Cigna Medical Coverage Policy

Subject: Stem-Cell Transplantation for Non-Hodgkin Lymphoma

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Coverage Policy

Cigna covers autologous hematopoietic stem-cell transplantation (HSCT) as medically necessary for the treatment of an adult with noncontiguous stage II, stage III or stage IV non-Hodgkin lymphoma (NHL).

Cigna covers allogeneic HSCT as medically necessary for the treatment of an adult with noncontiguous stage II, stage III or stage IV non-Hodgkin lymphoma NHL who is not a candidate for autologous HSCT when an appropriate human leukocyte antigen (HLA) donor is available.

Cigna covers myeloablative allogeneic or autologous HSCT as medically necessary for the treatment of a child with recurrent NHL with chemosensitive disease.

Cigna does not cover ANY of the following therapies for the treatment of NHL because each is considered experimental, investigational or unproven:

- autologous OR allogeneic HSCT for stage I or contiguous stage II disease in an adult
- non-myeloablative allogeneic HSCT in a child
- tandem autologous OR allogeneic HSCT in an adult or a child

General Background

Non-Hodgkin lymphoma (i.e., non-Hodgkin’s lymphoma or NHL) is a complex, heterogeneous group of lymphoproliferative malignancies that originates in the lymphoid tissues (i.e., B-lymphocytes, T-lymphocytes, natural killer (NK) lymphocytes) and can spread to the bone marrow and other organs. The prognosis depends
on the histologic type, stage, and treatment. Non-Hodgkin lymphoma (NHL) may occur at any age; however, the incidence increases with age. It is uncommon in children. In general overall median five-year survival for aggressive NHL is 50% to 60% (National Cancer Institute [NCI], 2013a).

**Non-Hodgkin Lymphoma in Adults:** The classification of NHL in adults has evolved over time to include chemical and genetic characteristics as well as cell appearance. Several classification systems are in use including the International Working Formulation (IWF), and more recently the Revised European-American Lymphoma (REAL) classification system, with proposed modifications by the World Health Organization (WHO).

NHL can generally be divided into prognostic groups: indolent, intermediate-grade and aggressive. Indolent or slowly progressing NHL has a relatively good prognosis with a median survival of 10-years; however, it is usually not curable in advanced stage. Indolent lymphomas include the following (NCI, 2013a):

- follicular lymphoma (grades I and II, and diffuse small cleaved cell)
- chronic lymphocytic leukemia/small lymphocytic lymphoma
- lymphoplasmacytic lymphoma
- marginal zone B-cell lymphoma (extranodal, nodal, and splenic)
- hairy cell leukemia
- mycosis fungoides/Sezary syndrome
- T-cell granular lymphocytic leukemia
- primary cutaneous anaplastic large cell lymphoma
- nodular lymphocyte-predominant Hodgkin lymphoma

Aggressive types of NHL, which are rapidly progressing or high-grade subtypes, have a shorter natural history, but a significant number of patients can be cured with intensive combination chemotherapy regimens. These include the following (NCI, 2013a):

- diffuse large cell lymphoma
- Burkitt lymphoma/Burkitt cell leukemia/Burkitt-like lymphoma
- precursor B-cell or T-cell lymphoblastic lymphoma/leukemia
- primary central nervous system lymphoma
- adult T-cell leukemia/lymphoma
- mantle cell lymphoma
- polymorphic posttransplantation lymphoproliferative disorder (PTLD)
- acquired immune deficiency (AIDS)-related lymphoma
- true histiocytic lymphoma
- primary effusion lymphoma
- B-cell or T-cell prolymphocytic leukemia

In addition to subtype differentiation, NHL is staged according to the Ann Arbor staging system (American Cancer Society [ACS], 2012a). This staging system is used along with several prognostic indexes to predict the rate of disease progression and the individual’s response to treatment (NCI, 2013a).

**Non-Hodgkin Lymphoma (NHL) in Children:** NHL occurring in childhood is classified by chemical and genetic characteristics as well as cell appearance and include clinical behavior, response to treatment, phenotype and differentiation (NCI, 2013b). Groupings are relevant for the type of therapy given, and include lymphoblastic lymphoma, B-cell NHL (includes Burkitt, Burkitt-like lymphoma/leukemia and diffuse large B-cell lymphoma [DLBCL]); anaplastic large cell lymphoma (ALCL), and lymphoproliferative disease associated with immunodeficiency. It is staged according to several different systems; however, the most commonly used is that of St. Jude’s Research Hospital (Murphy Staging) (ACS, 2012b; NCI, 2013b).

