Donor Leukocyte Infusion for Hematologic Malignancies that Relapse after Allogeneic Cell Transplant

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1-4

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary donor lymphocyte infusion.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Donor lymphocyte infusion (DLI) – Also called donor leukocyte or buffy-coat infusion, is a type of therapy in which T lymphocytes from the blood of a donor are given to a patient who has already received a hematopoietic cell transplant (HCT) from the same donor. The DLI therapeutic effect results from a graft-versus-leukemic or graft-versus-tumor effect due to recognition of certain antigens on the cancer cells by the donor lymphocytes and the resultant elimination of the tumor cells.

PROCEDURES

Donor Leukocyte Infusion

DLI may be considered medically necessary for adults and children following allogeneic HCT that was originally considered medically necessary for the treatment of a hematologic malignancy that has relapsed, or does not respond, to prevent relapse in the setting of a high risk of relapse, or to convert a patient from mixed to full donor chimerism with ANY ONE of the following conditions:

- Individuals with acute myeloid leukemia (AML); or
- Individuals with chronic myeloid leukemia (CML); or
- Individuals with Hodgkin's disease (HD); or
- Individuals with acute lymphocytic leukemia (ALL); or
- Individuals with multiple myeloma.

DLI is considered experimental/investigational following allogeneic HCT that was originally considered investigational for the treatment of a hematologic malignancy and therefore noncovered because the safety and/or effectiveness of this services cannot be established by the available published peer-reviewed literature.

DLI is considered experimental/investigational as a treatment of non-hematologic malignancies following a prior allogeneic HCT and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Other applications of DLI are considered experimental/investigational, including but not limited to its use in patients with, myelodysplastic syndromes, non-Hodgkin's lymphoma and autism spectrum disorder and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Charges for the leukapheresis procedure for the donor are eligible for payment when the donor leukocyte infusion is covered. Payment for eligible donor leukapheresis procedures may be equated to therapeutic apheresis; for white blood cells.

Genetic Modification of Donor Leukocytes

Genetic modification of donor leukocytes is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service

Experimental/investigational (E/I) services are not covered regardless of place of service.

Donor leukocyte infusion for hematologic malignancies that relapse after allogeneic cell transplant are typically outpatient procedures which are only eligible for coverage as inpatient procedures in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
36511	Therapeutic apheresis; for white blood cells.
38242	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic donor lymphocyte infusions.

Covered diagnosis codes for procedure code 38242

C81.00	C81.01	C81.02	C81.03	C81.04	C81.05	C81.06
C81.07	C81.08	C81.09	C81.10	C81.11	C81.12	C81.13
C81.14	C81.15	C81.16	C81.17	C81.18	C81.19	C81.20
C81.21	C81.22	C81.23	C81.24	C81.25	C81.26	C81.27
C81.28	C81.29	C81.30	C81.31	C81.32	C81.33	C81.34
C81.35	C81.36	C81.37	C81.38	C81.39	C81.40	C81.41
C81.42	C81.43	C81.44	C81.45	C81.46	C81.47	C81.48
C81.49	C81.70	C81.71	C81.72	C81.73	C81.74	C81.75
C81.76	C81.77	C81.78	C81.79	C81.90	C81.91	C81.92
C81.93	C81.94	C81.95	C81.96	C81.97	C81.98	C81.99
C90.00	C90.01	C90.02	C91.00	C91.01	C91.02	C91.10
C91.11	C91.12	C91.30	C91.31	C91.32	C91.50	C91.51
C91.52	C91.60	C91.61	C91.62	C91.90	C91.91	C91.92
C91.A0	C91.A1	C91.A2	C91.Z0	C91.Z1	C91.Z2	C92.00
C92.01	C92.02	C92.10	C92.11	C92.12	C92.20	C92.21
C92.22	C92.30	C92.31	C92.32	C92.40	C92.41	C92.42
C92.50	C92.51	C92.52	C92.60	C92.61	C92.62	C92.90
C92.91	C92.92	C92.A0	C92.A1	C92.A2	C92.Z0	C92.Z1
C92.Z2						

Non-Covered diagnosis codes for procedure code 38242

F84.0	F84.3	F84.5	F84.8	F84.9

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

References

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POLICY UPDATE HISTORY

<Date>	<Event>