



CIGNA MEDICAL COVERAGE POLICY

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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 adults with noncontiguous stage II, stage III or stage IV non-Hodgkin lymphoma (NHL).

CIGNA covers allogeneic HSCT as medically necessary for the treatment of adults with noncontiguous stage II, stage III or stage IV non-Hodgkin lymphoma NHL who are not candidates for autologous HSCT when a human leukocyte antigen (HLA) matched donor (at least five of six match) is available.

CIGNA covers myeloablative allogeneic or autologous HSCT as medically necessary for the treatment of children with recurrent NHL with chemosensitive disease.

CIGNA does not cover ANY of the following therapies for the treatment of NHL because they are considered experimental, investigational or unproven:

- autologous OR allogeneic HSCT for stage I or contiguous stage II disease (adults only)
- non-myeloablative allogeneic HSCT (children only)
- tandem autologous OR allogeneic HSCT (adults and children)

General Background

Non-Hodgkin lymphoma (i.e., non-Hodgkin's lymphoma or NHL) is a complex, heterogeneous group of lymphoproliferative malignancies that originate 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. NHL may occur at any age; it is uncommon in children and the incidence increases with age. In general, overall median five-year survival for aggressive NHL is 50% to 60% (National Cancer Institute [NCI], 2010a). Relative five-year survival rate for children age 0–19 years is 81.9% (Leukemia & Lymphoma Society, 2010).

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 two prognostic groups: the indolent lymphomas and the aggressive lymphomas (NCI, 2010). In addition, some individuals are considered to have 'intermediate-grade' disease, which is a progression between indolent and aggressive. Indolent types, which are slowly progressing, or low-grade subtypes, have a relatively good prognosis, with a median survival of ten years; however, they usually are not curable in the advanced stages. Indolent lymphomas include the following (NCI, 2010a):

- 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, 2010a):

- diffuse large cell lymphoma
 - mediastinal large B-cell lymphoma
 - follicular large cell lymphoma (grade III)
 - anaplastic large cell lymphoma
 - extranodal NK/T-cell lymphoma
 - lymphomatoid granulomatosis
 - angioimmunoblastic T-cell lymphoma
 - peripheral T-cell lymphoma, unspecified
 - enteropathy –type T-cell lymphoma
 - intravascular large B-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, non-Hodgkin lymphoma (NHL) is staged according to the Ann Arbor staging system (American Cancer Society [ACS], 2010). This staging system is used, along with several prognostic indexes to predict the rate of disease progression and the individual's response to treatment (National Cancer Institute [NCI], 2010a). Significant risk factors predictive of overall survival include age, stage of lymphoma, presence or absence of extranodal involvement, number of involved nodal areas, lactate dehydrogenase (LDH) levels, hemoglobin level, and performance status.

Non-Hodgkin Lymphoma in Children: These malignancies are classified by chemical and genetic characteristics as well as cell appearance and include clinical behavior, response to treatment, phenotype and differentiation (NCI, 2010b). 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. NHL in children is staged according to several different systems; however, the most commonly used is that of St. Jude's Research Hospital (Murphy Staging) (ACS, 2010b; NCI, 2010b).

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 HSCT may be pursued (NCI, 2010b).

Treatment

For both adults and children, treatment depends on the histologic type and stage of disease. Late effects of treatment have been observed, including sterility, left ventricular dysfunction and an increased risk of second primary cancers (NCI, 2010a); therefore, especially in children, the less intensive therapy that will result in good outcomes is given. Autologous and allogeneic hematopoietic stem-cell transplantation (HSCT) have been proposed for the treatment of selected adults and children with 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).

Autologous HSCT

Adults: Controversies exist regarding the use of autologous or allogeneic stem-cell support in adults. These include autologous HSCT as upfront consolidation for certain groups of high-risk NHL, 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). Individuals with indolent early-stage or low-grade disease are not candidates for autologous HSCT as this procedure does not confer any survival benefit beyond that of conventional chemotherapy (Apostolidis, 2000).

Greb et al. (2008) performed a meta-analysis of clinical trials reporting the effects of high-dose chemotherapy and autologous HSCT in first-line treatment of aggressive NHL. Fifteen trials with a total of 2728 randomized patients were included in the analysis. 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 is no conclusive evidence that HSCT improves OS when compared with conventional chemotherapy in the first-line treatment of patients with NHL. Although 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.

