Hematopoietic Stem-Cell Transplantation for Primary Amyloidosis

**Policy Number:** 8.01.42  
**Origination:** 12/2004  
**Last Review:** 6/2017  
**Next Review:** 6/2018

**Policy**
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for hematopoietic stem-cell transplantation for primary amyloidosis when it is determined to be medically necessary because the criteria shown below are met.

**When Policy Topic is covered**
Autologous stem-cell transplantation may be considered **medically necessary** to treat primary systemic amyloidosis.

**When Policy Topic is not covered**
Allogeneic stem-cell transplantation is considered **investigational** to treat primary systemic amyloidosis.

**Considerations**
In 2003, CPT centralized codes describing allogeneic and autologous hematopoietic cell transplantation services to the hematology section (38204-38242). Not all codes are applicable for each stem cell transplant procedure. For example, Plans should determine if cryopreservation is performed. A range of codes describes services associated with cryopreservation, storage, and thawing of cells (38207-38215).

CPT 38208 and 38209 describe thawing and washing of cryopreserved cells  
CPT 38210-38214 describe certain cell types being depleted  
CPT 38215 describes plasma cell concentration.

**Description of Procedure or Service**

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Individuals:  
  • With primary amyloidosis | Interventions of interest are:  
  • Autologous hematopoietic cell transplantation | Comparators of interest are:  
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  • Disease-specific survival  
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Hematopoietic cell transplantation (HCT) refers to the infusion of hematopoietic stem cells 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).

For individuals who have primary amyloidosis who receive autologous HCT, the evidence includes a randomized controlled trial (RCT), nonrandomized comparative studies, and large case series. Relevant outcomes are overall survival, disease-specific survival, change in disease status, treatment-related morbidity and treatment-related mortality. Use of autologous HCT for primary amyloidosis rapidly eradicates the amyloid light chain produced by the clonal plasma cell populations, which is the proximal cause of pathology and subsequent death. This procedure has extended survival rates to a reported 77% at 5 years and 56% at 10 years in patients who respond to treatment. Complete response to treatment has been reported in 34% to 66% of patients, while transplant-related mortality rates have declined to less than 14% in current studies. Therefore, autologous HCT is an important treatment option for patients who are deemed eligible. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary amyloidosis who receive allogeneic HCT, the evidence includes case reports. Relevant outcomes are overall survival, disease-specific survival, change in disease status, treatment-related morbidity and treatment-related mortality. Evidence on the use of allogeneic HCT is sparse and shows high treatment-related mortality. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input and national and international clinical guidelines support the use of autologous HCT as a treatment of amyloidosis. For primary amyloidosis, allogeneic HCT is not recommended. Thus, autologous HCT may be considered medically necessary for primary amyloidosis and allogeneic HCT for primary amyloidosis is considered investigational.

**Background**

**Primary Systemic Amyloidosis**
The primary amyloidoses comprise a group of diseases with an underlying clonal plasma cell dyscrasia. They are characterized by the extracellular deposition of pathologic, insoluble protein fibrils with a beta-pleated sheet configuration that exhibit a pathognomonic red-green birefringence when stained with Congo red dye and examined under polarized light. These diseases are classified on the basis of the type of amyloidogenic protein involved and by the distribution of amyloid deposits. In systemic amyloidosis, the unnatural protein is produced at a site that is remote from the site(s) of deposition, whereas in localized disease, the amyloid light chain (AL) protein is produced at the site of deposition. Primary or AL amyloidosis, the most common type of systemic amyloidosis, has an incidence similar to that of Hodgkin lymphoma or chronic myelogenous leukemia, estimated at 5 to 12 people per million annually. The median age at diagnosis is 60 years. The amyloidogenic protein in primary amyloidosis is an immunoglobulin light chain or light-chain fragment produced by a clonal population of plasma cells in the bone marrow. While the plasma cell burden in primary amyloidosis is typically low, ranging from 5% to 10%, this disease also may occur in association with multiple myeloma in 10% to 15% of patients. Deposition of primary amyloidogenic proteins causes organ dysfunction, most frequently in the kidneys, heart, and liver, although the central nervous system and brain may be affected.

