

Aphexda™ (motixafortide) (Subcutaneous)

Document Number: IC-0729

Last Review Date: 11/05/2024
 Date of Origin: 10/03/2023
 Dates Reviewed: 10/2023, 11/2024

I. Length of Authorization

Coverage will be provided for 2 doses only.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Aphexda 62 mg single-dose vial: 2 vials per dose for two doses only

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

- 496 billable units (124 mg) per dose for up to two doses, separated by at least 2 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient will not in combination with other CXCR4-antagonists (e.g., mavorixafor, plerixafor, etc.) **AND**

Peripheral mobilization of stem cells for transplantation † ‡ ◻ ^{1,2,4}

- Used for autologous transplantation in multiple myeloma patients; **AND**
- Used in combination with filgrastim (G-CSF) (or its biosimilars) or tbo-filgrastim

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

IV. Renewal Criteria ¹

Coverage cannot be renewed.

V. Dosage/Administration ¹

Indication	Dose
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Peripheral mobilization of stem cells for transplantation	<p>Administer filgrastim* 10 mcg/kg subcutaneously once daily for 4 days prior to the first dose of Aphexda and on each day prior to each apheresis.</p> <p>The recommended dosage of Aphexda is 1.25 mg/kg administered via slow (approximately 2 minutes) subcutaneous injection 10 to 14 hours prior to the initiation of the first apheresis (Day 5).</p> <ul style="list-style-type: none"> • If cell collection goal was not achieved, another dose of filgrastim* may be administered on Day 6 within 1 hour prior to the second apheresis. • If cell collection goal was still not achieved, a second dose of Aphexda can be administered 10 to 14 hours before a third apheresis (preceded by filgrastim*) on Day 7, if necessary. <p>Monitor patients for one hour after administration.</p> <p><i>*Note: Tbo-filgrastim or an FDA-approved biosimilar is an appropriate substitute for filgrastim</i></p>
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VI. Billing Code/Availability Information

HCPCS code:

- J2277 – Injection, motixafortide, 0.25 mg; 1 billable unit = 0.25 mg

NDC:

- Aphexda 62 mg lyophilized powder in a single-dose vial: 82737-0073-xx

VII. References

1. Aphexda [package insert]. Waltham, MA; BioLineRx USA, Inc; September 2023. Accessed September 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) motixafortide. National Comprehensive Cancer Network, 2024. 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 September 2024.
3. Crees ZD, Stockerl-Goldstein K, et al. GENESIS: Phase III trial evaluating BL-8040 + G-CSF to mobilize hematopoietic cells for autologous transplant in myeloma. Future Oncol. 2019 Nov;15(31):3555-3563. doi: 10.2217/fon-2019-0380. Epub 2019 Sep 9. PMID: 31495201; PMCID: PMC7421992.
4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Cell Transplantation Version 2.2024. National Comprehensive Cancer Network, 2023. 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 September 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
Z94.84	Stem cells transplant status

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/LCA/LCD): 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)
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