Hayes (2006) conducted a review of the literature on the efficacy of high-dose chemotherapy with autologous stem-cell support for low-grade NHL. The studies estimated three- to four-year failure-free survival rates ranging

from 44–63%. Historically, the survival rate for patients with low-grade non-Hodgkin lymphoma (NHL) who receive standard-dose chemotherapy is eight–10 years. The survival rates in two studies assessing conventional chemotherapy for low-grade NHL were similar to survival rates reported by the studies using high-dose chemotherapy with hematopoietic stem-cell support. There appears to be no benefit to high-dose chemotherapy with autologous hematopoietic stem-cell transplantation (HSCT) for patients with indolent or aggressive stage I and contiguous stage II NHL.

The published medical literature supports the use of high-dose chemotherapy with autologous HSCT as a standard treatment option for selected individuals with aggressive or advanced disease. Individuals with advanced indolent, aggressive or recurrent chemosensitive disease are candidates for autologous HSCT as there is a clear survival benefit for compared with conventional chemotherapy (Song, 2007; Chang, 2006; Ovan, 2006; Dreyling, 2005; Ganguly, 2005, Khouri, 2005; Laudi, 2005; Brugger, 2004; Lenz, 2004; Milpied, 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 (Ovan, 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 (Ardehna, 2005; Rodriguez, 2004; Cabellero, 2003; Kewalramani, 2000).

The National Cancer Institute ([NCI], 2010a) notes that intensive therapy with chemotherapy followed by autologous or allogeneic bone marrow transplantation or hematopoietic stem-cell transplantation (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.

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 overall survival 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.

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.

Myeloablative Allogeneic HSCT

Adults: In highly selected patients, myeloablative and non-myeloablative HSCT have shown long-term survival benefit. According to Razvani (2008), allogeneic HSCT can produce a graft-versus-lymphoma (GVL) effect, resulting in disease regression even in chemotherapy-resistant patients. Trials of myeloablative HSCT are characterized by transplant-related mortality (TRM) rates of 19%–42% (Kim, 2006; Doocey, 2005; Ganti, 2005) and are usually restricted to younger patients who have a human-leukocyte antigen (HLA)-identical sibling donor. Published, clinical studies demonstrate similar results for allogeneic HSCT when compared to the overall survival (OS) achieved by the use of autologous HSCT in the treatment of NHL. These trials were not randomized, as treatment groups were selected based on the availability of a matched donor as well as factors that are used to determine the success of a transplant, including age, performance status and bone marrow involvement. At a range of two–five years, OS survival rates range from 41%–70%, with event-free survival (EFS) rates of 43%–51% for the same time intervals (Kim, 2006; Laudi, 2006; Doocey, 2005; Kassamon, 2005).

Children: Kasamon et al. (2005) retrospectively reviewed outcomes for patients with central nervous system (CNS) lymphoma who underwent HSCT. Thirty-seven adults and children with central nervous system-involved lymphoma in remission underwent allogeneic or autologous HSCT. Age older than 18 years, resistant systemic disease, busulfan/cyclophosphamide conditioning, and lack of intrathecal consolidation after HSCT were

statistically associated with inferior survival. The five-year event-free survival and overall survival (OS) rates were 36% and 39%, respectively.

Although data are not robust, myeloablative allogeneic hematopoietic stem-cell transplantation (HSCT) is considered an acceptable treatment option for selected adults and children with non-Hodgkin lymphoma (NHL).

Non-myeloablative Allogeneic HSCT

Adults: Non-myeloablative allogeneic HSCT has recently been introduced as a novel, potentially curative option for patients with relapsed or refractory NHL (Gopal, 2006). Many patients are ineligible for myeloablative allogeneic HSCT due to age, previous treatment with chemotherapy, and comorbid conditions. This therapy has the potential to reduce treatment-related mortality (TRM) and potentially enhance the graft-versus-lymphoma (GVL) effect.

Several studies have published results regarding the effectiveness of non-myeloablative or reduced-intensity conditioning regimens for various subtypes of NHL. Patient populations include those who have previously received autologous or allogeneic HSCT, usually within a few months of the non-myeloablative therapy (Rezvani, 2008; Vigouroux, 2007; Baron, 2006; Rodriguez, 2006; Dean, 2005; Gutman, 2005; Morris, 2004; Faulkner, 2004). OS rates ranged from 18%-73%, at two–three year time intervals. Transplant-related mortality ranged from 11%–43% for the same time intervals.

Toze and Barnett (2002) conducted a review of six studies utilizing non-myeloablative HSCT in the treatment of 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 has not been established.

Autologous or Allogeneic Tandem HSCT: Tandem, or sequential planned HSCTs have been proposed as a treatment option for individuals with non-Hodgkin lymphoma. 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 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.