Historically, this disease has had a poor prognosis, with a median survival from diagnosis of approximately 12 months, although outcomes have improved with combination chemotherapy using alkylating agents and autologous hematopoietic cell transplantation (HCT). Emerging approaches include the use of immunomodulating drugs (eg, thalidomide, lenalidomide) and the proteasome inhibitor bortezomib. Regardless of the approach, treatment of primary amyloidosis aims at rapidly reducing the production of amyloidogenic monoclonal light chains by suppressing the underlying plasma cell dyscrasia, with supportive care to decrease symptoms and maintain organ function. The therapeutic index of any chemotherapy regimen is a key consideration in the context of underlying organ dysfunction.

Hematopoietic Cell Transplantation
Hematopoietic cell transplantation refers to in the infusion of hematopoietic stem cells 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 “naive” and thus are associated with a lower incidence of rejection or graft-versus-host disease (GVHD). Cord blood is discussed in greater detail in separate policy.

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 allogeneic HCT. Compatibility is established by typing human leukocyte antigen
(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.

**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 (GVM) effect that develops 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 pretransplant conditioning. However, intense conditioning regimens are limited to patients who are sufficiently fit medically to tolerate substantial adverse effects 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 GVHD, which also increases susceptibility 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 response. Patients who undergo autologous HCT are susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not GVHD.

**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 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 treatment-related morbidity and nonrelapse 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 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.

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

**Rationale**
This evidence review was originally created in October 2003 and has been updated regularly with searches of the MEDLINE and EMBASE databases. The most recent literature update was performed through October 13, 2016.

Chemotherapy for the treatment of light-chain amyloidosis was introduced in 1972 in the form of melphalan and prednisone. This chemotherapy regimen has yielded higher response and longer survival rates than colchicine or prior therapies. Survival after oral melphalan with prednisone (typically 12-18 months) is longer than for untreated patients or those given older therapies (10-14 months), but more effective regimens have been sought. Combination therapy with vincristine, doxorubicin, and dexamethasone (VAD), a well-established regimen for myeloma, has been investigated. However, because of its toxicity, VAD therapy usually is limited to patients without peripheral neuropathy or cardiomyopathy, both common complications of amyloidosis.

Because conventional regimens rarely cure systemic amyloidosis, and because of the close biologic similarity to multiple myeloma, myeloablative chemotherapy with autologous hematopoietic stem transplantation (HCT) is being investigated for this disease. Following is a summary of key literature to date.

**Autologous HCT**
Initial results of autologous HCT in uncontrolled patient series were published in 1998. Clinical response rates (50%-60%) were nearly twice those reported for conventional therapy, and 2-year survival ranged from 56% to 68%. Kaplan-Meier analysis of a matched comparison study (63 pairs) showed greater overall survival (OS) for those given autotransplants (71% at 4 years) than for patients who were eligible for transplantation but managed conventionally (41%; p=0.004). However, procedure-related mortality rates of 15% to 43% were substantially higher than those observed in myeloma patients, usually in cases involving more than 2 organ systems or symptomatic cardiac involvement.

**Randomized Controlled Trials**
One randomized multicenter trial from the Myelome Autogreffe and Intergroupe Francophone du Myelome Intergroup compared conventional chemotherapy (melphalan plus dexamethasone, n=50) to myeloablative melphalan followed by autologous HCT (n=50). Randomization was stratified by age (<65 years or ≥65 years) and the affected organ system (cardiac, renal, neurologic, other). Of note,
approximately two-thirds of patients had 2 or more organs affected. Hematopoietic stem cells were obtained from peripheral blood following granulocyte colony-stimulating factor (G-CSF) mobilization. According to intention-to-treat (ITT) analysis, the hematologic response rate did not differ between groups, with 12 complete responses (CR; 24%) and 14 partial responses (28%) in the chemotherapy recipients versus 11 CR (22%) and 7 partial responses (14%) in the HCT group (p=0.11). At a median follow-up of 24 months, 20 patients in the chemotherapy group had died versus 31 in the autologous HCT group. Among 65 patients who could be evaluated, the ITT median survival for patients assigned to chemotherapy was 56.9 months, versus 22.2 months in the autologous HCT group (p=0.04). Analysis of patients who survived for at least 6 months and who received their assigned treatment, showed no significant difference in survival rates between treatments.

