# Medical Policy:

## Grafapex (treosulfan) Intravenous

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



## 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.