Hematopoietic Stem-Cell Transplantation for Miscellaneous Solid Tumors in Adults

Policy Number: 8.01.24  Last Review: 12/2016

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for hematopoietic stem-cell transplantation for miscellaneous solid tumors in adults. This is considered investigational.

When Policy Topic is not covered
Autologous or allogeneic stem-cell transplant is **investigational** for the following malignancies in adults:
- Cancer of the bile duct
- Cancer of the fallopian tubes
- Cervical cancer
- Colon cancer
- Esophageal cancer
- Gall bladder cancer
- Lung cancer, any histology
- Malignant melanoma
- Nasopharyngeal cancer
- Neuroendocrine tumors
- Pancreas cancer
- Paranasal sinus cancer
- Prostate cancer
- Rectal cancer
- Renal cell cancer
- Soft tissue sarcomas
- Stomach cancer
- Thyroid tumors
- Tumors of the thymus
- Tumors of unknown primary origin
Uterine cancer

### Description of Procedure or Service

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<th>Populations</th>
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<th>Comparators</th>
<th>Outcomes</th>
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Hematopoietic stem-cell transplantation (HSCT) is an established treatment for certain hematologic malignancies and has been investigated for a variety of adult solid tumors. Interest continues in exploring nonmyeloablative allogeneic HSCT for a graft-versus-tumor effect of donor-derived T cells in metastatic solid tumors.

The evidence for HSCT for individuals who have small cell lung cancer (SCLC) includes a Blue Cross and Blue Shield Association (BCBSA) TEC Assessment, several randomized controlled trials (RCTs), and systematic reviews of these studies. Relevant outcomes include overall survival, disease-specific survival, and treatment-related morbidity and mortality. 1995 and 1999 TEC Assessments focusing on HSCT as primary and salvage therapy for a variety of solid tumors found that the available evidence did not permit conclusions about the effect of HSCT on patient survival. Studies published since the TEC Assessments have not reported increased overall survival for patients with SCLC treated with HSCT. The currently available evidence does not support the use of HSCT for SCLC.

The evidence for HSCT for individuals who have adult soft tissue sarcomas includes a BCBSA TEC Assessment, 1 RCT, and a number of phase 2 single arm studies, a number of which have been summarized in a Cochrane systematic review. Relevant outcomes include overall survival, disease-specific survival, and treatment-related morbidity and mortality. 1995 and 1999 TEC Assessments focusing on HSCT as primary and salvage therapy for a variety of solid tumors found that the available evidence did not permit conclusions about the effect of HSCT on patient survival. Although one small phase 2 study reported longer survival for patients treated with HSCT than standard chemotherapy, the available RCT did not show a survival benefit with HSCT. The evidence is insufficient to determine that autologous HSCT improves outcomes in adults with soft tissue sarcoma.

The evidence for HSCT for individuals who have renal cell cancer, colorectal cancer, pancreatic cancer, or nasopharyngeal cancer includes a BCBSA TEC Assessment and small single-arm series. Relevant outcomes include overall survival, disease-specific survival, and treatment-related morbidity and mortality. 1995 and 1999 TEC Assessments focusing on HSCT as primary and salvage therapy for a variety of solid tumors found that the available evidence did not permit conclusions about the effect of HSCT on patient survival. Since the publication of the TEC Assessments, the evidence for HSCT adult soft tissue sarcomas, renal cell carcinoma, colorectal cancer, pancreatic cancer, and nasopharyngeal cancer has been limited to small case series, which are insufficient to demonstrate improved outcomes with autologous or allogeneic HSCT.

**HSCT**

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

Immunologic compatibility between infused stem cells and the recipient is not an issue in autologous HSCT. However, immunologic compatibility between donor and patient is a critical factor for achieving a good outcome of allogeneic HSCT. 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 class I and class II loci on chromosome 6. Depending on the disease being treated, an acceptable donor will match the patient at all or most of the HLA loci (with the exception of umbilical cord blood).

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

The success of autologous HSCT 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 HSCT is typically performed as consolidation therapy when the patient’s disease is in CR. Patients who undergo autologous HSCT are susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not GVHD.

