

Department:	Pharmacy Management	Original Approval:	07/10/2024
Policy No:	PM595	Last Approval:	04/03/2026
Policy Title:	Motixafortide (Aphexda) Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	<input checked="" type="checkbox"/> Washington Apple Health (Medicaid) <input type="checkbox"/> Behavioral Health Services Only <input checked="" type="checkbox"/> Apple Health Expansion <input checked="" type="checkbox"/> Medicare Advantage/Special Needs Plan <input checked="" type="checkbox"/> Medicare Advantage Only <input checked="" type="checkbox"/> Cascade Select		

Required Clinical Documentation for Review

Documentation required to determine medical necessity for Motixafortide (Aphexda):

1. History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service
2. Diagnosis
3. Labs/Diagnostics
4. Dosing and duration requested
5. Initial/Extended approval
6. Medical records from the last 6 months showing the patient's problems, history, prior treatments, response to treatment, imaging and laboratory studies, details of the skilled needs, details of any specific needs related to risk/trauma/cultural etc., assessment and plan
7. Prescribed by or in consultation with a specialist, when indicated

Background

Motixafortide (Aphexda) is a CXCR4 inhibitor that blocks the binding of CXCL12 and promotes mobilization of hematopoietic stem cells to the peripheral blood for autologous stem cell transplant (ASCT)¹. In conjunction with Filgrastim a Granulocyte colony-stimulating factor (G-CSF), Motixafortide reduces the number of filgrastim injections and apheresis sessions required to meet the goal cell count for transplantation. 40–50% of patients are unable to collect optimal numbers of hematopoietic stem and progenitor (HSPC) cells for ASCT with filgrastim alone². ASCT treatment requires a minimum amount of $>2 \times 10^6$ CD34+ Cells to promote remission of the multiple myeloma after high dose chemotherapy and ideally $>6 \times 10^6$ cells for improved outcomes³. Mobilization of adequate healthy stem cells is difficult even with G-CSF and often requires multiple sessions of apheresis. In clinical trials, 92.5% of patients met the primary

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

endpoint of $\geq 6 \times 10^6$ CD34+ cells/kg in 2 apheresis sessions vs 26.2 % compared to placebo. The secondary endpoint of $\geq 6 \times 10^6$ CD34+ cells/kg in 1 apheresis sessions². Patients receiving Motixafortide and G-CSF were shown to receive 3 fewer injections of G-CSF (5.26 vs 8.12) compared to placebo to meet the required number of cells for ASCT. Patients also had a reduced amount of apheresis procedures from 3.24 for placebo down to 1.23 procedures when treated with Motixafortide. Overall time spent collecting cells for ASCT is reduced with higher success and less medication. The reduction in procedures allows for more patient recovery time while also utilizing less healthcare resources.

Definitions

Autologous stem cell transplant (ASCT): A procedure in which the patient’s damaged stem cells are replaced by their own from apheresis.

Apheresis: A filtration process where the machine filters out specified components of the blood.

Granulocyte colony-stimulating factor (G-CSF or filgrastim): Granulocyte colony stimulating factor promotes the growth of granulocyte colonies from hemopoietic stem cells.

Hematopoietic stem and progenitor (HSPC): Stem cells that can be differentiated into various blood cell lineages. Cells are created by the bone marrow and through stimulation with G-CSF

Indications/Criteria

Medicaid Members	<i>Continue to criteria for approval below.</i>
Individual & Family (Cascade Select) Members	<i>Continue to criteria for approval below.</i>
Medicare Members	<i>Continue to criteria for approval below.</i>

FDA-Approved Indications

- Multiple Myeloma. Approve for 6 months if the patient meets all of the following criteria (A, B, C, D, and E):**
 - Patient is >18 years of age; AND
 - Patient has a diagnosis of multiple myeloma; AND
 - Patient is receiving a filgrastim product; AND
 - Patient is undergoing for Hematopoietic cell mobilization for Autologous stem cell transplant (ASCT); AND
 - Rationale on why plerixafor would be inappropriate for the patient; AND
 - Medication is prescribed by a hematologist or stem cell transplant specialist physician.

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

Dosing: Approve the following dose: 1.25 mg/kg (actual body weight) subcutaneously over the course of 2 minutes 10-14 hours prior to initiation of apheresis.

Note: Patient may receive a 2nd dose 10-14 hours prior to 3rd apheresis if necessary.

Special Considerations

Box warning for leukemia patients. Tumor Cell Mobilization in Patients with Leukemia: Apherda may mobilize leukemic cells and should not be used in leukemia patients.

Box warning for pregnancy. Embryo-fetal Toxicity: Can cause fetal harm. Advise women of reproductive potential of the potential risk to a fetus and to use effective contraception.

Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the “Plans” drop down on the top navigation bar.
Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Cascade Select	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

Citations & References

CFR	42 CFR § 438.210	
WAC	284-43-2050	
RCW		
LOB & Contract Citation	<input checked="" type="checkbox"/> WAHIMC	IMC Section 11.3: Medical Necessity Determination
	<input type="checkbox"/> BHSO	
	<input type="checkbox"/> Wraparound	
	<input type="checkbox"/> SMAC	
	<input type="checkbox"/> HH	
	<input type="checkbox"/> AHE	
	<input checked="" type="checkbox"/> MA/DSNP	P&P supports all LOB requirements
<input checked="" type="checkbox"/> CS	P&P supports all LOB requirements	

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

Other Requirements	
NCQA Elements	
References	<ol style="list-style-type: none"> 1. Aphexda [prescribing information]. USA: BioLineRx Ltd; October 2024. 2. Crees Z, Rettig MP, Jayasinghe RG, et al. Motixafortide and G-CSF to mobilize hematopoietic stem cells for autologous transplantation in multiple myeloma: a randomized phase 3 trial. 2023;29(4):869-879. doi: https://doi.org/10.1038/s41591-023-02273-z 3. Giralt S, Costa L, Schriber J, et al. Optimizing Autologous Stem Cell Mobilization Strategies to Improve Patient Outcomes: Consensus Guidelines and Recommendations. Biology of Blood and Marrow Transplantation. 2014;20(3):295-308. doi:https://doi.org/10.1016/j.bbmt.2013.10.013 4. UpToDate. www.uptodate.com. Accessed May 23, 2024. https://www.uptodate.com/contents/motixafortide-drug-information?search=aphexda&usage_type=panel&kp_tab=drug_general&source=panel_search_result&selectedTitle=1%7E5&display_rank=1.

Revision History

Revision Date	Revision Description	Revision Made By
07/09/2024	New Policy	Nicholas Nguyen, PharmD Candidate; Alan Gabot, PharmD
07/10/2024	Approval	UM Criteria Committee
05/13/2025	Annual review. No criteria updates.	Alan Gabot, PharmD
05/14/2025	Approval	UM Criteria Committee
04/02/2026	Annual review. Added criteria requiring rationale on why plerixafor would be inappropriate for the patient. Extended duration of approval from one month to six months.	Alan Gabot, PharmD
04/03/2026	Approval	UM Criteria Committee

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.