Donor Leukocyte Infusion for Malignancies Treated with an Allogeneic Hematopoietic Cell Transplant

Archived Medical Policy

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Policy # 00027
Original Effective Date: 08/26/2002
Archived Date: 11/15/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider donor lymphocyte infusion (DLI) following allogeneic hematopoietic cell transplantation (HCT) that was originally considered medically necessary for the treatment of a hematologic malignancy that has relapsed or is refractory, to prevent relapse in the setting of a high risk of relapse, or to convert a patient from mixed to full donor chimerism to be eligible for coverage.

Note: Settings considered high risk for relapse include T cell depleted grafts or nonmyeloablative (reduced-intensity conditioning [RIC]) allogeneic hematopoietic cell transplantation (HCT).

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers donor lymphocyte infusion (DLI) following allogeneic hematopoietic cell transplantation (HCT) that was originally considered investigational for the treatment of a hematologic malignancy to be investigational.*

Based on review of available data, the Company considers donor lymphocyte infusion (DLI) as a treatment of nonhematologic malignancies following a prior allogeneic hematopoietic cell transplantation (HCT) to be investigational.*

Based on review of available data, the Company considers genetic modification of donor lymphocytes to be investigational.*

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**Background/Overview**
Approximately 40% to 60% of patients who receive a DLI develop graft-versus-host disease (GVHD), and the development of GVHD predicts a response to the DLI. Treatment-related mortality after DLI is 5% to 20%. There does not seem to be a correlation between the type of hematologic malignancy for which the DLI is given and the development of GVHD. The risk of developing GVHD is related, in part, to DLI dose and therapy before DLI.

DLI may be used for various indications such as relapse after allogeneic HCT, to prevent disease relapse in the setting of T cell–depleted grafts or nonmyeloablative conditioning regimens, or to convert mixed to full donor chimerism. Management of relapse, which occurs in approximately 40% of all hematologic malignancy patients, is the most common indication for DLI.

The literature is heterogeneous when reporting methods of cell collection, indication (e.g., planned after chemotherapy, in early relapse), cell dose infused, and cell subtype used. In addition, many studies include multiple diseases with little information on disease-specific outcomes; however, DLI is used in nearly all hematologic malignancies for which allogeneic HCT is performed, including chronic myeloid leukemia, acute myeloid and lymphoblastic leukemias, myelodysplastic syndromes, multiple myeloma, and Hodgkin and NHL.

**FDA or Other Governmental Regulatory Approval**
U.S. Food and Drug Administration (FDA)
The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation (CFR) title 21, parts 1270 and 1271. Hematopoietic stem cells are included in these regulations.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Rationale/Source**
Several review articles have summarized studies reporting the use of DLI for the treatment of patients with hematologic malignancies that relapse following allogeneic HCT.
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Donor Lymphocyte Infusion

Chronic Myelogenous Leukemia

DLI has been most effective in chronic myelogenous leukemia (CML), inducing a molecular complete remission (CR) in up to 80% of patients who relapse in chronic phase. Only a 12% to 33% response rate has been reported in patients in accelerated or blast phase. Response duration to DLI in patients with relapsed CML after HCT is long-standing in most patients.

Several large series have reported outcomes of patients with relapsed CML after receiving DLI. These studies comprise more than 1000 patients, approximately half of whom had only molecular or cytogenetic relapse at the time of DLI. The cell doses varied among patients, with some receiving multiple DLI infusions and others, planned dose escalations. Despite these variations, a molecular or cytogenetic CR was achieved in 74% (746/1007) of patients. Overall survival (OS) at 3 years or more ranged from 53% to 95%, was 64% at 5 years, and was 59% at 10 years after DLI in another series.

The role of DLI in CML has changed since the introduction of tyrosine kinase inhibitors (TKIs) in CML treatment, which keeps the disease under control instead of proceeding to HCT. However, for patients who develop resistance to TKIs or are unable to tolerate their adverse effects, HCT and DLI may be a disease management option.

