



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Stem-Cell Transplantation for Adult Solid Tumors

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Coverage Policy

CIGNA does not cover hematopoietic stem-cell transplantation for the treatment of ANY of the following solid tumors in adults because it is considered experimental, investigational and unproven (this list may not be all-inclusive):

- adult soft tissue sarcomas
- cancer of the bile duct
- cancer of the cervix
- cancer of the colon and rectum
- cancer of the esophagus
- cancer of the gallbladder
- cancer of the lung
- cancer of the nasopharynx
- cancer of the pancreas

- cancer of the paranasal sinus
 - cancer of the prostate
 - cancer of the stomach (gastric cancer)
 - cancer of the thymus
 - cancer of the thyroid
 - cancer of the uterus
 - malignant melanoma
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General Background

Solid tumors in adults are a heterogeneous group of disorders encompassing a wide spectrum of body systems. Also called solid neoplasms, some tumors are chemoradiosensitive; however, as a whole they are not curable by chemotherapy. Although most malignancies demonstrate significant disease responsiveness to conventional dose chemotherapy, many such responses are incomplete or not durable. The use of hematopoietic stem-cell transplantation (HSCT) has been proposed for the treatment of selected solid tumors in adults.

Stem-Cell Transplantation

Stem-cell transplantation refers to transplantation of hematopoietic stem cells (HSCs) from a donor into a recipient. HSC transplantation can be either autologous (i.e., using the patient's own stem cells) or allogeneic (i.e., using stem cells from a donor).

Dose intensification and autologous hematopoietic stem-cell transplantation (HSCT) is a strategy that has been proposed as a means to overcome inadequate response. Dose intensification has provided a survival advantage to selected individuals with hematologic malignancies; however, reviews of the efficacy of high-dose therapy in adult solid tumors have concluded that no role for this approach has been established, even in the diseases most sensitive to chemotherapy and radiation (Murren, 2005; Niebor, 2005).

Theoretically, allogeneic HSCT for solid tumors can induce a graft-versus-tumor (GVT) reaction, in which the infused donor cells mount an immune response that eradicates the recipient's cancer cells. Early studies of ablative regimens for treatment of chemotherapy-refractory metastatic solid tumors demonstrated that the high doses of chemotherapy required to ablate the recipient's bone marrow lead to unacceptably high treatment-related mortality (TRM) rates of 20–35% (Arya, et al., 2004). The high TRM associated with standard myeloablative preparative regimens has led to the study of non-myeloablative preparative regimens as conditioning for allogeneic stem-cell transplantation. These studies have not shown improved survival outcomes for participating patients and are limited by a lack of randomization, small patient populations, and limited follow-up. At this time, insufficient data are available to determine whether GVT effects can occur in most solid tumors (Storb, 2003).

Hematopoietic stem-cell transplantation (HSCT) for breast cancer, testicular cancer, epithelial ovarian cancer, and renal cell cancer are discussed in separate Coverage Policies (see Related Coverage Policy section). The use of HSCT for the treatment of adult solid tumors including adult soft tissue sarcomas, cancers of the bile duct, cervix, colon, rectum, esophagus, gallbladder, lung, nasopharynx, pancreas, paranasal sinus, prostate, stomach (gastric cancer), thymus, thyroid, and uterus, and malignant melanoma are briefly discussed below.

Adult Soft Tissue Sarcoma: Soft tissue sarcomas may arise from the mesodermal tissues of the extremities, trunk and retroperitoneum, the head and neck, and rarely in the gastrointestinal stroma (National Cancer Institute [NCI], 2010a). Chemotherapy may be beneficial for patients with advanced sarcoma; however, high-dose chemotherapy (with or without transplantation) has not influenced disease-free survival (DFS) or overall survival (OS) in published studies (NCI, 2010a). HSCT remains under clinical evaluation for individuals with metastatic disease in first complete remission, after resection of pulmonary metastases, or for inoperable large primary tumors. Because treatment for this disease is evolving, participation in clinical trials is encouraged (NCI, 2010a).