**Reduced-Intensity Conditioning for Allogeneic SCT**
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 traditional full-dose myeloablative conditioning treatments. The goal of RIC is to reduce disease burden but also to minimize as much as possible associated treatment-related morbidity and nonrelapse 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 HSCT 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 evidence review, RIC will refer to all conditioning regimens intended to be nonmyeloablative, as opposed to fully myeloablative (conventional) regimens.

**SCT in Solid Tumors in Adults**

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

Hematopoietic SCT as a treatment either of breast, ovarian, ependymoma, or malignant glioma is addressed in separate policies. This evidence review collectively addresses other solid tumors of adults for which SCT has been investigated, including lung cancer; malignant melanoma; tumors of the gastrointestinal tract (include colon, rectum, pancreas, stomach, esophagus, gallbladder, and bile duct); male and female genitourinary systems (e.g., renal cell carcinoma, cervical carcinoma, cancer of the uterus, fallopian tubes, and prostate gland); tumors of the head and neck; soft tissue sarcoma; thyroid tumors; tumors of the thymus; and tumors of unknown primary origin.

**Rationale**

This evidence review was created based on a 1995 TEC Assessment (described next) and has been updated periodically with literature reviews, most recently through October 27, 2015.

This evidence review was initially based on a 1995 TEC Assessment that focused on section adult solid tumors other than breast cancer, epithelial ovarian cancer, germ cell tumors, and glial-cell-derived brain cancers. Solid tumors reported in the literature identified in the Assessment included lung cancers, melanoma, tumors of gastrointestinal organs, genitourinary system tumors, tumors of the
head and neck, soft tissue sarcomas of the extremities and torso, thyroid tumors, tumors of the thymus, undifferentiated tumors, and tumors of unknown primary. The Assessment offered the following conclusions:

- While 125 articles were identified that reported on the results of hematopoietic stem cell transplantation (HSCT) in a variety of solid tumors, only 17 included survival data from groups of patients with the same cancer. These studies reported on 4 indications: advanced small-cell lung cancer, advanced colorectal cancer, malignant melanomas, and inoperable gastric cancer.
- The evidence did not permit conclusions as to the effect of HSCT on patient survival.

A 1999 TEC Assessment evaluated the use of allogeneic HSCT as a salvage therapy after a failed autologous HSCT for solid tumors. Data were inadequate to permit conclusions.

**Autologous HSCT in Solid Tumors of Adults**

Data on the use of autologous HSCT for the solid tumors of adults addressed in this policy consists primarily of small series.

**Adult Soft Tissue Sarcomas**

The prognosis of patients with unresectable or metastatic soft tissue sarcomas is poor, with a median survival of approximately 1 year and less than a 10% 5-year survival. A variety of single-agent and combination regimens are used for treatment, with targeted therapies available for some subtypes. Based on initial observations as it was shown that patients who achieved complete remission (CR) had longer survival; several phase 1 and 2 trials using autologous HSCT were conducted in the 1990s in an attempt to improve outcomes. These trials were composed of small numbers of patients (range, 2-55 patients), yielding overall response rates from 20% to 65%, with CR from 10% to 43%. The longest reported 5-year progression-free survival (PFS) rate was 21%, and 5-year OS was 32%. One study of 21 patients with soft tissue sarcoma showed a PFS and OS benefit only in patients with no evidence of disease before undergoing HSCT. In another phase 2 study, 21 of 55 (38%) patients responded to doxorubicin-based induction chemotherapy (14% vs 3%; p=0.003), but estimated OS was not statistically different between those who received an autologous HSCT and those who did not.

In 2014, a Cochrane systematic review evaluated the use of autologous HSCT following high-dose chemotherapy for nonrhabdomyosarcoma soft tissue sarcomas. The authors included 62 studies reporting on 294 transplanted patients, with a variety of soft tissue sarcomas. One randomized controlled trial (RCT), including 83 patients, was identified; the remaining studies were single-arm studies. In the RCT, OS was not statistically significantly different between autologous HSCT following high-dose chemotherapy compared with standard-dose chemotherapy (hazard ratio [HR], 1.26; 95% confidence interval [CI], 0.70 to 2.29; p=0.44), and the point estimate for survival at 3 years was 32.7%.
compared with 49.4%. The pooled treatment-related mortality rate across the single-arm studies was 15 of 294 (5.1%).