Acute Leukemias, Myelodysplasia, and Other Myeloproliferative Diseases

In a 2013 systematic review, El-Jurdi et al evaluated 39 prospective and retrospective studies using DLI to treat relapse after HCT for lymphoid malignancies including acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), multiple myeloma, non-Hodgkin lymphoma (NHL), and Hodgkin lymphoma (HL). No randomized controlled trials were identified. Studies selected were heterogeneous, thus limiting interpretation of the review. Reported pooled proportions of CR (95% confidence interval [CI]) were 27% (16% to 40%) for ALL, 55% (15% to 92%) for CLL, 26% (19% to 33%) for multiple myeloma, 52% (33% to 71%) for NHL, and 37% (20% to 56%) for HL.

An observational study compared different treatments for 147 consecutive patients who relapsed after allogeneic HCT for myelodysplastic syndrome. Sixty-two patients received HCT or DLI, 39 received cytoeductive treatment, and 46 were managed with palliative or supportive care. Two-year OS rates were 32%, 6%, and 2%, respectively (p<.001). In multivariate analysis, 4 factors adversely influenced 2-year OS rates: history of acute graft-versus-host disease (GVHD; hazard ratio [HR], 1.83; 95% CI, 1.26 to 2.67; p=0.002), relapse within 6 months (HR=2.69; 95% CI, 0.82 to 3.98; p<0.001), progression to acute myelogenous leukemia (HR=2.59; 95% CI, 1.75 to 3.83; p<0.001), and platelet count less than 50 g/L at relapse (HR=1.68; 95% CI, 1.15 to 2.44; p=0.007). HCT or DLI was an independent factor that favorably impacted OS (HR=0.40; 95% CI, 0.26 to 0.63; p<0.001).
Acute Myelogenous Leukemia

Use of DLI for patients with relapsed acute myelogenous leukemia (AML) after allogeneic HCT has yielded overall remission rates ranging from 15% to 42%, with an OS of 15% to 20%. (For comparison, a second HCT in this group of patients results in 10% to 35% long-term survival, with a treatment-related mortality of approximately 50%.) Patients with lower initial disease burden, reduction in the tumor burden with chemotherapy before DLI, and favorable cytogenetics appeared to benefit more with DLI.

A large retrospective analysis from the European Blood and Marrow Transplant Group compared OS in 399 patients with AML with posttransplant relapse who either were treated with (n=171) or without (n=228) DLI. Patients who received DLI had an improved 2-year OS (21%) compared with those who did not (9%; p<0.001).

A 2015 large retrospective series from the Center for International Blood and Marrow Transplant Research (CIBMTR) reported outcomes for 1788 AML patients who experienced a first or second relapsed after allogeneic HCT, among whom 1231 (69%) received subsequent intensive therapy that included DLI. Among the 1231 patients who received treatment, 660 (54%) received chemotherapy alone; 202 (16%) received DLI with or without chemotherapy; and 369 (30%) received a second allogeneic HCT with or without additional chemotherapy or DLI. Among all patients who received DLI, 87 (33%) survived more than 1 year after relapse; median survival was 7 months (range, 1-177 months). Cell-based therapy (DLI or second HCT) resulted in significantly better postrelapse OS than chemotherapy alone. These results are consistent with other reports of DLI in patients who had AML relapse after allogeneic HCT.

The literature for myelodysplasia syndromes (MDS) and other myeloproliferative diseases treated with DLI either after relapse or for mixed chimerism consists of small sample sizes, inconsistent pre-DLI therapy, and varied DLI cell doses, making it difficult to draw definite conclusions about outcomes. However, it appears that some patients attain durable remissions with DLI after posttransplant relapse.

Warlick et al reported CR after DLI in 49% (17/35) patients with relapsed non-CML, including AML and MDS, after allogeneic HCT. OS at 1 year was 30% and 19% at 2 years. The authors reported that a lower dose regimen of DLI was more tolerable and reduced GVHD occurrence to 25% compared with 66% with higher dose DLI.

