

Aphexda® (motixafortide) (Subcutaneous)

Document Number: IC-0729

Last Review Date: 11/04/2025

Date of Origin: 10/03/2023

Dates Reviewed: 10/2023, 11/2024, 11/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 2 doses
- Renewal: Prior authorization validity may NOT be renewed

II. Dosing Limits

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

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient will not in combination with other chemokine receptor 4 (CXCR4) antagonists; **AND**

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

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

† 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 |
|------------|------|
|------------|------|

| | |
|---|--|
| 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>*Note: Tbo-filgrastim or an FDA-approved biosimilar is an appropriate substitute for filgrastim</p> | |

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: 73441-0062-xx

VII. References

1. Aphexda [package insert]. Dublin, Ireland; Ayrmid Pharma Ltd.; May 2025. Accessed October 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) motixafortide. National Comprehensive Cancer Network, 2025. 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 2025.
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 2.2025. National Comprehensive Cancer Network, 2025. 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 2025.

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 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 | No: PA not a priority |
| 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 |
|---------|-------------------------------|
| 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 |