Although sequential doses of chemotherapy may be used prior to a single HSCT, 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 co morbid 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 (2010a) notes that intensive therapy with chemotherapy, with or without total-body irradiation or high-dose radioimmunotherapy followed by 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. Autologous or allogeneic HSCT are also noted to be under clinical evaluation for the treatment of patients at high risk of relapse with aggressive, noncontiguous stage II/III/IV adult NHL. Bone marrow transplantation is noted to be the treatment of choice for patients whose lymphoma has relapsed. The NCI (2010 [b]) notes that allogeneic and autologous bone marrow transplantations are noted to be treatment options for recurrent childhood Burkitt lymphoma, lymphoblastic lymphoma and anaplastic large-cell lymphoma (ALCL) types.

National Comprehensive Cancer Network Network™ (NCCN™): Clinical Practice Guidelines in Oncology for NHL (2009) note:

- **Follicular Lymphoma:** “High-dose therapy (HDT) and autologous stem-cell rescue (ASCR) is an appropriate option for patients with refractory, relapsing or progressive disease, if a subsequent remission can be induced. In highly selected patients, trials of fully ablative and non-myeloablative allogeneic stem cell transplant have shown a long-term survival advantage, although there is a non-treatment-related mortality rate of 10%-25% for non-myeloablative and 40% for myeloablative.”
- **Mantle Cell Lymphoma:** “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 stem-cell rescue. Alternatively, these patients can also be treated with second-line chemotherapy or HDT/ASCR rescue.”
- **Diffuse Large B-Cell Lymphoma:** “First-line consolidation with high-dose therapy and autologous stem-cell rescue is an option for eligible patients although there is no consensus on the value of this approach. Consideration of autologous stem-cell rescue or completing the course of therapy with a higher dose of radiation therapy is recommended for patients with localized disease (stage I-II) with partial response. High-dose therapy/autologous stem-cell rescue is the treatment of choice for patients with relapsed or refractory disease. 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. Pertinent clinical trials including the option of allogeneic stem-cell rescue is another option.”
- **Lymphoblastic Lymphoma:** “Poor risk patients can be considered for treatment with HDT/ASCR or allogeneic stem-cell rescue.”
- **Peripheral T-Cell Lymphoma (PTCL):**
 - **PTCL-Not Otherwise Specified and Anaplastic Large Cell Lymphoma:** “First-line consolidation with HDT/ASCR is a reasonable treatment option only in patients showing a good response to induction therapy. First-line consolidation with high-dose therapy/autologous HSCT for patients with stages I or II disease (low intermediate) showing partial response at interim staging. A clinical trial with allogeneic HSCT is also an option. Patients with stage I or II (high-intermediate) or stages III or IV and complete response can be consolidated with HDT/ASCR. Patients with relapsed or refractory disease who have a complete or partial response after consolidation with second-line therapy can be considered for allogeneic or autologous stem-cell rescue.”

American Society for Blood and Marrow Transplantation (ASBMT): The ASBMT (2003) issued practice guidelines for the role of cytotoxic therapy in the treatment of DLCL. These guidelines note that HSCT is recommended for the treatment of chemotherapy-sensitive relapse, use in first complete remission in high/intermediate risk International Prognosis Index (IPI) disease, and as high-dose sequential chemotherapy in intermediate-high/high-risk IPI untreated disease. Stem-cell transplantation is not recommended for the following: first complete remission in low/intermediate risk IPI patients, or after abbreviated induction therapy. Autologous stem cell transplantation is currently the standard of care and is preferred over allogeneic stem cell transplantation; however, studies are ongoing to further evaluate the role of allogeneic transplantation.

National Marrow Donor Program/ASBMT (2009): 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
 - Second relapse
 - Transformation to DLCL
- 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
- Mantle Cell lymphoma
 - Following initial therapy

Summary

Data in the published, peer-reviewed medical 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: 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; cry preservation 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
200.00-200.08	Reticulosarcoma
200.10-200.18	Lymphosarcoma
200.20 – 200.28	Burkitt's tumor or lymphoma
200.30-200.38	Marginal zone lymphoma
200.40-200.48	Mantle cell lymphoma
200.50-200.58	Primary central nervous system lymphoma
200.60-200.68	Anaplastic large cell lymphoma
200.70-200.78	Large cell lymphoma
202.00-202.08	Nodular lymphoma,
202.10-202.18	Mycosis fungoides
202.20-202.28	Sezary's disease
202.50-202.58	Letterer-Siwe disease
202.70-202.78	Peripheral T-cell lymphoma

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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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	12/15/2007	0263	Stem-Cell Transplant for Non-Hodgkin's Lymphoma

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