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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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. 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™**).

### 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. Preferred product criteria is met for the products listed in the 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 Plans:**

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

**Individual and Family Plans:**

Product	Criteria
<b>Aphexda</b> (motixafortide)	Documentation of <b>ONE</b> 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.

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

## 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):

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

## Coding Information

**Note:** 1) This list of codes may not be all-inclusive.

- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

HCPCS Codes	Description
J2277	Injection, motixafortide, 0.25 mg (Code effective 04/01/2024)

## 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.**<sup>1</sup>

**Disease Overview**

Multiple myeloma is a cancer formed by malignant plasma cells found in the bone marrow.<sup>2,3</sup> 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.

**Guidelines**

Aphexda is addressed in the National Comprehensive Cancer Network guidelines for Hematopoietic Cell Transplantation (version 2.2024 – August 30, 2024).<sup>4</sup> Aphexda is listed as an alternative in combination with G-CSF to mobilize hematopoietic stem cells for autologous donors (category 2A) in patients with multiple myeloma; the regimen is more specific for filgrastim.

**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 1.2025 – September 17, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on September 24, 2024.
4. The NCCN Hematopoietic Cell Transplantation Guidelines in Oncology (version 2.2024 – August 30, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on September 24, 2024.

**Revision Details**

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	12/15/2024
Selected Revision	<b>Added HCPCS coding table:</b> <b>Added J2277 (Code effective 04/01/2024)</b>	12/27/2024

The policy effective date is in force until updated or retired.

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