A small number of studies not included in the Cochrane review have described outcomes after HSCT for soft tissue sarcoma. Kasper et al reported the results of a prospective, single-institution phase 2 study that enrolled 34 patients with advanced and/or metastatic soft tissue sarcoma. After 4 courses of chemotherapy, patients with at least a partial response underwent high-dose chemotherapy and autologous HSCT (n=9). All other patients continued chemotherapy for 2 more cycles. The median PFS for patients treated with HSCT was 11.6 months (range, 8-15 months) versus 5.6 months for patients treated with standard chemotherapy (p=0.047) and median OS for the 2 groups was 23.7 months (range, 12-34 months) versus 10.8 months (range 0-39 months) (p=0.027), respectively.

Hartmann et al reported results from a phase 2 study of high-dose chemotherapy with ifosfamide, carboplatin, and etoposide followed by peripheral blood stem cell transplantation in patients with grade 2 or 3 histologically proven soft tissue sarcoma that were considered unresectable or marginally resectable. After a median follow-up period of 50 months (range, 26-120 months) in surviving patients, the median PFS of all patients was 21 months (range, 1-94 months) and median OS was 37 months (range, 3-120 months), corresponding to 5-year PFS and OS rates of 39 % and 48 %, respectively.

One case report of the use of allogeneic HSCT for treatment of an adult histiocytic sarcoma was identified, in which the patient was alive with no evidence of disease 30 months posttreatment.

Overall, one RCT and several small phase 2 studies have reported outcomes after autologous HSCT in adult patients with soft tissue sarcoma. Although one small phase 2 study reported longer survival for patients treated with HSCT than standard chemotherapy, the available RCT did not show a survival benefit with HSCT. The evidence is insufficient to determine that autologous HSCT improves outcomes in adults with soft tissue sarcoma.

**Small-Cell Lung Carcinoma**

The interest in treating small-cell lung carcinoma (SCLC) with HSCT stems from the extremely high chemosensitivity and poor prognosis of this tumor type. A phase 3 trial of 318 patients with SCLC randomly assigned patients to standard chemotherapy or HSCT. No statistically significant difference in response rates was seen between the 2 groups (80% response rate in the standard arm vs 88% in the HSCT group; difference, 8%; 95% CI, -1% to 17%; p=0.09). There was no statistically significant difference in OS between the 2 groups, with a median OS of 13.9 months in the standard arm (95% CI, 12.1 to 15.7 months) versus 14.4 months in the HSCT arm (95% CI, 13.1 to 15.4; p=0.76). One smaller,
randomized study and several single-arm studies of HSCT and autologous HSCT for SCLC are summarized in a review article.\textsuperscript{14} Overall, most of the data from these studies, including the randomized study, showed no increased OS with autologous HSCT.

Jiang et al performed a meta-analysis of the medical literature through October 2008 of English-language studies using intensified chemotherapy with autologous hematopoietic progenitors to treat SCLC.\textsuperscript{15} The meta-analysis consisted of 5 RCTs (3 phase 3 trials, 2 phase 2), for a total of 641 patients. They found no significant increase in the odds ratio for response rate with autologous transplant versus control chemotherapy (odds ratio, 1.29; 95% CI, 0.87 to 1.93; \( p=0.206 \)). No statistically significant increase in OS was seen among the autologous transplant patients compared with control regimens (HR=0.94; 95% CI, 0.80 to 1.10; \( p=0.432 \)). The authors concluded that current evidence does not support the use of intensified chemotherapy and autologous HSCT for treating SCLC.

**Miscellaneous**

Uncontrolled pilot studies of HSCT for patients with refractory urothelial carcinoma\textsuperscript{16} and recurrent or advanced nasopharyngeal carcinoma\textsuperscript{17} did not demonstrate adequate evidence of improved outcomes to alter previous conclusions. In a small series (\( n=8 \)) of bilateral retinoblastoma survivors with secondary osteosarcoma, 2 patients (of 7 treated with multimodal chemotherapy) received high-dose chemotherapy with autologous peripheral blood stem cell support.\textsuperscript{18} The 2 HSCT-treated patients were alive with no evidence of disease at 33.4 and 56.4 months of follow up.