Verma et al. (2008) performed a systematic review of the literature to determine whether first-line dose-intensive chemotherapy supported by growth factor or autologous bone marrow/stem cell transplantation improves response rate, time-to-disease progression, or survival compared with standard-dose chemotherapy in patients

with inoperable, locally advanced, or metastatic soft tissue sarcoma. The authors noted that to date only two randomized clinical trials (RCT) have been performed to determine whether dose-intensive chemotherapy with growth factor support or autologous bone marrow/stem cell support improves survival, response, or time-to-progression compared with standard-dose chemotherapy in the first-line setting. Only one RCT (n=314) reported data on all three outcomes. No significant difference was noted between treatments for response rate (p=.65). Progression-free survival (PFS) was significantly longer in the high-dose arm (p=.03). One-year PFS rates were 20% in the standard-dose arm and 28% in the high-dose arm (p=.03). Thirteen phase II trials investigated dose intensification in patients with soft tissue sarcoma. Various chemotherapy regimens were used. Several small phase II trials have reported response rates of 31% to 63% with overall median survival ranging from 13-24 months. This analysis was unable to discern any consistent benefits in patients with metastatic unresectable soft tissue sarcoma when doses higher than standard-dose chemotherapy are used in this setting.

The safety and effectiveness of non-myeloablative or reduced-intensity allogeneic hematopoietic stem-cell transplantation (HSCT) has also been investigated for soft tissue sarcoma in adults. Secondino et al. (2007) performed a retrospective review of 14 patients with soft tissue sarcoma. All patients had received reduced-intensity stem-cell transplantation for chemorefractory disease. At a median follow-up of 201 days, treatment-related mortality was 14%. At a median follow-up of 326 days, 66% of patients had died of progressive disease. Median overall survival (OS) was 326 days, and median PFS was 103 days. A well-designed study is required to define the possible role of reduced-intensity stem-cell transplantation for patients with soft tissue sarcoma in whom conventional treatments have failed.

There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate improved survival with HSCT for this indication. Although results are promising, the role of this therapy has not been established for the treatment of soft tissue sarcomas in adults.

Cancer of the Colon and Rectum: Cancer of the colon and rectum is highly treatable and often curable when localized (National Cancer Institute [NCI], 2010c; NCI, 2010r). Prognosis is related to the degree of penetration of the tumor through the bowel wall and the involvement of lymph nodes.

Non-myeloablative allogeneic HSCT has been investigated for the treatment of colorectal cancer in non-randomized clinical trials (Carnevale-Schianca, 2006; Hentschke, 2003). Trials are limited by small patient populations and study design. Disease progression was common after HSCT; however, the regression of some metastases associated with graft-versus-host disease (GVHD) is suggestive of a graft-versus-tumor (GVT) effect.

Although cancer of the colon and rectum may be responsive to chemotherapy in selected individuals, there is insufficient evidence in the published, peer-reviewed scientific literature to support the safety and effectiveness of HSCT for this indication. The role of this therapy has not been established for the treatment of colon and/or rectal cancer.

Cancer of the Lung:

Non-Small Cell Lung Cancer (NSCLC): NSCLC is an aggregate of several different types of cells; some of the most common include epidermoid or squamous carcinoma, adenocarcinoma and large cell carcinoma (NCI, 2009n). Despite new combinations of surgery, radiation and chemotherapy, the survival of patients with NSCLC has improved only minimally over the past 20 years (Fetscher, 2002). Five-year survival for nonmetastatic and metastatic NSCLC is 5–15% and 0–3%, respectively (NCI, 2010n).

The need for more effective therapy has led to the investigation of autologous HSCT in several non-randomized clinical trials involving a total of 61 patients with NSCLC (De Giorgi, 2008; Schilder, 2000; Fetscher, 1997). Response rates were 34%–44% with a median survival of seven to 17 months. It does not appear that high-dose chemotherapy with autologous HSCT improves the response rate or overall survival for patients with NSCLC (Schilder, 2000).

Small Cell Lung Cancer (SCLC): Without treatment, SCLC has the most aggressive course of any type of pulmonary tumor, with a tendency to be more widely disseminated at time of diagnosis. The median survival is two to four months (NCI, 2010s). Compared to other cell types of lung cancer; however, small cell lung cancer (SCLC) is more responsive to chemoradiation therapies (NCI, 2010s; Chua, 2004). Approximately 50% of

patients with limited-disease SCLC receiving standard doses of combination chemotherapy will achieve clinical remission; although remission rates for patients with extensive disease are only 20%–40% (Chua, 2004).

