary for a diagnosis of WM. (2)

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/µL; significant adenopathy or organomegaly; symptomatic Ig-related hyperviscosity (>50 g/L); severe neuropathy; amyloidosis; cryoglobulinemia; cold-agglutinin disease; or evidence of disease transformation. (3)

Primary chemotherapeutic options in patients that may undergo autologous HCT often combine rituximab with other agents (e.g., 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 (e.g., 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 pre-transplant conditioning. However, intense conditioning regimens are limited to patients who are sufficiently fit medically to tolerate substantial adverse events 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 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 GVHD.

Reduced-Intensity Conditioning for Allogeneic HCT

Reduced-intensity conditioning (RIC) refers to the pre-transplant use of lower doses or less intense regimens of cytotoxic drugs or radiotherapy than are used in conventional full-dose myeloablative conditioning (MAC) 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 non-relapse 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 medical policy, the term reduced-intensity conditioning will refer to all conditioning regimens intended to be nonmyeloablative, as opposed to fully myeloablative (conventional) regimens.

Regulatory Status
The U.S. Food and Drug Administration (FDA) regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research (CBER), under Code of Federal Regulation (CFR) title 21, parts 1270 and 1271. Hematopoietic stem-cells are included in these regulations. (4)

Rationale

This policy was created in 2013. This policy has been updated periodically with reviews of the PubMed database. The most recent literature review was performed through March 11, 2024.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function--including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Hematopoietic Cell Transplantation for Waldenström Macroglobulinemia
Clinical Context and Therapy Purpose
The purpose of hematopoietic cell transplantation (HCT) is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with Waldenström macroglobulinemia (WM).

The question addressed in this medical policy is: Does the use of HCT improve the net health outcomes of individuals with Waldenström macroglobulinemia?

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with Waldenström macroglobulinemia.

Interventions
The therapy being considered is hematopoietic cell transplantation.

Comparators
Comparators of interest include chemotherapy, targeted therapy drugs, and biologic therapy drugs.

Outcomes
The general outcomes of interest include overall survival, quality of life, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Few published data are available and there is a lack of studies comparing HCT with other treatments (e.g., chemotherapy) in patients who have WM. Several retrospective series have been published.

Kyriakou et al. (2010) evaluated 158 adults with WM reported to the European Group for Blood and Marrow Transplantation between 1991 and 2005. (5) Median time from diagnosis to autologous HCT was 1.7 years (range, 0.3-20.3 years); 32% of the patients experienced treatment failure with at least 3 lines of therapy; and 93% had sensitive disease at the time of HCT. Median follow-up for surviving patients was 4.2 years (range, 0.5-14.8 years). Nonrelapse mortality was 3.8% at 1 year. Relapse rate was 52.1% at 5 years. Progression-free survival and overall survival (OS) were 39.7% and 68.5%, respectively, at 5 years and were significantly influenced by number of lines of therapy and chemo-refractoriness at HCT. Authors concluded that autologous HCT is a feasible procedure in young patients with advanced WM but that it should not be offered to patients with chemoresistant disease or to those who have received more than 3 lines of therapy.

Kyriakou et al. (2010) retrospectively analyzed data on 86 patients who had allogeneic HCT for WM. (6) Patients underwent MAC (n=37) or RIC (n=49) regimens. Median age was 49 years (range, 23-64 years); 47 patients had received 3 or more previous lines of therapy; and 8 patients had experienced failure on a prior autologous HCT. Fifty-nine (68.6%) patients had chemosensitive disease at the time of allogeneic HCT. Median follow-up of the surviving patients was 50 months. The overall response rate was 75.6%. Relapse rates at 3 years were 11% for MAC and 25% for RIC. The OS rate at 5 years was 62% for MAC and 64% for RIC. Thirty deaths were reported; causes of death included GVHD (23%) and primary disease (23%). The occurrence of chronic GVHD was associated with a lower relapse rate.

