

Medical Policy:

Aphexda (motixafortide) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.403	February 18, 2025	December 18, 2023

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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

Length of Authorization

Coverage will be provided for two doses only.

Dosing Limits [Medical Benefit]

- Aphexda 62mg single dose vial 2 vials per dose for two doses only
- Max Units per dose and over time: 124mg (2 vials) per dose up to two doses.

Guideline

I. Initial

1. **Multiple Myeloma.** Approve if the patient meets the following (A, B, C, **AND** D):

A. Patient is \geq 18 years of age; **AND**

- B. Patient will not in combination with other CXCR4-antagonists (e.g., mavorixafor, plerixafor, etc.)
- C. The agent is utilized for mobilization of hematopoietic stem cells for subsequent autologous transplantation; **AND**
- D. Use is in combination with filgrastim; **AND**
Note: Examples of filgrastim products include Granix (tbo-filgrastim subcutaneous injection) and Neupogen (filgrastim subcutaneous injection and intravenous infusion), as well as related biosimilars.
- E. Medication is prescribed by a hematologist and/or a stem cell transplant specialist physician.

II. Renewal

Coverage cannot be renewed.

Dosage/Administration

Indication	Dose
Peripheral mobilization of stem cells for autologous 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>

Applicable Procedure Codes

Code	Description
J2277	Injection, Motixafortide, 0.25mg

Applicable NDCs

Code	Description
82737-0073-01	Aphexda 62 mg One single-dose vial

ICD-10 Diagnoses

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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/18/2025	Addition to initial criteria: of Patient will not in combination with other CXCR4-antagonists (e.g., mavorixafor, plerixafor, etc.)
EmblemHealth & ConnectiCare	12/18/2023	New Policy

References

1. Aphexda™ subcutaneous injection [prescribing information]. Waltham, MA and Modi'in, Israel: BioLineRx; September 2023.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 4.2023 – August 25, 2023). © 2023 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on December 11, 2023
3. Aphexda. Lexicomp [database online]. Waltham, MA, Available at <https://online.lexi.com>. Accessed December 11, 2023.
4. Aphexda. IPD Analytics. Available at: <http://secure.ipdanalytics.com>. Accessed on December 4, 2023
5. Aphexda IBM Micromedex® [database online]. Waltham, MA, 2023. BioLineRx USA Inc Health Analytics. Available at: <https://www.micromedexsolutions.com>. Updated September 26, 2023. Accessed December 11, 2023.
6. US Food & Drug Administration (FDA): Orphan Drug Designation Database. US Food & Drug Administration (FDA). Silver Spring, MD. 2022. Available from URL: <https://www.access...> . As accessed December 11, 2023.