**Allogeneic HSCT in Solid Tumors of Adults**

Single-case reports and small series of patients with various types of solid tumors have been treated with allogeneic HSCT, including some of the tumor types addressed in this policy.\textsuperscript{19,1,20}

**Renal Cell Carcinoma**

Metastatic renal cell carcinoma (RCC) has an extremely poor prognosis, with a median survival of less than 1 year and a 5-year survival of less than 5%.\textsuperscript{21} RCC is relatively resistant to chemotherapy but is susceptible to immune therapy, and interleukin-2 and/or interferon-\( \alpha \) have induced responses and long-term PFS in 4% to 15% of patients.\textsuperscript{20} In addition, 7 targeted therapies have Food and Drug Administration (FDA) approval for treatment of advanced RCC: sunitinib, sorafenib, pazopanib, axitinib, temsirolimus, everolimus, and bevacizumab.\textsuperscript{22} Based on the susceptibility of RCC to immune therapies, the immune-based strategy of a graft-versus-tumor effect possible with an allogeneic transplant has led to an interest in its use in RCC. In 2000, Childs et al published the first series of patients with RCC treated with nonmyeloablative allogeneic HSCT.\textsuperscript{21} The investigators showed regression of the tumor in 10 of 19 (53%) patients with cytokine-refractory, metastatic RCC who received an human leukocyte antigen (HLA)–identical sibling allogeneic HSCT. Three patients had a CR and remained in
remission 16, 25, and 27 months after transplant. Four of 7 patients with a partial response were alive without disease progression 9 to 19 months after transplantation. Other pilot trials have demonstrated the graft-versus-tumor effect of allogeneic transplant in metastatic RCC, but most have not shown as high a response rate as the Childs study. Overall response rates in these pilot trials have been approximately 25%, with CR rates of approximately 8%. Prospective, randomized trials are needed to assess the net impact of this technique on the survival of patients with cytokine-refractory RCC.

Bregni et al assessed the long-term benefit of allografting in 25 patients with cytokine-refractory metastatic RCC who received an RIC allograft from a sibling who is HLA identical. All patients received the same conditioning regimens. Response to allograft was available in 24 patients, with a CR in 1 patient and partial response in 4 patients. Twelve patients had minor response or stable disease, and 7 had progressive disease. Overall response rate (complete plus partial) was 20%. Six patients died because of transplant-related mortality. Median survival was 336 days (range, 12-2332+ days). One-year OS was 48% (95% CI, 28% to 68%), and 5-year OS was 20% (95% CI, 4% to 36%). The authors concluded that allografting is able to induce long-term disease control in a small fraction of cytokine-resistant patients with RCC but that with the availability of novel targeted therapies for RCC, future treatment strategies should consider the incorporation of these therapies into the transplant regimen.

Colorectal Carcinoma

Aglietta et al reported their experience with 39 patients with metastatic colorectal cancer who underwent reduced-intensity conditioning (RIC) allogeneic HSCT between 1999 and 2004 at 9 European Group for Blood and Marrow Transplantation (EBMT) centers. Patients were treated with 1 of 5 different RIC regimens. End points that were assessed were achievement of mixed chimerism, incidence graft-versus-host disease (GVHD), treatment-related mortality and toxicities, OS, and time to treatment failure (in patients who responded to the therapy). Patient population characteristics were heterogeneous; pretransplant disease status was partial response in 2 patients, stable disease in 6 patients, and progressive disease in 31. Thirty-eight patients (97%) had been previously treated, some with only chemotherapy and others with surgery and/or chemotherapy. After transplant, tumor responses were complete and partial in 2% and 18% of patients, respectively, and 26% of patients had stable disease, for overall disease control in 46% of patients. Transplant-related mortality was 10%. Median overall follow-up was 202 days (range, 6-1020 days), after which time 33 patients had died and 6 were still alive. Tumor progression was the cause of death in 74% of patients. A comparison of OS of patients was performed after stratifying by some potential prognostic factors. Achievement of response after transplantation was associated with a difference in OS, with the 18 patients who had a response having a median OS of approximately 400 days versus approximately 120 days for those who had no response (p<0.001). The authors concluded that the HSCT approach should probably be reserved for patients with a partial response or stable disease after second-line therapy for metastatic
Pancreatic Cancer
Kanda et al reported on the efficacy of RIC allogeneic HSCT against advanced pancreatic cancer in 22 patients from 3 transplantation centers in Japan.  