Childhood lymphoma is distinct from disease found in adults; about 70% is aggressive and diffuse on presentation. The extent of the disease at diagnosis is one of the most important prognostic indicators. Appropriate treatment for each type differs, making accurate diagnosis critical for successful treatment. Children with recurrent disease generally have a poor prognosis. If remission can be achieved, autologous or allogeneic hematopoietic stem-cell transplantation (HSCT) may be pursued (NCI, 2013b).
Treatment
For both adults and children, treatment depends on the histologic type and stage of disease. Late effects of treatment have been observed; therefore, especially in children, the less intensive therapy that will result in good outcomes is given (National Cancer Institute [NCI], 2013a). Autologous and allogeneic HSCT have been proposed for the treatment of selected adults and children with non-Hodgkin lymphoma (NHL).

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

In allogeneic HSCT it is preferable for donors to have a human leukocyte antigen (HLA) type that is identical to the recipient. Matching is performed on the basis of variability at three or more loci of the HLA gene (e.g., HLA-A, HLA-B, HLA-DRB1). As HLA variability increases, transplant-related morbidity and mortality, including graft rejection and graft-versus-host disease, also increase.

Various studies demonstrate the safety and effectiveness of autologous HSCT for the treatment of NHL. It is considered an acceptable treatment option for selected adults and children.

Autologous HSCT
Adults: Controversies exist regarding the timing and effectiveness of autologous and allogeneic stem-cell HSCT in adults. These include whether autologous HSCT is effective as upfront consolidation for certain high-risk NHL groups, identification of the most appropriate treatment for chemotherapy-resistant patients, and the use of allogeneic versus autologous HSCT for some subgroups of NHL where an allogeneic graft-versus-lymphoma effect has been demonstrated (Bradley, 2008).

The published medical literature supports the safety and effectiveness of high-dose chemotherapy with autologous HSCT as a standard treatment option for selected individuals with aggressive or advanced indolent, aggressive or recurrent chemo-sensitive disease. There is a clear survival benefit for compared with conventional chemotherapy (Song, 2007; Oyan, 2006, Dreyling, 2005; Ganguly, 2005, Laudi, 2005; Lenz, 2004; Mounier, 2004). Survival rates at four years to twelve years range between 69.4%–34%. Complete remission prior to autologous HSCT is associated with better outcomes than partial remission (Oyan, 2005; Waheed, 2005). Individuals with disease that is not sensitive to chemotherapy may not respond well to high-dose therapy with autologous HSCT, and may be offered clinical trials (Ardeshna, 2005; Rodriguez, 2004; Cabellero, 2003; Kewalramani, 2000).

The NCI (2013a) notes that intensive therapy with chemotherapy followed by autologous or allogeneic bone marrow transplantation or HSCT is a potential treatment option for adults with indolent, noncontiguous stage II/III/IV NHL as well as individuals at high risk of relapse with aggressive, noncontiguous stage II/III/IV NHL. Transplantation is noted to be the treatment of choice for patients whose lymphoma has relapsed.

Regarding the effects of high-dose chemotherapy and autologous HSCT in first-line treatment of aggressive NHL, Greb et al. (2008) noted results of a meta-analysis of fifteen trials involving a total of 2728 randomized patients. The authors noted there is no conclusive evidence that autologous HSCT improves overall survival (OS) when compared with conventional chemotherapy in the first-line treatment of individuals with NHL. Thirteen studies including 2018 patients showed significantly higher complete remission rates in the HSCT group (p=0.004). There was some evidence for increased treatment-related mortality (TRM) in the group receiving HSCT compared with conventional chemotherapy, but the effect was not statistically significant (5.7% versus 4.3%, respectively). There was no significant difference in terms of overall survival (OS) between the groups (p=0.58). The authors noted that there may be a benefit if high-dose therapy is used for high-risk patients, it should not be arbitrarily used as a first-line treatment. Additionally the authors noted that there is no evidence that high-dose chemotherapy significantly improves event-free survival (EFS) in the first-line treatment of good- and poor-risk patients with aggressive NHL (p=0.31). There were differences between risk groups: patients with good risk had better overall outcomes after conventional chemotherapy.

Individuals with indolent early-stage or low-grade disease are not candidates for autologous HSCT as this procedure does not confer a survival benefit beyond that of conventional chemotherapy (Apostolidis, 2000). Similarly there appears to be no benefit to high-dose chemotherapy with autologous hematopoietic stem-cell
transplantation (HSCT) for individuals with indolent or aggressive stage I and contiguous stage II non-Hodgkin lymphoma (NHL).

