

Drug and Biologic Coverage Policy



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Coverage Policy Number IP0597

Motixafortide

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for motixafortide (**Aphexda™**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Motixafortide (Aphexda™) is considered medically necessary when the following are met:

Multiple Myeloma. Individual meets **ALL** of the following criteria:

- A. 18 years of age or older
- B. Agent is utilized for mobilization of hematopoietic stem cells for subsequent autologous transplantation
- C. Use is in combination with filgrastim
- D. Medication is prescribed by a hematologist and/or a stem cell transplant specialist physician
- E. Non-Covered Product Criteria is met, refer to below table(s)

Dosing. Approve up to two doses at 1.25 mg/kg given by subcutaneous injection. Aphexda is given 10 to 14 hours prior to the initiation of apheresis. A second dose can be administered 10 to 14 hours before a third apheresis.

Employer Group Plans Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Aphexda (motixafortide)	Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to plerixafor injection 2. Has already started therapy with Aphexda

Individual and Family Plans Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Aphexda (motixafortide)	Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to plerixafor injection 2. Has already started therapy with Aphexda

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Authorization is for up to 1 month.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

Leukemia. Aphexda may cause mobilization of leukemia cells and subsequent contamination of the apheresis product.¹ Aphexda is not intended for hematopoietic stem cell mobilization and harvest in patients with leukemia.

Background

OVERVIEW

Aphexda, a hematopoietic stem cell mobilizer, is indicated in combination with filgrastim (granulocyte colony stimulating factor) to **mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.**¹

Disease Overview

Multiple myeloma is a cancer formed by malignant plasma cells found in the bone marrow.^{2,3} In 2023, it is estimated that there will be approximately 35,730 new cases of multiple myeloma and 12,590 deaths due to the disease. There are many therapies available for multiple myeloma. Autologous stem cell transplantation (ASCT) has a vital role in the treatment of multiple myeloma. The outcomes of ASCT relies on the collection of sufficient hematopoietic stem and progenitor cells, usually from peripheral blood.

References

1. Aphexda™ subcutaneous injection [prescribing information]. Waltham, MA and Modi'in, Israel: BioLineRx; September 2023.
2. Cowan AJ, Green DJ, Kwok M, et al. Diagnosis and management of multiple myeloma. A review. *JAMA*. 2022;327(5):464-477.
3. 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 August 7, 2023.

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