VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Hematology – Aphexda Utilization Management Medical Policy
- Aphexda™ (motixafortide subcutaneous injection – BioLineRx)

REVIEW DATE: 11/15/2023

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.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Aphexda. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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, the agent is required 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 for patients who meet the following criteria:

FDA-Approved Indication

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1. **Multiple Myeloma.** Approve for 1 month if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 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.

Dosing. Approve up to two doses at 1.25 mg/kg given by subcutaneous injection.
Note: 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.

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.[1] 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 4.2023 – August 25, 2023). © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 7, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/15/2023