Hematopoietic stem-cell transplantation (HSCT) has been studied in multiple prospective randomized and non-randomized clinical trials, and retrospective studies; however, a consistent survival advantage for patients treated with higher doses of chemotherapy has not been demonstrated (Iwasaki, 2005; Elias, 2002; Rizzo, 2002). In a non-randomized comparative study by Bucholtz (2007, individuals with limited disease who received HSCT achieved significant improvements in median survival and time to progression. Several randomized studies are ongoing and should help define whether this approach is of value in this disease (National Cancer Institute [NCI], 2010q; Murren, 2005).

Jiang et al. (2009) performed a meta-analysis of five randomized phase II and III clinical trials involving 641 patients with small cell lung cancer. The studies compared intensified chemotherapy with hematopoietic progenitors and control therapy, including chemotherapy and radiation. No significant increase in the odds ratio for response was attributed to the use of intensified chemotherapy ($p=0.206$). No statistically significant increase in overall survival was found with the use of intensified chemotherapy compared with control regimens ($p=0.432$). The use of intensified chemotherapy does not improve outcomes compared with standard therapy in patients with small cell lung cancer.

Although HSCT is the subject of ongoing research, there is insufficient evidence in the published peer-reviewed scientific literature to support the safety and effectiveness for the treatment of NSCLC or SCLC. Improved complete remission rates and prolonged relapse-free survival rates suggest that this approach is promising; however, the role of HSCT has not yet been established for this indication.

Cancer of the Pancreas: Pancreatic cancer comprises many types of carcinomas, including duct cell carcinoma, which accounts for 90% of all tumors. Cancer of the exocrine pancreas is rarely curable and has an overall survival (OS) of 4% (NCI] 2010o).

According to the NCI (2010o), the role of chemotherapy with or without radiation remains uncertain for the treatment of pancreatic cancer. Non-myeloablative allogeneic HSCT has been investigated in several non-randomized clinical trials (Kanda, 2008; Kanda, 2004), with median survival of 139 and 229 days, respectively. The authors noted that a graft-versus-tumor (GVT) effect appears possible; however, the effect was not durable. These studies were limited by small patient populations and study design.

There is insufficient evidence in the published peer-reviewed scientific literature to demonstrate the safety and effectiveness of HSCT for this indication. At this time the role of this therapy has not been established for the treatment of pancreatic cancer.

Cancer of the Prostate: Cancer of the prostate may be cured when the disease is localized, and frequently responds to treatment even when widespread. The approach to treatment is influenced by age and co-morbid medical conditions (NCI, 2009q). Treatment provides prolonged disease-free survival (DFS) for many patients with local disease but is rarely curative in patients with locally extensive tumor; metastatic tumor is currently not curable (NCI, 2010q

There are scarce data regarding the use of HSCT for the treatment of prostate cancer. O'Sullivan et al. (2006) reported the results of a phase II study testing high activities Rhenium-186 followed by autologous HSCT in 38 patients. Median survival was 21 months. One- and two-year actuarial survival rates were 83% and 40%, respectively.

There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and effectiveness HSCT for this indication. Response rates and survival data were encouraging; however, further research is needed to define the optimal role of this therapy.

Cancer of the Stomach (Gastric Cancer): Adenocarcinoma accounts for up to 95% of all gastric malignancies. The prognosis of gastric cancer is related to tumor extent and grade. Fifty percent of patients with localized distal gastric cancer can be cured; however, patients with disseminated disease have an extremely poor five-year survival rate (NCI, 2010h). The standard treatment having curative intent is surgical resection. Chemotherapy may be appropriate for patients with certain stages of gastric cancer.

There are scarce data in the published peer-review scientific literature regarding the use of hematopoietic stem-cell transplantation (HSCT) for the treatment of gastric cancer. Reichle et al. (2004) reported the results of a study in which 18 consecutive patients with metastatic or locally far-advanced unresectable tumors received dose-intensive chemotherapy with autologous stem-cell support and surgery. For all patients, the median progression-free survival (PFS) was 6.23 months; the median overall survival (OS) was 8.43 months.