Although this randomized controlled trial (RCT) suggested that autologous HCT may be no more efficacious than conventional chemotherapy in prolonging survival, the results were limited by the proportion of patients not receiving treatment. Among 50 patients assigned to autologous HCT, 13 (26%) did not receive the planned treatment (1 declined, 2 had insufficient stem cell harvest, 10 died before treatment), while 7 (14%) of 50 assigned to chemotherapy did not receive planned treatment (5 died before treatment, 1 did not tolerate treatment, 1 received incorrect treatment).

Nonrandomized Comparative Studies
A retrospective comparative analysis from a single treatment center published in 2014 provides long-term evidence for improved survival among patients with AL amyloidosis who underwent autologous HCT compared with conventional therapies (CTR).11 Patients underwent autologous HCT (n=80) or CTR (n=65) following induction therapy. Patients were heterogeneous with respect to age, organ involvement, cardiac involvement, renal involvement, and percent of bone marrow blast cells; all were significantly overrepresented in the CTR group compared with the HCT group. Median follow-up was 3 years for the entire cohort, with some survivors followed for up to 14 years postdiagnosis. Median 5-year survival was 63% in the HCT group compared with 38% in the CTR group (p<0.001); median survival at 10 years was 56% in the HCT group and 10% in the CTR group (p<0.001). Among HCT recipients, the transplant-related mortality rate was 7.5% at 100 days and 12.5% within 1 year of transplant.

Observational Studies
The evidence has also suggested improvement in symptoms for amyloidosis patients treated with autologous HCT in addition to survival benefits (see Table 1).

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>N</th>
<th>FU</th>
<th>N at FU</th>
<th>CR Rate</th>
<th>OS Rate</th>
<th>Median Survival</th>
<th>TRM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skinner et al</td>
<td>312</td>
<td>≥1</td>
<td>181</td>
<td>40%</td>
<td>4.6 y</td>
<td>13%</td>
<td></td>
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</tbody>
</table>
In a series of 312 amyloidosis patients eligible for transplant, estimated median survival was 4.6 years. Of 181 evaluable patients (alive and followed-up for ≥1 year), 40% achieved complete hematologic response, defined as no evidence of plasma cell dyscrasia at 1 year after transplant with functional improvement in at least 1 affected organ.

A registry analysis evaluated 107 amyloidosis patients who received transplants between 1995 and 2001 at 48 centers. For those with no or 1 organ involved at transplant, survival at 1 year was 72%, while for those with 2 or more organs involved, survival at 1 year was 54%. Treatment-related mortality at 30 days was mostly among patients with cardiac and/or multiple organ involvement.

Patients with primary amyloidosis and cardiac involvement were treated in a series from a single center. Overall, hematologic and cardiac responses were observed in 66% and 41% of patients, respectively.

A series of 421 consecutive patients treated with HCT at a single referral center compared outcomes for patients with and without a CR. Eighty-one patients died within the first year after HCT and were not evaluable for hematologic and organ response. Of 340 evaluable patients, 43% achieved CR and 78% of them experienced an organ response. Thus, treatment of selected AL amyloidosis patients with autologous HCT resulted in high organ response and longer OS rates, even for those patients who did not achieve CR. These results are compatible with others previously cited.

Several additional retrospective and prospective series have been reported on the use of autologous HCT in patients with primary amyloidosis. Results from these series are consistent with others that have suggested autologous HCT is feasible and beneficial in selected patients with primary amyloidosis.
Long-term survival and outcomes were evaluated in a series of 80 patients. Among the 32 patients who achieved CR, median survival had not been reached at the time of reporting. In contrast, the median survival for patients who failed to achieve a CR was 50 months, with a 6% estimated probability of survival at 10 years (p<0.001 vs patients with CR).