Data from the Center for International Blood and Marrow Transplant Research registry have been published periodically, most recently in 2017. Cornell et al. (2017) reported retrospectively on 144 adults with WM entered in the registry between 2001 and 2013 who underwent allogeneic HCT. (7) Patients had relapsed after receiving at least 1 line of prior therapy. Hematopoietic cells were obtained from human leukocyte antigen-matched or -mismatched donors; cord blood stem-cells were excluded. Sixty-seven patients received myeloablative conditioning (MAC) and 67 received reduced-intensity conditioning (RIC). Over half of patients (n=82 [57%]) had chemosensitive disease. Median follow-up after transplant was 70 months. OS rates were 74% at 1 year and 52% at 5 years. Patients with chemosensitive disease had significantly better 1- and 5-year OS rates compared with patients who had chemoresistant disease. Conditioning intensity (MAC versus RIC) did not impact treatment-related mortality, relapse, or progression-free survival (PFS) rates. Sixty-five deaths were reported, with the most common causes being graft-versus-host-disease (GVHD) (28%) and primary disease (23%).

Maffini et al. (2018) stated that irrespective of age, patients with aggressive WM who have exhausted chemo-immunotherapy-based approaches may be candidates for allogeneic hematopoietic cell transplantation, a strategy that has been rarely attempted. (8) In Seattle, conditioning with a single fraction of low-dose total body irradiation (TBI), combined with a GVHD prophylaxis consisting of cyclosporine and mycophenolate mofetil, led to near-uniform allogeneic engraftment in a canine DLA-identical model. Clinical trials based on this approach demonstrated rapid engraftment and graft-versus-tumor effects in a wide variety of hematologic malignancies, with higher sustained response rates for patients with indolent diseases. The researchers presented a retrospective analysis of outcomes among 15 heavily pre-treated and largely chemo-refractory WM patients who received a minimal intensity conditioning regimen consisting of 200 cGy TBI ± fludarabine, in preparation for HLA-matched related or unrelated HCT. They concluded that despite improvements in chemotherapeutic drugs, WM has remained an incurable illness. However, these investigators and others have shown that allogeneic HCT can achieve cures in nearly half of the patients with advanced WM including those with chemotherapy-resistant disease. The risk of non-relapse mortality must be carefully evaluated before the procedure. Moreover, they stated that it is possible that results of allogeneic HCT can be further improved by transplanting earlier in the disease course when patients are in a better general condition or before they become refractory to chemotherapy or develop secondary cancers.

Sakurai et al. (2020) retrospectively evaluated the outcome of autologous and allogeneic HCT for patients with WM using the registry database of the Japan Society for Hematopoietic Cell Transplantation. (9) Forty-six patients receiving autologous and 31 receiving allogeneic HCT were analyzed. The allogeneic HCT group included more patients with advanced disease status at transplant and received more lines of chemotherapy. The cumulative incidences of non-relapse mortality (NRM) at 1 year were 30.0% (95% confidence interval [CI], 14.7-46.9%) in the allogeneic HCT and 0% in the autologous HCT group. The estimated 3-year overall (OS) and progression-free (PFS) survival rates were 84.5% (95% CI, 66.0-93.4%) and 70.8% (95% CI, 53.0-82.9%) in the autologous HCT group, and 52.2% (95% CI, 32.5-68.6%) and 45.0% (95% CI, 26.3-62.0%) in the allogeneic HCT group. No patients died after the first 2 years following allogeneic HCT. In univariate analyses, disease status at HCT was significantly associated with PFS in autologous HCT, and with OS and PFS in allogeneic HCT. These results suggest that both autologous and allogeneic HCT have each potential role in WM. Allogeneic HCT is more curative for WM, but is associated with high NRM.

Parrondo et al. (2020) performed a comprehensive literature search using PubMed/Medline and EMBASE on September 10, 2019. (10) Data on clinical outcomes related to benefits and harms was extracted independently by 3 authors. Fifteen studies (8 autologous HCT [n = 278 patients], 7 allogeneic HCT [n = 311 patients]) were included in this systematic review/meta-analysis. Pooled OS, PFS, and NRM rates post autologous HCT were 76% (95% CI, 65%-86%), 55% (95% CI, 42%-68%), and 4% (95% CI, 1%-7%), respectively. Pooled OS, PFS, and NRM rates post allografting were 57% (95% CI, 50%-65%), 49% (95% CI, 42%-56%), and 29% (95% CI, 23%-34%), respectively. OS and PFS rates were reported at 3 to 5 years, and NRM was reported at 1 year in most studies. Pooled overall response rate (ORR) (at day 100) post autologous HCT and allogeneic HCT were 85% (95% CI, 72%-94%) and 81% (95% CI, 69%-91%), respectively. Pooled complete response rates post autologous HCT and allogeneic HCT were 22% (95% CI, 17%-28%) and 26% (95% CI, 7%-50%), respectively. Relapse rates post autologous HCT and allogeneic HCT were 42% (95% CI, 30%-55%) and 23% (95% CI, 18%-28%), respectively. The authors concluded that both autologous HCT and allogeneic HCT are effective in the treatment of WM. A 2-fold lower relapse rate but a 7-fold higher NRM was noted for allogeneic HCT compared with autologous HCT. The role of transplant in WM needs to be addressed in the era of novel agents.

