Reference number(s)
6866-A

Standard Medicare Part B Management Grafapex

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Grafapex	treosulfan

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Acute Myeloid Leukemia

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

Myelodysplastic Syndrome

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this policy should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Acute Myeloid Leukemia (AML)[1]

Authorization of 1 month may be granted for treatment of acute myeloid leukemia when all of the following criteria are met:

- Member has a diagnosis of acute myeloid leukemia.
- Member is 1 year of age or older.
- The requested drug will be used in combination with fludarabine as a preparative regimen for allogenic hematopoietic stem cell transplantation.
- Member has not previously received an allogenic hematopoietic stem cell transplant.

Myelodysplastic Syndrome[1]

Authorization of 1 month may be granted for treatment of myelodysplastic syndrome when all of the following criteria are met:

- Member has a diagnosis of myelodysplastic syndrome.
- Member is 1 year of age or older.
- The requested drug will be used in combination with fludarabine as a preparative regimen for allogenic hematopoietic stem cell transplantation.
- Member has not previously received an allogenic hematopoietic stem cell transplant.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Grafapex.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Grafapex are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Grafapex. [package insert]. Chicago, IL: Medexus Pharma, Inc.; January 2025.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.