The RIC regimens differed among the centers, and the patient population was fairly heterogeneous, with 15 patients having metastatic disease and 7 locally advanced disease. All but 1 patient received chemotherapy of various combinations before transplant, and 10 patients received local radiation. After HSCT, 1 patient achieved CR, 2 patients had partial response, 2 had minor response, and 8 had stable disease, with an overall response rate of 23%. Median survival was 139 days, and the major cause of death was tumor progression (median duration of survival in advanced pancreatic cancer in the nontransplant setting is less than 6 months, even in patients treated with gemcitabine). Only 1 patient survived longer than 1 year after transplantation. The authors concluded that a tumor response was observed in one fourth of patients with advanced pancreatic cancer who underwent HSCT and that the response was not durable. However, they felt their observation of a relationship between longer survival and the infusion of a higher number of CD34-positive cells or the development of chronic GVHD warranted future studies to enhance the immunologic effect against pancreatic cancer.

Abe et al reported the outcomes for 5 patients with chemotherapy-resistant, unresectable pancreatic adenocarcinoma who received a nonmyeloablative allogeneic peripheral blood HSCT. The conditioning regimen consisted of fludarabine and low-dose total body irradiation. The median patient age was 54 years (range, 44-62 years). All patients had advanced disease, either with metastases or peritonitis, and had received at least 1 course of chemotherapy including gemcitabine. After HSCT, tumor response was only observed in 2 patients—one had complete disappearance of the primary tumor and 1 had a 20% reduction in tumor size; the remaining patients had progressive disease (n=2) or stable disease (n=1). Four patients died of progressive disease, ranging from posttransplant day 28 to day 209 (median, 96 days). One patient died at day 57 secondary to rupture of the common bile duct from rapid tumor regression. The authors concluded that their study showed a graft-versus-tumor effect but that to obtain durable responses, an improved conditioning regimen and new strategies to control tumor growth after nonmyeloablative allogeneic HSCT are needed.

Nasopharyngeal Carcinoma
Toh et al reported the outcomes of a phase 2 trial of 21 patients with pretreated metastatic nasopharyngeal carcinoma. Median patient age was 48 years (range, 34-57 years), and patients had received a median of 2 previous chemotherapy regimens (range, 1-8 regimens). All patients had extensive metastases. Patients underwent a nonmyeloablative allogeneic HSCT with sibling allografts. Seven patients (33%) showed a partial response and 3 (14%) achieved stable disease. Four patients were alive at 2 years, and 3 showed prolonged disease control of colorectal cancer and that second-generation clinical trials in these patients are warranted.
344, 525, and 550 days. After a median follow-up of 209 days (range, 4-1147 days), the median PFS was 100 days (95% CI, 66 to 128 days), and median OS was 209 days (95% CI, 128 to 236 days). One- and 2-year OS rates were 29% and 19%, respectively, comparable with the median 7- to 14-month OS for metastatic nasopharyngeal patients in the literature treated with salvage chemotherapy without HSCT.

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 1.

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<td>NCT00011921</td>
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NCT: national clinical trial.

**Summary of Evidence**
The evidence for HSCT for individuals who have small cell lung cancer (SCLC) includes a Blue Cross and Blue Shield Association (BCBSA) TEC Assessment, several randomized controlled trials (RCTs), and systematic reviews of these studies. Relevant outcomes include overall survival, disease-specific survival, and treatment-related morbidity and mortality. 1995 and 1999 TEC Assessments focusing on HSCT as primary and salvage therapy for a variety of solid tumors found that the available evidence did not permit conclusions about the effect of HSCT on patient survival. Studies published since the TEC Assessments have not reported increased overall survival for patients with SCLC treated with HSCT. The currently-available evidence does not support the use of HSCT for SCLC.

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The evidence for HSCT for individuals who have renal cell cancer, colorectal cancer, pancreatic cancer, or nasopharyngeal cancer includes a BCBSA TEC Assessment and small single-arm series. Relevant outcomes include overall survival, disease-specific survival, and treatment-related morbidity and mortality. 1995 and 1999 TEC Assessments focusing on HSCT as primary and salvage therapy for a variety of solid tumors found that the available evidence did not permit conclusions about the effect of HSCT on patient survival. Since the publication of the TEC Assessments, the evidence for HSCT adult soft tissue sarcomas, renal cell carcinoma, colorectal cancer, pancreatic cancer, and nasopharyngeal cancer has been limited to small case series, which are insufficient to demonstrate improved outcomes with autologous or allogeneic HSCT.

