



CIGNA MEDICAL COVERAGE POLICY

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

Subject Stem-Cell Transplantation for Myelodysplastic Syndromes

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Coverage Policy

CIGNA covers allogeneic hematopoietic stem-cell transplantation (HSCT) as medically necessary for the treatment of individuals with intermediate- or high-risk myelodysplastic syndrome (MDS) who have an available human leukocyte antigen (HLA) matched donor (at least five of six match).

CIGNA covers autologous HSCT as medically necessary for the treatment of intermediate- or high-risk MDS when ALL of the following criteria are met:

- The individual is in complete remission.
- The individual is not a candidate for allogeneic HSCT.
- A suitable HLA-matched donor (at least five of six match) is not available.

General Background

The myelodysplastic syndromes (MDS) are a heterogeneous group of disorders characterized by peripheral blood cytopenias secondary to bone marrow dysfunction (National Cancer Institute [NCI], 2010). MDS primarily affects adults \geq age 60 with a two-year overall survival of $<20\%$ with advanced MDS (Kindwall-Keller, 2009). Although rare in children and young adults, MDS has an aggressive clinical course in these subgroups. The syndromes may arise de novo, or secondarily after treatment with chemotherapy and/or radiation therapy for other diseases. Secondary myelodysplasia usually has a poorer prognosis (NCI, 2010).

Prognosis is directly related to the number of bone marrow blast cells and to the amount of peripheral blood cytopenias. Independent adverse factors include poor performance, older age, thrombocytopenia, anemia, increased bone marrow blasts, leukocytosis, certain chromosome abnormalities, and earlier transfusions (Kindwall-Keller, 2009, Faderl, 2008; NCI, 2010). In a large percentage of cases, the syndromes progress to overt acute myeloid leukemia (DeAngelo, 2008).

Several classification systems have been developed to determine prognosis and guide treatment, including the French-American-British (FAB) system, the World Health Organization (WHO) system, and the International Prognostic Scoring System (IPSS). The IPSS system has been used to assign patients to prognostic risk groups in terms of survival and evolution to acute myelogenous leukemia: low, intermediate-1, intermediate -2, and high risk, based on bone marrow blast percentage, number of peripheral blood cytopenias, and cytogenetic subgroup. Corresponding median survival rates are 5.7 years, 3.5 years, 1.2 years, and 0.4 years, respectively.

Treatment

Stem-Cell Transplantation

The use of hematopoietic stem-cell transplantation has been proposed for the treatment of MDS. Stem-cell transplantation refers to the transplantation of hematopoietic stem cells (HSCs) into an individual. Hematopoietic stem-cell transplantation (HSCT) can be either autologous (using the person's own stem cells) or allogeneic (using stem cells from a donor).

Allogeneic HSCT: There are limited randomized controlled trial data comparing high-dose chemotherapy and HSCT with standard dose chemotherapy; nonetheless, myeloablative conditioning followed by allogeneic HSCT is considered a preferred treatment approach for treating a portion of individuals with MDS, particularly those with high-risk disease (National Comprehensive Cancer Network[®] [NCCN[®]], 2010). According to the NCI (2010), allogeneic HSCT offers the potential for long-term disease-free survival (DFS), and is a component of the standard of care for individuals with good performance status and no significant comorbidity for individuals with de novo and secondary myelodysplastic syndrome. Transplant outcome in patients with MDS is related to disease stage (marrow myeloblast count), prognostic score (IPSS), cytogenetic findings, possibly remission status before transplantation, iron overload, source of stem cells, co-morbid conditions, and preparative regimen. In early clinical trials, transplant success showed a strong inverse correlation with patient age. Age continues to be a relevant factor for transplant success; the development of reduced intensity nonmyeloablative conditioning strategies has further attenuated the impact of age (Scott, 2008).

