

Medical Policy:

Grafapex (treosulfan) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.435	April 30, 2025	April 30, 2025

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Grafapex is indicated in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients 1 year of age and older with acute myeloid leukemia (AML) and Grafapex is indicated in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients 1 year of age and older with myelodysplastic syndrome (MDS).

Length of Authorization

Coverage will be provided for 30 days.

Dosing Limits [Medical Benefit]

Guideline

I. INITIAL CRITERIA

1. Acute Myeloid Leukemia. Approve for 30 days if the patient meets ALL of the following (A, B, C, and D):

A. Patient is ≥ 1 year of age; **AND**

B. Patient is using Grafapex in combination with fludarabine; **AND**

- C. Patient is undergoing allogeneic hematopoietic stem cell transplantation; **AND**
- D. The medication is prescribed by or in consultation with a hematologist, oncologist, transplant specialist physician, or a physician associated with a transplant center.

2. Myelodysplastic Syndrome. Approve for 30 days if the patient meets ALL of the following (A, B, C, and D):

- A. Patient is ≥ 1 year of age; **AND**
- B. Patient is using Grafapex in combination with fludarabine; **AND**
- C. Patient is undergoing allogeneic hematopoietic stem cell transplantation; **AND**
- D. The medication is prescribed by or in consultation with a hematologist, oncologist, transplant specialist physician, or a physician associated with a transplant center

Applicable Procedure Codes

Code	Description
C9399	Unclassified drugs or biologicals
J9999	Not otherwise classified, antineoplastic drugs

Applicable NDCs

Code	Description
59137-0335-xx	Grafapex 1gm
59137-0365-xx	Grafapex 5gm

ICD-10 Diagnoses

Code	Description
C92.00	Acute Myeloblastic Leukemia, Not Having Achieved Remission
C92.02	Acute Myeloblastic Leukemia, In Relapse
C92.A0	Acute Myeloid Leukemia With Multilineage Dysplasia, Not Having Achieved Remission
C92.A2	Acute Myeloid Leukemia With Multilineage Dysplasia, In Relapse
D46.9	Myelodysplastic Syndrome, Unspecified
D46.Z	Other Myelodysplastic Syndromes

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/30/2025	New Policy

References

1. Grafapex™ intravenous infusion [prescribing information]. Chicago, IL: Medexus; January 2025.