**Practice Guidelines and Position Statements**

**National Comprehensive Cancer Network**
As of December 2015, National Comprehensive Cancer Network guidelines on the tumors addressed in this policy do not discuss HSCT as a treatment option.²⁸

**American Society of Blood and Marrow Transplantation**
As of December 2015, the American Society of Blood and Marrow Transplantation has not issued guidelines, policy statements, or evidence-based reviews on the use of HSCT for solid tumors.²⁹

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination (NCD) for HSCT. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**References**


**Billing Coding/Physician Documentation Information**

38204 Management of recipient hematopoietic progenitor cell donor search and cell acquisition

38205 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic

38206 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous

38208 Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing

38209 Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing

38210 Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion

38211 Transplant preparation of hematopoietic progenitor cells; tumor cell depletion

38212 Transplant preparation of hematopoietic progenitor cells; red blood cell removal

38213 Transplant preparation of hematopoietic progenitor cells; platelet depletion

38214 Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion

38215 Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer

38220 Bone marrow; aspiration only

38221 Bone marrow; biopsy, needle or trocar

38240 Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor

38241 Hematopoietic progenitor cell (HPC); autologous transplantation

38242 Allogeneic lymphocyte infusions

Q0083 Chemotherapy administration by other than infusion technique only
(e.g., subcutaneous, intramuscular, push), per visit

Q0084 Chemotherapy administration by infusion technique only, per visit
Q0085 Chemotherapy administration by both infusion technique and other technique(s) (e.g., subcutaneous, intramuscular, push), per visit

S2140 Cord blood harvesting for transplantation, allogeneic
S2142 Cord blood-derived stem cell transplantation, allogeneic
S2150 Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre and post transplant care in the global definition

ICD10 Codes:

C11.0- Malignant neoplasm of nasopharynx code range
C11.9
C15.3- Malignant neoplasm of esophagus code range
C15.9
C16.0- Malignant neoplasm of stomach code range
C16.9
C18.0- Malignant neoplasm of colon code range
C18.9
C20 Malignant neoplasm of rectum
C23 Malignant neoplasm of gallbladder
C24.0- Malignant neoplasm of other and unspecified parts of biliary tract code range
C24.9
C25.0- Malignant neoplasm of pancreas code range
C25.9
C31.0- Malignant neoplasm of accessory sinuses code range
C31.9
C34.00- Malignant neoplasm of bronchus and lung code range
C34.92
C37 Malignant neoplasm of thymus
C43.0- Malignant melanoma of skin code range
C43.9
C46.1 Kaposi's sarcoma of soft tissue
C53.0- Malignant neoplasm of cervix uteri code range
C53.9
C54.0- Malignant neoplasm of corpus uteri code range
C54.9
C55 Malignant neoplasm of uterus, part unspecified
C57.00- Malignant neoplasm of fallopian tube code range
C57.02
C61 Malignant neoplasm of prostate
C64.0- Malignant neoplasm of kidney, except renal pelvis code range
C64.9
C65.0- Malignant neoplasm of renal pelvis code range
C65.9
C73  Malignant neoplasm of thyroid gland
C7a.00-  Malignant neuroendocrine tumors code range
C7b.8  Malignant (primary) neoplasm, unspecified

Additional Policy Key Words
N/A

Policy Implementation/Update Information
9/1/02  New policy added to the Surgery and Transplant sections.
9/1/03  No policy statement changes.
9/1/04  Policy statement revised to include malignant melanoma to the list of investigational indications.
9/1/05  No policy statement changes.
9/1/06  No policy statement changes.
9/1/07  No policy statement changes.
9/1/08  No policy statement changes.
9/1/09  Policy statement revised to add allogeneic stem-cell transplant as investigational. High-dose chemotherapy” removed from title and policy statement.
9/1/10  No policy statement changes.
9/1/11  No policy statement changes.
9/1/12  No policy statement changes.
11/1/12  No policy statement changes.
12/1/13  No policy statement changes.
12/1/14  Updated CPT definitions. No policy statement changes.
12/1/15  No policy statement changes.
1/1/16  No policy statement changes.
3/1/16  No policy statement changes.
12/1/16  No policy statement changes.

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