An analysis from the German Cooperative Transplant Study Group reported outcomes among a cohort of patients (N=154) who relapsed after undergoing allogeneic HCT to treat AML (n=124), MDS (n=28), or myeloproliferative syndrome (n=2). All patients received a median of 4 courses of azacitidine, and DLI was administered to 105 (68%). OS among all patients was 29% at 2-year follow-up, which compares favorably
with other reports. The overall incidence of acute GVHD based on the total cohort (N=154) was 23%, and 31% in those given DLI (n=105).

**Acute Lymphoblastic Leukemia**
The graft-versus-tumor effect is thought to be less robust in patients with ALL than in the myeloid leukemias. Smaller studies have reported DLI response rates ranging from 0% to 20% and OS rates of less than 15%. By comparison, a second allogeneic HCT provides a 5-year OS of 15% to 20%, with a treatment-related mortality rate of approximately 50%.

The clinically evident graft-versus-leukemia effect of DLI requires weeks to months to manifest, and, because ALL is a rapidly proliferating disease, DLI only does not control the disease without a significant reduction in leukemia burden before DLI. Management of patients with relapsed ALL leading to the best OS is achieved through a combination of salvage chemotherapy and DLI. Although it is unclear whether DLI adds benefit to salvage chemotherapy, long-term survival has been reported with relapsed ALL treated with chemotherapy plus DLI.

**Lymphomas**
Studies in which patients received DLI for lymphomas consist of small numbers of patients and various histologies (both HL and high- and low-grade NHL). In general, the highest response rates have been seen in the indolent lymphomas. For NHL, too few patients have been reported with any single histologic subtype of lymphoma to provide adequate information on the benefit of DLI for specific subtypes.

The largest series reported for NHL (N=21) using DLI showed response rates in 3 of 9 patients with high-grade NHL, 1 of 2 patients with mantle cell lymphoma, and 6 of 10 patients with low-grade disease.

A series of 14 patients with multiply relapsed HL who received RIC allogeneic HCT and DLI showed a CR of 57% and 2-year survival of 35%.

**Multiple Myeloma**
Observational data have suggested a graft-versus-tumor effect in multiple myeloma, because the development of GVHD has correlated with response in several analyses.

Allogeneic HCT is currently considered experimental for this indication. Most patients with multiple myeloma who undergo HCT receive an autologous HCT. However, the overall role of HCT for multiple myeloma is changing with the advent of highly active novel agents like lenalidomide and bortezomib.
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Five studies (sample size range, 5-63 patients) have reported the role of DLI in relapsed multiple myeloma, with the highest response to DLI being reported as 62%, with approximately half of the responders attaining CR. One confounding factor for high response rates for multiple myeloma treated with DLI is that corticosteroids used for treating GVHD have a known antimyeloma effect, which could potentially enhance response rates in these patients.

Section Summary: Donor Lymphocyte Infusion
There are a few nonrandomized comparative studies and numerous case series of DLI treatment for various hematologic malignancies and other myeloproliferative disorders. The nonrandomized studies, in patients with acute leukemia and myelodysplastic syndrome, have reported higher response rates for patients treated with DLI than with alternatives. The case series report higher response rates than expected for relapsed disease compared with historical controls. Although there are no high-quality RCTs for DLI treatment, this evidence permits the conclusion that response rates improve with DLI treatment for patients with previous HCT treatment and relapsed disease.

Modified DLI
In an effort to control GVHD, a group in Italy explored use of genetically modified lymphocytes engineered to express the suicide gene thymidine kinase of herpes simplex virus. These lymphocytes were infused into 23 patients with various hematologic malignancies who relapsed after allogeneic HCT. Six patients died of progressive disease within 4 weeks of infusion. Eleven patients experienced disease response (CR in 6, partial remission in 5). Three patients were still in CR at a median of 471 days. Twelve patients were evaluable for GVHD, 3 of whom developed acute or chronic GVHD, which was successfully treated with ganciclovir.

In a phase 2 trial, donor lymphocytes were treated with rapamycin ex vivo to produce rapamycin-resistant DLIs. Forty patients undergoing low-intensity HCT for hematologic malignancy were treated preemptively with chemotherapy and DLI. There were no infusional toxicities or serious events attributable to DLI. Classical acute GVHD occurred in 4 of 40 patients. By the end of the study (follow-up range, 42-84 months), 18 of 40 patients remained in sustained remission.