There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate the safety and effectiveness of HSCT for this indication. At this time, the role of this therapy for the treatment of gastric cancer has not been established.

Cancer of the Thymus: The thymus gland is composed of three types of cells: lymphocytes, epithelial cells and less frequently, Kulchitsky cells. Lymphocytes, whether in the thymus or lymph nodes, may give rise to Hodgkin disease and non-Hodgkin's lymphoma, which are discussed in other Coverage Policies (see Related Coverage Policy section).

Thymomas and thymic carcinomas arise from the epithelial cells of the thymus gland. Ninety percent of thymus tumors are thymomas which are usually indolent and result in local recurrence rather than metastasis. Thymic carcinomas are a type of thymoma and are extremely rare, but typically invasive, with a high rate of relapse and death). Five-year survival for thymoma depends on the extent of the disease. Overall five-year survival rates for thymic carcinoma and carcinoids are approximately 35% and 60%, respectively (National Cancer Institute [NCI], 2010t).

Autologous HSCT has been proposed for selected individuals with cancer of the thymus; however, there are scarce data in the published peer-reviewed scientific literature demonstrating safety and effectiveness. Uncontrolled study design, small patient populations, short follow-up, diverse tumor histology, and multiple conditioning regimens are limitations to these studies. At this time, the role of HSCT has not been established for this indication.

Malignant Melanoma: Melanoma is a malignant tumor of melanocytes, cells that make the pigment, melanin. Most melanomas are found in the skin but may also be present in the eye and mucosal areas, such as the bowel. Prognosis is affected by several factors, including thickness and/or level of invasion, mitotic index, presence of infiltrating lymphocytes and involvement of lymph nodes.

Treatment options vary according to presentation and stage, and include surgical excision with the width of margins dependent on stage of disease. Tumors that have not spread beyond the site at which they developed are highly curable. Recurrent melanoma is resistant to most standard systemic therapy; if responses are achieved, they are usually short-lived. According to the NCI (2009l), the use of high-dose chemotherapy with autologous HSCT has not been shown to improve survival.

There are scarce data in the published peer-reviewed scientific literature demonstrating the safety and effectiveness of this therapy for malignant melanoma. Schrader et al. (2000) reported the results of 27 consecutive patients who received autologous HSCT for progressive metastatic malignant melanoma. After transplantation, 44% of patients achieved a partial response with a median duration of five months; 30% of patients had stable disease, and 30% of patients did not respond and had progressive disease. Complete responses were not achieved. The median overall survival (OS) for all patients was six months, and for surviving patients it was 12 months. The median progression-free survival (PFS) was three months. Although the response rate was higher than expected, it was not durable. In a prospective randomized trial by Meisenberg (1993), outcomes of patients treated with autologous HSCT were compared with those of patients who were observed until relapse and then treated with autologous HSCT. There were no statistically significant differences in overall survival between the two treatment arms. Predicted five-year OS was 30%–35% for both groups. Median time to progression was longer in the group that received transplantation compared to the group that was initially observed (35 weeks versus 16 weeks, respectively). Immediate treatment with high-dose alkylating agents followed by bone marrow transplantation resulted in a prolonged time to disease progression, although it was not statistically significant.

At this time there is insufficient evidence in the published peer-reviewed scientific evidence to support improved survival outcomes with the use of hematopoietic stem-cell transplantation (HSCT) for this indication. The role of this therapy for the treatment malignant melanoma has not been established.

Other Adult Solid Tumors: There are scarce data in the published peer-reviewed scientific literature to support the safety and effectiveness of autologous or allogeneic HSCT for the treatment of other adult soft tumors including, but not limited to, cancers of the bile duct, cervix, esophagus, gallbladder, nasopharynx, paranasal sinus, thyroid, or uterus. At this time the role of HSCT has not been established for these indications.

