

## PRIOR AUTHORIZATION POLICY

**POLICY:** Hematology – Aphexda Prior Authorization Policy

- Aphexda™ (motixafortide subcutaneous injection – BioLineRx)

**REVIEW DATE:** 10/02/2024

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### 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.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Aphexda. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Aphexda as well as the monitoring required for adverse events and long-term efficacy, approval requires Aphexda to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Aphexda is recommended in those who meet the following criteria:

#### FDA-Approved Indication

1. **Multiple Myeloma.** Approve for 1 month if the patient meets ALL of the following (A, B, C, and D):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) The agent is utilized for mobilization of hematopoietic stem cells for subsequent autologous transplantation; AND
  - C) 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.

**D)** Medication is prescribed by a hematologist and/or a stem cell transplant specialist physician.

### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Aphexda is not recommended in the following situations:

- 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.
- 2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### **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.