A 2015 report from the Center for International Blood and Marrow Transplant Research (CIBMTR) study identified 1536 patients with amyloidosis who had undergone autologous HCT between 1995 and 2012. Early mortality and OS were analyzed for 3 time cohorts: 1995 to 2000, 2001 to 2001, and 2007 to 2012. Over this time period, OS improved from 55% to 77%, while early mortality decreased from 20% to 5%. Multivariate analysis showed that cardiac involvement was associated with high mortality and inferior OS. Higher doses of melphalan were associated with a lowered relapse risk.

**Section Summary: Autologous HCT**
The evidence related to autologous HCT for the treatment of primary amyloidosis includes an RCT, nonrandomized comparative studies, and large case series. The RCT has a number of limitations, and its results are insufficient to determine the effect of the treatment. A retrospective comparison with 10-year follow-up showed a considerable survival advantage for patients treated with HCT. Although retrospective, with evident interstudy patient heterogeneity, this report suggested autologous HCT may yield long-term survival benefits in patients with this disease. Additional case series have shown a CR rate ranging from 34% to 66%, with a clear survival advantage in patients who achieve a CR. Patients who do not achieve a CR may obtain some benefits in organ function. Treatment-related mortality rates from the CIBMTR study have decreased to 5% in recent years, but remain between 11% and 16% in other studies.

**Allogeneic HCT**
Evidence on the use of allogeneic HCT to treat primary amyloidosis is sparse, with no systematic evaluation in a clinical trial. Concerns about the use of allogeneic HCT include high treatment-related mortality (>40%), morbidity secondary to graft-versus-host disease, and the efficacy of a proposed graft-versus-malignancy effect on low-grade plasma cell dyscrasias.

**Summary of Evidence**
For individuals who have primary amyloidosis who receive autologous hematopoietic cell transplantation (HCT), the evidence includes a randomized controlled trial (RCT), nonrandomized comparative studies, and large case series. Relevant outcomes are overall survival, disease-specific survival, change in disease status, treatment-related morbidity and treatment-related mortality. Use of autologous HCT for primary amyloidosis rapidly eradicates the amyloid light chain produced by the clonal plasma cell populations, which is the proximal cause of pathology and subsequent death. This procedure has extended survival rates to a reported 77% at 5 years and 56% at 10 years in patients who respond to treatment. Complete response to treatment has been reported in 34% to 66% of patients, while transplant-related mortality rates have declined to less than 14% in
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Supplemental Information

Clinical Input 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 5 academic medical centers, including 3 transplant centers, while this policy was under review in 2011. There was support for the policy statements on hematopoietic stem transplantation in the treatment of amyloidosis.

Practice Guidelines and Position Statements

American Society for Blood and Marrow Transplantation
In 2015, the American Society for Blood and Marrow Transplantation (ASBMT) issued guidelines on the indications for autologous and allogeneic hematopoietic cell transplantation (HCT). ASBMT gave the rating of N (not generally recommended; neither evidence nor clinical practice support the routine use) for the use of allogeneic HCT for the treatment of primary amyloidosis in adults. ASBMT gave a rating of C (standard of care; clinical evidence available) for the use of autologous HCT in the treatment of primary amyloidosis in adults.

British Committee for Standards in Haematology
The British Committee for Standards in Haematology convened a working group to develop guidelines on the management of light chain (primary) amyloidosis. Below is a summary of the recommendations from 2015 guidelines on high-dose melphalan and autologous stem cell transplantation (HDM-ASCT) and allogeneic transplantation as treatments of primary amyloidosis:

- HDM-ASCT recommended as “the preferred first line treatment for patients up to 65-70 years of age with estimated glomerular filtration rate (eGFR) >50 ml/min, low cardiac biomarkers, low level plasma cell infiltration in bone marrow at time of transplant and lacking the contraindications ...(Grade 1c) ...
with any of the following: Cardiac amyloidosis with N-terminal pro-brain natriuretic peptide >590 pmol/l and/or troponin-T > 0.06 ng/ml, severe autonomic neuropathy, significant gastrointestinal (GI) bleeding due to amyloid, ... recurrent amyloid related pleural effusions or poor Eastern Cooperative Oncology Group performance status (>2) (Grade 1c).”

“HDM-ASCT may be a treatment for selected patients up to 65-70 years of age with relapsed/refractory disease or with early relapse of plasma cell dyscrasia after chemotherapy (Grade 1c).”