Professional Societies/Organizations

National Cancer Institute (NCI): The NCI (2010[a]) notes that high-dose chemotherapy (with or without transplantation) has not influenced disease-free survival or overall survival in published studies for adult soft tissue sarcomas. It remains under clinical evaluation for patients with metastatic disease in first complete remission, after resection of pulmonary metastases, or for inoperable large primaries. According to the NCI (2010[1]), high-dose chemotherapy with autologous HSCT has not been shown to improve survival for patients with stage II or stage III melanoma.

Cancer Care Ontario: Sarcoma Disease Site Group: On behalf of the Sarcoma Disease Site Group of Cancer Care Ontario’s Program in Evidence-Based Care, Verma et al. (2008) published a clinical practice guideline for Dose-Intensive Chemotherapy with Growth Factor or Autologous Bone Marrow or Stem-Cell Transplant Support in First-Line Treatment of Advanced or Metastatic Adult Soft Tissue Sarcoma. The recommendations note:

Dose-intensive chemotherapy with growth factor support is not recommended in the first-line treatment of patients with inoperable locally advanced or metastatic soft tissue sarcoma. The data are insufficient to support the use of high dose chemotherapy with autologous bone marrow or stem-cell transplantation as first-line treatment in this group of patients. Eligible patients should be encouraged to enter clinical trials assessing novel approaches or compounds.

Summary

There is insufficient evidence to support the safety and effectiveness of hematopoietic stem-cell transplantation (HSCT) for the treatment of adults with selected solid tumors. At this time, the role of HSCT has not been established.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
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
38230	Bone marrow harvesting for transplantation
38240	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic
38241	Bone marrow or blood-derived peripheral stem cell transplantation; autologous
38242	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic donor lymphocyte infusions

HCPCS Codes	Description
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 or pre-and post-transplant care in the global definition

ICD-9-CM Diagnosis Codes	Description
147.0-147.9	Malignant neoplasm of nasopharynx
150.0-150.9	Malignant neoplasm of esophagus
151.0-151.9	Malignant neoplasm of stomach
153.0-153.9	Malignant neoplasm of colon
154.0-154.8	Malignant neoplasm of rectum, rectosigmoid junction, and anus
155.1	Malignant neoplasm of intrahepatic bile ducts
156.0-156.9	Malignant neoplasm of the gallbladder and extrahepatic bile ducts
157.0-157.9	Malignant neoplasm of pancreas
160.2	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, Maxillary sinus
160.3	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, Ethmoidal sinus
160.4	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, Frontal sinus
160.5	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, Sphenoidal sinus
162.2	Malignant neoplasm of main bronchus
162.3	Malignant neoplasm of upper lobe, bronchus, or lung
162.4	Malignant neoplasm of middle lobe, bronchus, or lung
162.5	Malignant neoplasm of lower lobe, bronchus, or lung
162.8	Malignant neoplasm of other parts of bronchus, or lung
162.9	Malignant neoplasm of bronchus and lung, unspecified site
164.0	Malignant neoplasm of thymus
171.9	Malignant neoplasm of connective and other soft tissue, site unspecified
172.0 – 172.9	Malignant melanoma of skin
176.1	Kaposi's sarcoma of soft tissue
180.0-180.9	Malignant neoplasm of cervix uteri
182.0-182.8	Malignant neoplasm of body of uterus
185	Malignant neoplasm of prostate
193	Malignant neoplasm of thyroid gland
230.0	Carcinoma in situ of digestive organs, Lip, oral cavity, and pharynx
230.1	Carcinoma in situ of esophagus
230.2	Carcinoma in situ of stomach

230.3	Carcinoma in situ of colon
230.4	Carcinoma in situ of rectum
230.7	Carcinoma in situ of other and unspecified parts of intestine
230.8	Carcinoma in situ of digestive organs, Liver and biliary system
230.9	Carcinoma in situ of digestive organs, Other and unspecified digestive organs,
231.2	Carcinoma in situ of bronchus and lung
231.8	Carcinoma in situ of other specified parts of respiratory system
233.1	Carcinoma in situ of cervix uteri
233.2	Carcinoma in situ of other and unspecified parts of uterus
233.4	Carcinoma in situ of prostate
	All other codes

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	1/15/2008	0479	Stem-Cell Transplant for Adult Solid Tumors

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