Schaaf et al. (2012) reported results of a Cochrane review for the effectiveness of autologous hematopoietic stem-cell transplantation (HSCT) in follicular lymphoma (FL). The authors reported a strong progression-free survival (PFS) benefit for autologous HSCT compared with chemotherapy or immunochemotherapy in previously untreated patients with follicular lymphoma. No statistically significant differences in terms of overall survival (OS), treatment-related mortality (TRM) and secondary cancers were detected. Longer follow-up data are necessary to find out whether the PFS advantage will translate into an OS advantage in previously untreated patients with FL. There is also evidence that high dose therapy is advantageous in patients with relapsed FL.

Children: Both allogeneic and autologous HSCT have met with similar success in the treatment of selected children with relapsed NHL. The chances for success are greater in those who have chemosensitive disease (Sandlund, 2002). Five-year OS rates range from 22–56%. As an appropriate donor may not be readily available, autologous HSCT has been more commonly used. The use of non-myeloablative HSCT or tandem cycles of chemotherapy with HSCT have not been identified as potential therapies for children with this disease.

Won et al. (2006) evaluated the results of 33 children who underwent autologous HSCT for refractory or recurrent NHL. The overall two-year event-free survival (EFS) rate was 59%. EFS for Burkitt, lymphoblastic and large-cell lymphoma were 66.7%, 50.5% and 82.1%, respectively. Status at transplantation was the most predictive factor for survival after HSCT. The authors noted that autologous HSCT is safe and applicable to pediatric patients with recurrent or refractory NHL.
Tomblyn et al. (2011) reported results of a prospective multi-center trial comparing outcomes of autologous hematopoietic stem-cell transplantation (HSCT) (n=22) and reduced-intensity allogeneic HSCT (n=8). Patients with relapsed, chemotherapy sensitive follicular lymphoma (FL) were assigned to treatment arms depending on the availability of a human leukocyte antigen (HLA)-matched sibling donor. Overall survival (OS) was 73% in autologous hematopoietic stem-cell transplantation (HSCT) versus 100% in allogeneic HSCT, and progression-free survival (PFS) was 63%, respectively. This study suggests that allogeneic and autologous HCT result in promising three-year OS and PFS in patients with relapsed FL.

Toze and Barnett (2002) conducted a review of six studies utilizing non-myeloablative HSCT in the treatment of non-Hodgkin lymphoma (NHL). The authors noted that non-myeloablative conditioning after previous auto- or allografting might be a less hazardous option due to treatment-related toxicity. They also note that a projected estimate of long-term disease-free survival (DFS) after second transplantation is likely to be less than 40%.

Although evidence does not include randomized controlled trial data, non-myeloablative allogeneic HSCT may result in improved OS and is considered an acceptable treatment option for selected adults with NHL.

**Children:** There are scarce data in the published peer-reviewed literature regarding the safety and effectiveness of non-myeloablative allogeneic HSCT in the treatment of children with NHL. In general, children have less toxicity and better outcomes than adults do after conventional allogeneic HSCT; thus, there is limited justification for studying non-myeloablative HSCT in this population. To determine if there are improved outcomes compared with standard-dose chemotherapy or myeloablative dose allogeneic HSCT, this therapy should be evaluated in prospective controlled trials. At this time the role of non-myeloablative allogeneic HSCT for the treatment of children with NHL has not been established.

**Tandem Autologous or Allogeneic Tandem HSCT:** Tandem, or sequential planned HSCTs have been proposed as a treatment option for individuals with NHL. Rationale includes increasing the graft-versus-lymphoma effect, or permitting multiple cycles of high-dose therapy by rescuing the patient from the effects of myeloablation.

Ahmed et al. (2005) reported on outcomes of 47 patients with refractory NHL who were treated with tandem cycles of high-dose chemotherapy and autologous HSCT. Five-year OS survival and event-free survival (EFS) were 12.76% and 6.38%, respectively.

Gianni et al. (2003) treated 28 patients with a series of high-dose chemotherapy regimens with three autologous HSCT procedures. The OS and EFS rates at 54 months were 89% and 79%, respectively. This study is limited by study design, small participant numbers, and lack of randomization.

There are scarce data supporting the safety or effectiveness of tandem autologous or allogeneic HSCT for the treatment of adults or children with NHL. At this time the role of tandem HSCT has not been established.

