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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	October 13, 2023
Subject:	Aphexda	**Page:**	1 of 4

Last Review Date: March 7, 2025

Aphexda

Description

Aphexda (motixafortide)

Background
Aphexda (motixafortide) is an inhibitor of the C-X-C Motif Chemokine Receptor 4 (CXCR4) and blocks the binding of its cognate ligand, stromal-derived factor-1α (SDF-1 α)/C-X-C Motif Chemokine Ligand 12 (CXCL12). SDF-1 α and CXCR4 play a role in the trafficking and homing of human hematopoietic stem cells to the marrow compartment. Once in the marrow, stem cell CXCR4 can help anchor these cells to the marrow matrix, either directly via SDF-1 α or through the induction of other adhesion molecules. Treatment with Aphexda resulted in leukocytosis, and elevations in circulating hematopoietic stem and progenitor cells into the peripheral circulation (1).

Regulatory Status
FDA-approved indication: Aphexda, a hematopoietic stem cell mobilizer, 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 (1).

Anaphylactic shock and hypersensitivity reactions may occur in patients treated with Aphexda. Patients should be premedicated prior to each dose with an H1-antihistamine, an H2 blocker, and a leukotriene inhibitor. Aphexda should be administered in a setting where personnel and therapies are available for immediate treatment. Patients should be monitored for signs and

symptoms of hypersensitivity reactions for one hour following treatment and managed promptly (1).

Injection site reactions have been reported with Aphexda use. Patients should be premedicated with an analgesic medication (e.g., acetaminophen) (1).

Aphexda may cause tumor cell mobilization. In patients with leukemia, Aphexda may cause mobilization of leukemic cells and subsequent contamination of the apheresis product. Therefore, Aphexda is not intended for hematopoietic stem cell (HSC) mobilization and harvest in patients with leukemia. When Aphexda is used with filgrastim for HSC mobilization, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product (1).

An increase in circulating leukocytes may occur during Aphexda use. Monitor white blood cell counts during treatment (1).

Aphexda can cause fetal harm in pregnant women. Advise women of reproductive potential of the potential risk to a fetus and to use effective contraception (1).

The safety and effectiveness of Aphexda in pediatric patients less than 18 years of age have not been established (1).

Related policies
Mozobil

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Aphexda may be considered **medically necessary** if the conditions indicated below are met.

Aphexda may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Mobilization of hematopoietic stem cells (HSCs)

AND ALL of the following

1. Multiple myeloma
2. The hematopoietic stem cells (HSCs) will be used for subsequent autologous transplantation
3. Used in combination with a granulocyte colony-stimulating factor (G-CSF)
4. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Aphexda and for 8 days after the last dose

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Aphexda (motixafortide) is indicated in combination with G-CSF to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma. Patients treated with Aphexda may experience anaphylactic shock, hypersensitivity reactions, injection site reactions, tumor cell mobilization, leukocytosis,

and embryo-fetal toxicity. The safety and effectiveness of Aphexda in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Aphexda while maintaining optimal therapeutic outcomes.

References

1. Aphexda [package insert]. Modi'in, Israel: BioLineRx Ltd; September 2023.

Policy History

Date	Action
October 2023	Addition to PA
December 2023	Annual review
March 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.