SmartPA Criteria Proposal

Drug/Drug Class:	Bleeding Disorder Agents PDL Edit
First Implementation Date:	TBD
Proposed Date:	July 18, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Inherited bleeding disorders are caused by a deficient aspect of normal physiological coagulation. Hemophilia is a rare X-linked congenital bleeding disorder characterized by a deficiency of clotting factor VIII (FVIII), called hemophilia A, or factor IX (FIX), called hemophilia B. Treatment of both types on hemophilia begins with replacement of the deficient factor by utilizing recombinant or plasma-derived agents. There are multiple commercially available clotting factor concentrates (CFCs) for hemophilia treatment and prophylaxis, with notable differences in half-life, manufacturing process, and concentration, amongst other variables. A small percentage of patients will develop antibodies that attack these CFCs, rendering them ineffective. When this occurs, other therapies (called bypass agents) may be utilized. These agents usually contain active clotting factors that are downstream in the clotting cascade of the deficient factor, bypassing the need for true FVIII or FIX replacement.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Agents to Treat Hemophilia A	
Standard Half-Life Factor VIII	
Preferred Agents	**Non-Preferred Agents**
• Alphanate® • Koate® • Kogenate® FS • Kovaltry® • Novoeight® • Nuwiq® • Wilate® • Xyntha® • Xyntha Solofuse®	• Advate® • Afstyla® • Hemofil-M® • Humate-P® • Recombinate®
Extended Half-Life Factor VIII	
Preferred Agents	**Non-Preferred Agents**
• Adynovate® • Jivi®	• Altuviiio® • Eloctate® • Esperoct®

Agents to Treat Hemophilia B	
Standard Half-Life Factor IX	
Preferred Agents	**Non-Preferred Agents**
• Alphanine® SD • Benefix® • Profilnine®	• Ixinity® • Rixubis®
Extended Half-Life Factor IX	
Preferred Agents	**Non-Preferred Agents**
• Alprolix® • Rebinyn®	• Idelvion®
Miscellaneous Agents for Bleeding Disorders	
Preferred Agents	**Non-Preferred Agents**
• FEIBA® NF • NovoSeven® RT • Sevenfact® • Hemlibra® • Obizur®	• Vonvendi®

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☐ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Agents for Bleeding Disorders
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Claim is for a preferred agent **OR**
- Claim for non-preferred agents:
  - Participant demonstrates compliance to prescribed therapy **OR**
  - **For Standard Half-Life Factor VIII agents:** Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred Standard Half-Life Factor VIII agents:
    - Documented trial period for preferred agents **OR**
    - Documented ADE/ADR to preferred agents
  - **For Extended Half-Life Factor VIII agents:** Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred Extended Half-Life Factor VIII agents:
    - Documented trial period for preferred agents **OR**
    - Documented ADE/ADR to preferred agents
  - **For Standard Half-Life Factor IX agents:** Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred Standard Half-Life Factor IX agents:
    - Documented trial period for preferred agents **OR**
    - Documented ADE/ADR to preferred agents
  - **For Extended Half-Life Factor IX agents:** Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred Extended Half-Life Factor IX agents:
    - Documented trial period for preferred agents **OR**
    - Documented ADE/ADR to preferred agents
  - **For Vonvendi:** Clinical consultant review for medical necessity

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: HEMATOLOGIC AGENTS: Agents for Bleeding Disorders”, Gainwell Technologies; Last updated June 1, 2023.
- Srivastava, A, Santagostino, E, Dougall, A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. *Haemophilia*. 2020: 26(Suppl 6): 1- 158. https://doi.org/10.1111/hae.14046
- WFH Online Registry of Clotting Factor Concentrates. Interactive Module. Online CFC Registry - eLearning Platform (wfh.org) . Accessed June 7, 2023.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.