Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Antihemophilic Factor IX Products***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***December 2018***

Last P & T Committee Approval Date: December 2018

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for antihemophilic factor IX products.

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Brand	Generic	FDA-Approved Indication(s)
Recombinant Factor IX Concentrates		
Idelvion	Antihemophilic factor [recombinant]	Hemophilia B
Rebinyn	Antihemophilic factor [recombinant]	Hemophilia B
Alprolix	Antihemophilic factor [recombinant]	Hemophilia B

DEFINITIONS

N/A

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POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drugs below, listed under antihemophilic factor products are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for non-preferred antihemophilic factor products are subject to the preferred medical drug list program. This program applies to the antihemophilic factor products specified in this policy. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product. Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

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Table. Antihemophilic Factor Products

	Product(s)
Preferred	• Idelvion® (coagulation factor IX [recombinant], albumin fusion protein) • Rebinyn® (coagulation factor IX [recombinant], glycoPEGylated
Non-Preferred	• Alprolix® (coagulation factor IX [recombinant], Fc fusion protein)

II. EXCEPTION CRITERIA *(Use for Non-Preferred Drug Requests Only)*

This program applies to members requesting treatment for an indication that is FDA approved for the preferred product. Coverage for the non-preferred product is provided when either of the following criteria is met:

1. Member is currently receiving treatment with the non-preferred product, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
2. Member has had a documented inadequate response or intolerable adverse event or has a contraindication to both of the preferred products.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Indefinite
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Alprolix [package insert]. Cambridge, MA: Biogen Idec Inc.; July 2016.
2. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; March 2016
3. Rebinyn [package insert]. DK-2880 Bagsvaerd, Denmark: Novo Nordisk A/S; May 2017.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	12/18