A phase 1 study evaluated patient response to DLI expressing the herpes simplex virus thymidine kinase suicide gene. Three patients were enrolled in the trial and received a single DLI. No local or systemic toxicity related to the gene-transfer procedure was observed. Two patients achieved stable disease. No patient had severe GVHD requiring systemic steroid and/or ganciclovir administration. Tyrosine kinase cells were detected in the peripheral blood of all 3 patients by polymerase chain reaction, but did not persist more than 28 days.
Section Summary: Modified DLI
These early-phase studies are insufficient to determine the efficacy of modified DLI in the treatment of hematologic malignancies. Randomized studies comparing modified DLI to standard treatment would be necessary to determine efficacy.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in December 2015 did not identify any ongoing or unpublished trials that would likely influence this review.

Summary of Evidence
For individuals who have had an allogeneic HCT who receive DLI, the evidence includes nonrandomized comparative studies and case series. Relevant outcomes are OS and change in disease status. In various hematologic malignancies and for various indications such as planned or preemptive DLI, treatment of relapse, or conversion of mixed to full donor chimerism, patients have shown evidence of responding to DLI. Response rates to DLI for relapsed hematologic malignancies following an allogeneic HCT are best in CML, followed by the lymphomas, multiple myeloma, and acute leukemias, respectively. Other than CML, clinical responses are most effective when chemotherapy induction is used to reduce the tumor burden before DLI. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have had an allogeneic HCT who receive a modified (genetic or other ex vivo modification) donor lymphocytes infusion, the evidence includes case series. Relevant outcomes are OS and change in disease status. The case series have demonstrated the feasibility of the technique and no serious adverse effects. Without a comparison to standard treatment, the efficacy of administering modified donor lymphocytes is unknown. The evidence is insufficient to determine the effects of the technology on health outcomes.

References
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07/18/2002 Medical Policy Committee review
07/26/2002 Managed Care Advisory Council approval
08/31/2004 Medical Director review
09/21/2004 Medical Policy Committee review. Format revision. No substance change to policy.
09/27/2004 Managed Care Advisory Council approval
08/03/2005 Medical Director review
08/16/2005 Medical Policy Committee review. No change to coverage eligibility.
08/24/2005 Managed Care Advisory Council approval
06/07/2006 Medical Director review
06/21/2006 Medical Policy Committee approval. Format revisions, Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
05/02/2007 Medical Director review
05/23/2007 Medical Policy Committee approval. Background section was added to the policy. Based on review of available data, the Company considers donor leukocyte infusion as a treatment of other malignancies that have relapsed after a prior marrow-ablative allogeneic SCT to be investigational was added.
11/05/2008 Medical Director review
11/18/2008 Medical Policy Committee approval. No change to coverage eligibility.
11/12/2009 Medical Policy Committee approval
11/04/2010 Medical Policy Committee review
11/03/2011 Medical Policy Committee review
11/16/2011 Medical Policy Implementation Committee approval. Title changed to "Donor Lymphocyte Infusion for Malignancies Treated with an Allogeneic Hematopoietic Stem-Cell Transplant." References extensively revised/added. Policy statements modified to indicate that donor lymphocyte infusion would be considered eligible for coverage "following an allogeneic-hematopoietic stem cell transplantation that was considered eligible for coverage for the treatment of a hematologic

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malignancy that has relapsed or is refractory, to prevent relapse in the setting of a high risk of relapse, or to convert a patient from mixed to full donor chimerism.

11/01/2012 Medical Policy Committee review
11/07/2013 Medical Policy Committee review
11/06/2014 Medical Policy Committee review
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015 Medical Policy Committee review
11/16/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2016 Medical Policy Committee review
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017 Medical Policy Committee review. Recommend archiving policy.
11/15/2017 Medical Policy Implementation Committee approval. “Hematopoietic stem cell transplantation (HSCT)” was replaced with “hematopoietic cell transplantation (HCT)” in the coverage statements, title, and text. Archived.

Next Scheduled Review Date: Archived medical policy.

Coding
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A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);

2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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