In 2022, Ahmed et al. conducted a multicenter retrospective cohort study and included adult patients with relapsed/refractory WM who underwent an auto-HCT between January 2007 and December 2017 at five U.S. academic centers. (11) The primary endpoint was post-relapse overall survival (PR-OS). Secondary endpoints were to identify factors prognostic of PR-OS. Of the 48 patients with WM who underwent auto-HCT, 22 (46%) experienced relapse following auto-HCT. Median PR-OS of relapsed WM patients after auto-HCT (n = 22) was not reached (NR) (95% confidence interval [CI]: 17.5 months-NR). Among patients who relapsed <1 year versus ≥1 year from auto-HCT, the median PR-OS was 18.4 months (95%CI: 0.8-NR) months and NR (95%CI: 17.5-NR), respectively (p = 0.06). Of note, disease status at the time of transplant, CR/VGPR (complete response/very good partial response) versus partial remission did not appear to impact PR-OS. The median PR-OS was significantly longer in patients who received

ibrutinib in the post-transplant setting compared to those who did not (NR vs. 18.4 months, 95%CI: 9.1-NR, p = 0.02). On univariable analysis, the presence of complex karyotype (RR = 4.87, 95% CI = 1.22-19.53) and a higher number of prior lines of therapy (RR = 1.81, 95% CI = 1.23-2.67) were associated with a significantly higher risk of relapse. This is the only study to date that evaluated outcomes of WM patients who relapsed following auto-HCT and provides a benchmark for future trials evaluating survival following auto-HCT relapse.

UpToDate

High-dose chemotherapy followed by autologous HCT is rarely used for the treatment of WM. The treatment-related mortality of autologous HCT seems to be below 10%, and it might induce long-term responses even in heavily pre-treated patients. Various conditioning regiments have been suggested, but none have shown clear superiority. HCT's role in WM is restricted, reserved for patients with good performance status after exhausting other treatment options. However, it entails a significantly higher risk of non-relapse mortality and should only be considered within clinical trial settings. Data on the effectiveness of HCT in WM is derived from a meta-analysis of 15 retrospective studies, encompassing 278 patients who underwent autologous HCT and 311 patients who underwent allogeneic HCT across several decades. All patients undergoing allogeneic HCT and most patients undergoing autologous HCT had relapsed or refractory disease. Most studies documented overall survival, progression-free survival, and relapse rates at 3-5 years, as well as one-year non-relapse mortality rates. Pooled estimates were as follows:

- Autologous HCT – OS 76 percent (95% CI 65-86 percent), PFS 55 percent (95% CI 42-68 percent), RR 42 percent (95% CI 30-55 percent), and NRM 4 percent (95% CI 1-7 percent).
- Allogeneic HCT – OS 57 percent (95% CI 50-65 percent), PFS 49 percent (95% CI 42-56 percent), NRM 29 percent (95% CI 23-34 percent), RR 23 percent (95% CI 18-28 percent). Acute graft-versus-host disease (GVHD) was reported in 71 percent and usually grade I to II. Chronic GVHD was reported in 51 percent. Results following allogeneic HCT were heterogeneous, likely reflecting diversity in conditioning regimens, donor type, stem cell source, and GVHD prophylaxis used at different institutions and across time. (3)

Summary of Evidence

For individuals who have Waldenström Macroglobulinemia (WM) who receive hematopoietic cell transplantation (HCT), the evidence includes several retrospective case series and a systematic review. Relevant outcomes are overall survival, change in disease status, quality of life, and treatment-related mortality and morbidity. The total number of patients studied is small and there is a lack of published controlled studies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

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.2.2024) 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). (12) 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. (13) 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)."

