Grafapex™ (treosulfan)
(Intravenous)

Document Number: IC-0818

Last Review Date: 05/05/2026
Date of Origin: 11/04/2025
Dates Reviewed: 11/2025, 05/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided one time only for 6 months (180 days).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1,500 billable units (500 billable units on day -4, day -3 and day -2 before stem cell transplant)

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 1 year of age; **AND**

Hematopoietic Stem Cell Transplantation (HSCT) † ‡ Φ [1-5]

- Member has Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS); **AND**
- Member is eligible for allogeneic hematopoietic stem cell transplant (allo-HSCT) and has not received a prior allo-HSCT; **AND**
- Used in combination with fludarabine as a preparative regimen prior to allo-HSCT; **AND**
- Member will receive prophylactic and supportive therapies for prevention or treatment of transplant complications (e.g., Graft-versus-Host-Disease [GVHD], infections, etc.) according to institutional guidelines

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded (*refer to Section I*)

V. Dosage/Administration [1]

Indication	Dose
HSCT in members with AML or MDS	Administer 10 g/m^2 by intravenous infusion given daily for three days on day -4, -3 and -2 prior to transplantation in combination with fludarabine
– *Premedicate members with antiemetics prior to the first dose and continue antiemetics on a fixed schedule through*	

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completion of treosulfan administration – *Treosulfan is a hazardous drug. Follow applicable special handling and disposal procedures.*

VI. Billing Code/Availability Information

HCPCS Code(s):

- J0614 – Injection, treosulfan, 50 mg; 1 billable unit = 50 mg

NDC(s):

- Grafapex 1 g single-dose vial as a lyophilized powder for reconstitution: 59137-0335-xx
- Grafapex 5 g single-dose vial as a lyophilized powder for reconstitution: 59137-0365-xx

VII. References

1. Grafapex [package insert]. Chicago, IL; Medexus Pharma, Inc.; February 2025. Accessed April 2026.
2. Kanate AS, Majhail NS, Savani BN, et al. Indications for Hematopoietic Cell Transplantation and Immune Effector Cell Therapy: Guidelines from the American Society for Transplantation and Cellular Therapy (ASTCT). Transplantation and Cellular Therapy. Volume 26, Issue 7, P1247-1256, July 2020. DOI: https://doi.org/10.1016/j.bbmt.2020.03.002
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Cell Transplantation 2.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed April 2026.
4. Beelen DW, Trenschel R, Stelljes M, et al. Treosulfan or busulfan plus fludarabine as conditioning treatment before allogeneic haemopoietic stem cell transplantation for older patients with acute myeloid leukaemia or myelodysplastic syndrome (MC-FludT.14/L): a randomised, non-inferiority, phase 3 trial. Lancet Haematol. 2020 Jan;7(1):e28-e39. doi: 10.1016/S2352-3026(19)30157-7. Epub 2019 Oct 9.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Treosulfan. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management

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NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C92.00	Acute myeloblastic leukemia, not having achieved remission
D46.9	Myelodysplastic syndrome, unspecified
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status
Z94.9	Transplanted organ and tissue status, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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