“Reduced intensity allogeneic transplantation is generally not recommended as an upfront treatment due to high treatment-related mortality (TRM). However, selected fitter younger patients with limited organ involvement who have a matched sibling donor may be considered following relapse of their disease. (Grade 1a).”

**National Comprehensive Cancer Network**

National Comprehensive Cancer Network guidelines (v 2.2017) on multiple myeloma include as a recommended primary treatment option high-dose melphalan followed by autologous stem cell transplant (category 1 evidence). In eligible patients, high-dose chemotherapy along with autologous stem cell support has been associated with higher response rates and improved overall survival compared to standard chemotherapy. The guidelines note that, in select patients, allogeneic stem cell transplant may be considered in relapsed patients, though heavily pretreated patients are unlikely to benefit. The guidelines also caution that the optimal therapy is not established and that such treatment would best be performed in a clinical trial.

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

Not applicable.

**Medicare National Coverage**

The Centers for Medicare and Medicaid Services has determined that the evidence is adequate to conclude that, when recognized clinical risk factors are employed to select patients for transplantation, high-dose melphalan together with autologous stem cell transplantation can provide a net health benefit for Medicare beneficiaries of any age group with primary amyloidosis. This technique

“is reasonable and necessary for patients of any age with primary AL amyloidosis who meet the following criteria:

- amyloid deposition in 2 or fewer organs, and
- cardiac left ventricular ejection fraction (EF) of greater than 45%.

To clarify existing coverage, autologous stem cell transplant must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy and/or radiotherapy used to treat various malignancies.
Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. 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>NCT02257905</td>
<td>Allo SCT in Amyloidosis Non-interventional Study</td>
<td>14</td>
<td>Jul 2015</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

References


**Billing Coding/Physician Documentation Information**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>38204</td>
<td>Management of recipient hematopoietic progenitor cell donor search and cell acquisition</td>
</tr>
<tr>
<td>38205</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic</td>
</tr>
<tr>
<td>38206</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous</td>
</tr>
<tr>
<td>38207</td>
<td>Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage</td>
</tr>
<tr>
<td>38208</td>
<td>Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing</td>
</tr>
<tr>
<td>38209</td>
<td>Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing</td>
</tr>
</tbody>
</table>
Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion

Transplant preparation of hematopoietic progenitor cells; tumor cell depletion

Transplant preparation of hematopoietic progenitor cells; red blood cell removal

Transplant preparation of hematopoietic progenitor cells; platelet depletion

Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion

Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer

Bone marrow; aspiration only

Bone marrow; biopsy, needle or trocar

Bone marrow harvesting for transplantation; allogeneic

Bone marrow harvesting for transplantation; autologous

Bone marrow or blood-derived peripheral stem cell transplantation; allogenic

Bone marrow or blood-derived peripheral stem cell transplantation; autologous

Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic donor lymphocyte infusions

Cord blood harvesting for transplantation, allogeneic

Cord blood-derived stem

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 pre- and post-transplant care in the global definition

ICD-10 Codes

E85.0- Amyloidosis code range (this policy would exclude E85.3 secondary systemic and E85.4 organ limited as they are not primary systemic)

E85.9

Additional Policy Key Words

N/A

Policy Implementation/Update Information

12/1/04  New policy. Added to Surgery and Transplant sections
12/1/05  No policy statement change
4/1/06  Considerations section revised to include general criteria.
12/1/06  No policy statement changes.
12/1/07  No policy statement changes.
12/1/08  “High-dose chemotherapy” removed from policy title and policy statements. “Stem-cell transplantation” (SCT) now used instead of
“stem-cell support” (SCS) in policy and policy statements. Allogeneic SCT added to policy statements as investigational; no change in policy statements for auto-SCT.

12/1/09  No policy statement changes.
12/1/10  No policy statement changes.
12/1/11  Waldenstrom macroglobulinemia moved from this policy into a new policy No. 8.01.54. Policy statements unchanged.
6/1/12  No policy statement changes.
6/1/13  No policy statement changes.
6/1/15  No policy statement changes.
6/1/16  No policy statement changes.
6/1/17  No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.