**Contraindications**

Many factors affect the outcome of a tissue transplant. The patient selection process is designed to obtain the best result for each patient. Overall health, age and disease stage are extremely important considerations in evaluating transplant candidates. The presence of any significant comorbid conditions which would significantly compromise clinical care and chances of survival is a contraindication to transplantation. Relative contraindications to HSCT include, but are not limited to:

- poor cardiac function (ejection fraction less than 45%)
- poor liver function (bilirubin greater than 2.0 mg/dl and transaminases greater than two times normal)
- poor renal function (creatinine clearance less than 50 mL/min)
- poor pulmonary function (diffusion capacity less than 60% of predicted)
- presence of human immunodeficiency virus or active hepatitis B; hepatitis C; or human T-cell lymphotropic virus (HTLV-1)
- Karnofsky rating less than 60% and/or Eastern Cooperative Oncology Group (ECOG) performance status greater than two
Professional Societies/Organizations

National Cancer Institute (NCI): The NCI (2013a): Adults: Under clinical evaluation: autologous or allogeneic bone marrow transplantation (BMT) or hematopoietic stem-cell transplantation (HSCT), is under clinical investigation for the treatment of indolent, noncontiguous stage II/III/IV non-Hodgkin lymphoma (NHL) in adults, patients at high risk of relapse with aggressive, noncontiguous stage II/III/IV adult NHL, relapsed indolent, recurrent disease, aggressive, noncontiguous stage II/III/IV disease, and lymphoblastic lymphoma. For aggressive, recurrent adult NHL, bone marrow transplantation (BMT) is the treatment of choice.

Children (2013b): Allogeneic and autologous bone marrow transplantations are also noted to be treatment options for recurrent or refractory B-lineage NHL, if remission can be achieved. The benefit of autologous versus allogeneic SCT is unclear. For recurrent/refractory anaplastic large cell lymphoma; standard chemotherapy, followed by autologous SCT or allogeneic SCT, if remission can be achieved, have all been employed in this setting."

National Comprehensive Cancer Network Network™ (NCCN™): Clinical Practice Guidelines in Oncology for NHL (2013) note:

- **Follicular Lymphoma**: second-line consolidation or extended dosing: “High-dose therapy (HDT) and autologous stem-cell rescue (ASCR) has been shown to prolong overall survival (OS) and progression-free survival (PFS) in patients with relapsed or refractory disease.”
- **Mantle Cell Lymphoma (stage II bulky and stage III-IV)**: “For patients with a complete response to first-line therapy participation in a clinical trial or high-dose therapy/autologous stem-cell rescue is recommended for eligible patients. Patients with relapsed disease following complete remission to induction therapy, those who obtain only a partial remission to induction therapy or those with progressive disease are appropriate candidates for clinical trials of high-dose therapy with autologous stem-cell rescue, allogeneic HSCT, or immunotherapy with nonmyeloablative stem-cell rescue. Allogeneic HSCT (myeloablative or reduced intensity is an appropriate option for patients with relapsed or refractory disease in remission following second-line therapy"
- **Diffuse Large B-Cell Lymphoma**: stage I-II with partial response: “A repeat biopsy can be performed and if positive the patient can proceed to second-line therapy followed by HDT/ASCR. Upfront HDT/ASCR is recommended only in selected high-risk circumstances or in the context of a clinical trial. High-dose therapy/autologous stem-cell rescue is the treatment of choice for patients with relapsed or refractory disease that is chemosensitive at relapse. Patients with complete response or partial response to second-line chemotherapy regimen should be considered for further consolidation with high-dose therapy/autologous stem-cell rescue. Patients with disease relapse following HDT/ASCR should be treated in the context of a clinical trial.”
- **Burkitt Lymphoma**: “Second-line chemotherapy with rituximab followed by HDT/ASCR can be considered in selected patients.”
- **Lymphoblastic Lymphoma**: “Poor risk patients can be considered for treatment with HDT/ASCR or allogeneic stem-cell rescue. Patients with biopsy-proven partial remission are considered treatment failure and should be treated in clinical trials. Allogeneic HSCT can be considered. The NCCN guidelines recommend reinduction with combination chemotherapy or allogeneic HSCT for patients with relapsed disease ”
- **Peripheral T-Cell Lymphoma (PTCL)**: “Stage I (aalPI low/low-intermediate): HDT/ASCR is considered for patients showing partial remission at interim staging. Stage I (aalPI high-intermediate or high):consolidation with HDT/ASCR or observation.” Relapsed or refractory disease: “Consolidation therapy with HDT/ASCR or an allogeneic HSCT is recommended for those with complete or partial response.”
- **Extra Nodal NK/T-Cell Lymphomas**: “HSCT is a reasonable option for patients with stage I nasal disease achieving a partial response. If eligible, HSCT should be considered for all patients with stage II-IV nasal disease and stage II-IV extranasal disease achieving complete or partial response to induction therapy.”