Tenth International Workshop on Waldenström's Macroglobulinemia

In 2020, consensus recommendations from the tenth International Workshop on WM were published. (14) The panel concluded that "autologous HCT is not appropriate for first-line therapy in patients who are responding to induction therapy, autologous HSCT [haematopoietic stem-cell transplantation] is appropriate following second or subsequent relapses in high-risk patients (i.e., aggressive clinical behaviour or refractory to previous therapies) with chemosensitive disease, and HSCT should not be considered in patients who are BTK [Bruton's tyrosine kinase] inhibitor-naive, provided that BTK inhibitors are available.

Myeloma Foundation of Australian

In 2022, the Myeloma Foundation of Australia published practice guidelines on the treatment of patients with WM. (15) 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)."

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	36511, 38204, 38205, 38206, 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214, 38215, 38220, 38221, 38222, 38230, 38232, 38240, 38241, 38242, 38243, 81265, 81266, 81267, 81268, 81370, 81371, 81372, 81373, 81374, 81375, 81376, 81377, 81378, 81379, 81380, 81381, 81382, 81383, 86805, 86806, 86807, 86808, 86812, 86813, 86816, 86817, 86821, 86822, 86825, 86826, 86828, 86829, 86830, 86831, 86832, 86833, 86834, 86835, 86849, 86950, 86985, 88240, 88241
HCPCS Codes	S2140, S2142, S2150

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
05/15/2024	Document updated with literature review. Coverage unchanged. Added references 1-4 and 11; others updated.
07/01/2023	Reviewed. No changes.
01/01/2023	Document updated with literature review. Coverage unchanged. Added/updated the following references: 4-7, 9 and 10.

02/15/2022	Reviewed. No changes.
11/01/2020	Document updated with literature review. Coverage unchanged. No new references added; some updated, others deleted. Title changed from: Hematopoietic Stem-Cell Transplantation for Waldenstrom Macroglobulinemia.
05/01/2019	Reviewed. No changes.
07/15/2018	Document updated with literature review. Coverage unchanged. Rationale reorganized. References 1,3, 6-8 were added; numerous references removed.
04/15/2017	Reviewed. No changes.
07/01/2016	Document updated with literature review. Coverage unchanged.
02/01/2015	Document updated with literature review. Coverage language modified, without change to coverage position. CPT/HCPCS code(s) updated. Title changed from: Stem-Cell Transplant for Waldenstrom Macroglobulinemia.
10/15/2013	New medical document originating from: SUR703.046, Stem-Cell Transplant for Primary Amyloidosis and Waldenström's Macroglobulinemia (WM). Allogeneic stem-cell support (AlloSCS), autologous stem-cell support (AutoSCS), tandem or triple stem-cell transplant, donor leukocyte infusion (DLI), and hematopoietic progenitor cell boost are considered experimental, investigational and unproven. Any related services for the treatment of WM, such as short tandem repeat (STR) markers, are considered experimental, investigational and unproven. Previously the coverage information originated from SUR703.046, Stem-Cell Transplant for Primary Amyloidosis and Waldenström's Macroglobulinemia (as a combined policy document) and from: SUR703.017, Peripheral/Bone Marrow Stem Cell Transplantation (PSCT/BMT) for Non-Malignancies; SUR703.018, Peripheral/Bone Marrow Stem Cell Transplantation (PSCT/BMT) for Malignancies; SUR703.022, Cord Blood as a Source of Stem Cells (CBSC); SUR703.023, Donor Leukocyte Infusion (DLI); and SUR703.024, Tandem/Triple High-Dose Chemoradiotherapy with Stem Cell Support for Malignancies. Stem cell transplant continues to be medically necessary when stated criteria are met. NOTE: A link to the medical policies with the following titles can be found at the end of the medical policy SUR703.002, Stem-Cell Reinfusion or Transplantation Following Chemotherapy (General Donor and Recipient Information): • Peripheral/Bone Marrow Stem Cell Transplantation (PSCT/BMT) for Non-Malignancies; • Peripheral/Bone Marrow Stem Cell Transplantation (PSCT/BMT) for Malignancies; • Cord Blood as a Source of Stem Cells; • Donor Leukocyte Infusion (DLI); and Tandem/Triple High-Dose Chemoradiotherapy with Stem Cell Support for Malignancies.