Reduced intensity or non-myeloablative preparative regimens have been suggested as treatment for selected patients, typically those with co-morbid medical conditions or older individuals who cannot tolerate the treatment-related effects of intensive therapy. These are designed to reduce regimen-related toxicities and to utilize the graft-versus-leukemia/graft-versus-myelodysplasia effect of the infused donor lymphocytes (de Witte, 2007).

Although relapse rates are higher with non-myeloablative conditioning, treatment-related mortality is higher with more intensive chemotherapy, with similar overall survival rates for both therapies. Randomized control trial data is scarce; however, several prospective case series and retrospective analyses have demonstrated similar disease-free and overall survival rates with myeloablative and non-myeloablative/reduced-intensity conditioning regimens. Two-, three-, and four-year overall survival rates are 33% versus 35%, 39% versus 33%, and 36% versus 27%, respectively, for individuals undergoing allogeneic HSCT with myeloablative or non-myeloablative/reduced-intensity therapy (Flynn, 2007; Martino, 2006; de Witte, 2001).

There is ongoing discussion regarding the most appropriate timing for HSCT. At present, data suggest that selected individuals with the International Prognostic Scoring System (IPSS) intermediate-2 and high-risk myelodysplastic syndromes (MDS) may benefit from immediate hematopoietic stem-cell transplantation (HSCT) while those with IPSS low- and intermediate-1-risk groups may improve overall survival by delay of HSCT until

disease progression (NCCN, 2010; Kindwall-Keller, 2009, Alessandrino, 2008). Prospective and retrospective case studies suggest that 20% to 40% of patients with high-risk disease can experience long-term disease-free survival (DFS) after allogeneic transplantation from a matched donor (DeAngelo, 2008). Whether transplantation should be performed before or after patients achieve remission after induction chemotherapy has not been established; however, individuals who receive allogeneic HSCT while in complete remission tend to have better outcomes than those who are transplanted with residual disease (Alessandrino, 2008; Kebriaei, 2005; Scott, 2005). Advanced age is associated with a higher incidence and severity of post-transplantation complications; nonetheless there is some evidence that allogeneic HSCT is feasible in persons up to age 70 (DeAngelo, 2008; Wallen, 2005). Allogeneic HSCT for selected individuals with intermediate- or high-risk MDS is considered an appropriate treatment option.

Autologous HSCT: Autologous HSCT provides an alternative stem-cell source for individuals who do not have a human leukocyte antigen (HLA)-identical donor, and may be used in older individuals as the conditioning regimens are less toxic than those for allogeneic HSCT (de Witte, 2006). The rationale for the use of autologous HSCT in MDS is the feasibility of collecting normal stem cells at the time of chemotherapy-induced remission (Alessandrino, 2002). For a carefully selected subgroup of individuals, autologous HSCT may be appropriate in those who achieve a complete remission following induction chemotherapy and in whom suitable autologous stem-cells can be collected. Outcomes with autologous HSCT appear comparable to allogeneic transplantation protocols that utilize donors other than HLA-identical siblings and phenotypically-identical family members.

In a retrospective study, Kroger et al. (2006) reported the results of 65 persons with treatment-related MDS/acute myelogenous leukemia (AML) who received an autologous HSCT. The Kaplan-Meier probabilities of five-year overall and disease-free survival were 35 and 32%, respectively. The cumulative incidence of relapse was 58%, and the transplant-related mortality (TRM) was 12%. In a multivariate analysis, transplantation in first complete remission and presence of younger age influenced OS. Although data are not robust, autologous HSCT is considered an appropriate treatment option for selected individuals with intermediate- or high-risk MDS.