American Society for Blood and Marrow Transplantation (ASBMT): The ASBMT (2003, updated 2011) includes the following practice guidelines for the role of cytotoxic therapy in the treatment of DLBCL. These Guidelines note that autologous SCT is recommended as part of salvage therapy for patients with chemosensitive relapsed DLBCL. It is not recommended for patients who achieve only a partial response to an abbreviated (3 cycles) induction regimen. Autologous SCT is not recommended as first-line therapy for any
International Prognostic Index group at this time. The Guidelines also note that planned tandem, or multiple sequential autologous HSCTs are not recommended.

Regarding follicular lymphoma (FL), ASBMT (2011) notes there is a statistically significant improvement in overall survival (OS) and progression-free survival (PFS) using autologous SCT as salvage therapy. Autologous SCT is not recommended as first-line treatment for most patients because of no significant improvement in OS, a higher incidence of secondary myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML), and a lack of comparative data with rituximab-containing regimens. Reduced intensity conditioning (RIC) appears to be an acceptable alternative approach in allogeneic SCT based on one study and expert opinion.

National Marrow Donor Program/ASBMT (2013): Recommendations for the timing of transplant evaluation for individuals with NHL are as follows:

- **Follicular lymphoma**
  - Poor response to initial treatment
  - Initial remission duration <12 months
  - First relapse
  - Transformation to diffuse B cell lymphoma (DBCL)

- **Diffuse B-Cell lymphoma**
  - at first or subsequent relapse
  - first complete remission for patients with high or high-intermediate IPI risk
  - no complete remission with initial treatment
  - second or subsequent remission

- **Mantle Cell lymphoma**
  - After initiation of therapy

- **Other high-risk lymphomas**
  - After initiation of therapy

Use Outside of the US
A number of international professional societies and organizations have published guidelines/recommendations regarding the treatment of non-Hodgkin lymphoma..

European Society for Medical Oncology ([ESMO], 2009): On behalf of the ESMO Working Group Tilly et al. published clinical recommendations regarding the diagnosis, treatment, and follow-up for diffuse B-cell NHL. Regarding treatment for newly diagnosed diffuse large B-cell lymphoma the recommendations note “High-dose chemotherapy with stem-cell transplantation remains experimental in first-line therapy. Regarding relapsed and refractory DLBCL the recommendations note “In suitable patients with adequate performance status (no major organ dysfunction, age <65–70 years), salvage regimen (rituximab and chemotherapy) followed in responsive patients by high-dose treatment with stem-cell support is recommended.”

Leukemia and Lymphoma Society of Canada ([LLS of Canada], 2006): This organization notes allogeneic transplantation is used for some non-Hodgkin lymphoma patients with disease that is resistant to chemotherapy. This approach is usually reserved for patients with high-grade (aggressive) non-Hodgkin lymphoma. Regarding autologous HSCT, the LLS of Canada notes “Autologous stem cell infusion permits more patients and older patients with a relapse of their disease to receive intensive chemotherapy and rescue of their marrow function by infusing stem cells but it may not be as effective as allogeneic transplantation. Some patients with aggressive lymphomas may benefit from this treatment. In addition, patients with low-grade lymphomas, including refractory or relapsed Hodgkin lymphoma (uncommonly), whose disease continues to progress after receiving other forms of treatment, may benefit from this approach.”

Summary
Treatment for non-Hodgkin lymphoma depends on the histologic type and stage of disease. The published, peer-reviewed scientific literature supports the safety and effectiveness of autologous and myeloablative
allogeneic hematopoietic stem-cell transplantation (HSCT) in selected adults and children with non-Hodgkin lymphoma (NHL). The evidence also supports the safety and effectiveness of non-myeloablative allogeneic HSCT in selected adults with NHL. The roles of non-myeloablative allogeneic HSCT in children and tandem transplantation in children or adults have not yet been established.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
       2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Covered when medically necessary:

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<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic</td>
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<td>38206</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous</td>
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<td>38207</td>
<td>Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage</td>
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<td>Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor</td>
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<td>38211</td>
<td>Transplant preparation of hematopoietic progenitor cells; tumor cell depletion</td>
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<td>Allogeneic lymphocyte infusions</td>
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<td>S2142</td>
<td>Cord blood-derived stem-cell transplantation, allogeneic</td>
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<td>S2150</td>
<td>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</td>
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References


33. Jantunen E. Autologous stem cell transplantation beyond 60 years of age. Bone Marrow Transplant. 2006 Oct 16;[Epub ahead of print]


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