Clinical Policy: Motixafortide (Aphexda)

Reference Number: PA.CP.PHAR.655
Effective Date: 02/2024
Last Review Date: 01/2024

Description
Motixafortide (Aphexda®) is a hematopoietic stem cell mobilizer.

FDA Approved Indication(s)
Aphexda is indicated in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma (MM).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Aphexda is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Mobilization of Hematopoietic Stem Cell (must meet all)**:**

1. Diagnosis of MM;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Prescribed in combination with a formulary G-CSF (i.e., Granix, Neupogen, Releuko);
   **Prior authorization may be required for G-CSF.*
5. Member is scheduled to receive autologous stem cell transplantation;
6. Failure of plerixafor, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed one of the following (a or b):
   a. The request meets both of the following (i and ii):
      i. Dose does not exceed 1.25 mg per kg of actual body weight;
      ii. Aphexda is prescribed to be administered for up to 2 doses per autologous stem cell transplantation;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Mobilization of Hematopoietic Stem Cell (must meet all)**:**

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
G-CSF: granulocyte-colony stimulating factor
HSCs: hematopoietic stem cells
MM: multiple myeloma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Plerixafor (Mozobil®)	The recommended dose of Mozobil by SC injection is based on actual body weight: • ≤ 83 kg: 20 mg fixed dose or 0.24 mg/kg of body weight • > 83 kg: 0.24 mg/kg of body weight Initiate Mozobil treatment after the patient has received G-CSF once daily for 4 days. Administer Mozobil approximately 11 hours prior to initiation of each apheresis for up to 4 consecutive days. Use actual body weight to calculate the volume of Mozobil to be administered: 0.012 x actual body weight (in kg) = volume to be administered (in mL).	40 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Mozobil dose and treatment if weight is more than 175% of ideal body weight have not been investigated.	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of serious hypersensitivity reaction to Aphexda
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	The recommended dose of Aphexda is 1.25 mg/kg actual body weight. Initiate Aphexda treatment after filgrastim has been administered daily for 4 days. Administer Aphexda via slow (approximately 2 minutes) subcutaneous injection 10 to 14 hours prior to the initiation of the first apheresis. A second dose of Aphexda can be administered 10 to 14 hours before a third apheresis, if necessary.	See dosing regimen

VI. Product Availability

Single-dose vial for injection: 62 mg of motixafortide as a lyophilized power for reconstitution

VII. References

1. Aphexda Prescribing Information. Waltham, MA: BioLineRx; September 2023. Available at: www.aphexda.com. Accessed September 13, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed September 29, 2023.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed September 29, 2023.
4. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed September 29, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-

date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date
Policy created	01/2024