Contraindications

Many factors affect the outcome of a tissue transplant; the selection process is designed to obtain the best result for each individual. Overall health, age and disease stage are extremely important considerations in evaluating transplant candidates. The presence of any significant co-morbid condition that would significantly compromise clinical care and chances of survival is a contraindication to transplant. Relative contraindications may include, but are not limited to:

- poor cardiac function (ejection fraction < 45%)
- poor liver function (bilirubin > 2.0mg/dl and transaminases greater than two times normal), unless related to acute myelogenous leukemia (AML)
- poor renal function (creatinine clearance < 50ml/min)
- poor pulmonary function (diffusion capacity [DLCO] < 60% of predicted)
- active central nervous system involvement
- a pattern of demonstrated noncompliance which would place a transplant at serious risk of failure
- presence of human immunodeficiency virus OR an active form of any ONE of the following:
 - hepatitis B virus (HBV)
 - hepatitis C virus (HCV)
 - human T-cell lymphotropic virus (HTLV)-1
- Karnofsky rating < 60% and/or Eastern Cooperative Oncology Group (ECOG) performance status > 2

Professional Societies/Organizations

National Cancer Institute (NCI): The NCI (2010) notes that myeloablative allogeneic HSCT is a standard treatment option and offers the potential for long-term disease-free survival for young persons with de novo and secondary MDS, and previously treated MDS. The NCI also notes that allogeneic HSCT with non-myeloablative conditioning is under clinical evaluation. Autologous bone marrow or peripheral blood progenitor cell transplantation is under clinical evaluation for subsets of individuals who achieve remission following cytotoxic remission induction therapy.

National Comprehensive Cancer Network Guidelines™ (NCCN Guidelines™): The NCCN (2010) notes “Allogeneic HSCT from a human leukocyte antigen (HLA)-matched sibling donor is a preferred approach for treating a portion of patients with myelodysplastic syndromes (MDS), particularly those with high-risk disease. Matched nonmyeloablative transplant regimens and matched unrelated donor stem-cell transplants are becoming options at some centers.” In addition, the NCCN notes “Autologous bone marrow or peripheral blood stem cell transplantation is being considered in certain investigative settings. Whether transplantation should be performed before or after patients achieve remission after induction chemotherapy has not been established.”

American Society for Blood and Marrow Transplantation (ASBMT): The Guideline titled “The Role of Cytotoxic Therapy with Hematopoietic Stem Cell Transplantation in the Therapy of Myelodysplastic Syndromes” notes that early stem-cell transplantation is recommended for patients with an International Prognostic Scoring System (IPSS) score of INT-2, considered high risk, at diagnosis who have a suitable donor and meet the transplanting center’s eligibility criteria, and for selected patients at low risk (IPSS score of INT-1) at diagnosis who have poor prognostic features not included in the IPSS (e.g., older age, refractory cytopenias). A human-leukocyte antigen (HLA)-matched allogeneic donor (i.e., sibling, other family member, unrelated individual, or cord blood) stem-cell transplantation is recommended if an appropriate donor is available. If an allogeneic donor is not available, and complete remission is achieved with induction therapy, then an autologous stem-cell transplant can be considered in the context of a clinical trial (2009).

National Marrow Donor Program (NMDP) and the ASBMT: In guidelines published jointly by the NMDP and the ASBMT (2008), a transplant consultation for individuals with MDS is recommended for individuals with an intermediate-1, intermediate-2, or high IPSS score which includes either >5% marrow blasts, other than good risk cytogenetics, or >1 lineage cytopenia.

Summary

The myelodysplastic syndromes (MDS) include an array of stem cell disorders characterized by peripheral blood cytopenias and variable risks of leukemic transformation. Although data are not robust, the published, peer-reviewed scientific literature supports the safety and effectiveness of allogeneic and autologous hematopoietic stem-cell transplantation (HSCT) for the treatment of MDS in selected individuals.

Coding/Billing Information

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

Covered when medically necessary:

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
238.72	Low grade myelodysplastic syndrome lesions
238.73	High grade myelodysplastic syndrome lesions
238.74	Myelodysplastic syndrome with 5q deletion
238.75	Myelodysplastic syndrome, unspecified

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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	10/15/2008	0187	Stem-Cell Transplant for Myelodysplastic Syndrome

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