Clinical Policy: Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors

Reference Number: OH.PHAR.PPA.26
Effective Date: 01/01/2020
Last Review Date: N/A
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION: Approval based upon diagnosis and dosage appropriate to weight, patient pharmacokinetic factors, and presence of inhibitors.

FDA Approved Indication(s): Varies by drug product, please see package insert; clinical pharmacology or other appropriate clinical reference.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

*****NOTE – Grandfathering: Members who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Members who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.***

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation® that a non-preferred Hemophilia Factor is **medically necessary** when the following criteria are met:

BLOOD AGENTS: FACTOR VII CONCENTRATE

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
NOVOSEVEN (factor VIIa recombinant)	

I. Initial Approval Criteria

A. Factor VII concentrate agents NOVOSEVEN

1. FDA-Approved Indications: FDA-approved or supported by standard pharmacopeias
2. Member must meet labeled age requirements for the medication;
3. Documentation that there have been therapeutic failures to no less than a 30 day trial of at least one medication not requiring prior approval unless one of the following (a,b, or c)
    a. Allergy to all medications not requiring prior approval
    b. Contraindication to all medications not requiring prior approval
    c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval duration: 12 months.

BLOOD AGENTS: FACTOR VIII

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ADVATE® (factor VIII recombinant)	ADYNOVATE® (factor VIII recombinant) †
AFSTYLA® (factor VIII recombinant)	ELOCTATE® (factor VIII recombinant, fc fusion protein) †
HEMOFIL M® (factor VIII human)	JIVI® (factor VIII recombinant, pegylated-aucl) †
KOATE® (factor VIII human)	KOVALTRY® (factor VIII recombinant)
KOGENATE FS® (factor VIII recombinant)	OBIZUR® (factor VIII recombinant, porcine sequence)
MONOCLATE-P® (factor VIII human)	
NOVOEIGHT® (factor VIII recombinant)	
NUWIQ® (factor VIII recombinant)	
RECOMBINATE® (factor VIII recombinant)	
XYNTHA® (factor VIII recombinant)	

†Denotes long half-life factor

B. Factor VIII agents

1. FDA-Approved Indications: FDA-approved or supported by standard pharmacopeias
2. Member must meet labeled age requirements for the medication;
3. Documentation that there have been therapeutic failures to no less than a 30 day trial of at least one medication not requiring prior approval unless one of the following (a,b, or c)
    a. Allergy to all medications not requiring prior approval
    b. Contraindication to all medications not requiring prior approval
    c. History of unacceptable/toxic side effects to medications not requiring prior approval
4. For extended half-life factors, prescribing physician attests that patient is not a suitable candidate for treatment with shorter-acting half-life product.

Approval duration: 12 months.

BLOOD AGENTS: FACTOR IX

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALPHANINE SD® (factor IX human)	IDELVION® (factor IX recombinant)†
ALPROLIX® (factor IX recombinant) †	REBINYN® (factor IX recombinant)†
BENEFIX® (factor IX recombinant)	
IXINITY® (factor IX recombinant)	
MONONINE® (factor IX human)	
PROFILNINE® (factor IX complex human)	
RIXUBIS® (factor IX recombinant)	

†Denotes long half-life factor

C. Factor IX agents

1. FDA-Approved Indications: FDA-approved or supported by standard pharmacopeias
2. Member must meet labeled age requirements for the medication;
3. Documentation that there have been therapeutic failures to no less than a 30 day trial of at least one medication not requiring prior approval unless one of the following (a,b, or c)

a. Allergy to all medications not requiring prior approval
b. Contraindication to all medications not requiring prior approval
c. History of unacceptable/toxic side effects to medications not requiring prior approval

4. For extended half-life factors, prescribing physician attests that patient is not a suitable candidate for treatment with shorter-acting half-life product.
5. If Rebinyn is requested, confirmation that it is not being used for routine prophylaxis

Approval duration: 12 months.

BLOOD AGENTS: ANTI-INHIBITOR COAGULATION COMPLEX

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FEIBA® (anti-inhibitor coagulant complex)	

D. ANTI-INHIBITOR COAGULATION COMPLEX

1. FDA-Approved Indications: FDA-approved or supported by standard pharmacopeias
2. Member must meet labeled age requirements for the medication;
3. Documentation that there have been therapeutic failures to no less than a 30 day trial of at least one medication not requiring prior approval, when such agent exists, unless one of the following (a,b, or c)
    a. Allergy to all medications not requiring prior approval
    b. Contraindication to all medications not requiring prior approval
    c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval Duration: 12months

BLOOD AGENTS: VON WILLEBRAND FACTOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
WILATE® (factor VIII/Von Willebrand factor human)	VONVENDI® (Von Willebrand factor recombinant)

E. VON WILLEBRAND FACTOR

1. FDA-Approved Indications: FDA-approved or supported by standard pharmacopeias
2. Member must meet labeled age requirements for the medication;
3. Documentation that there have been therapeutic failures to no less than a 30 day trial of at least one medication not requiring prior approval unless one of the following (a,b, or c)
    a. Allergy to all medications not requiring prior approval
    b. Contraindication to all medications not requiring prior approval
    c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval Duration: 12months

BLOOD AGENTS: VON WILLEBRAND FACTOR/FACTOR VIII

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"

ALPHANATE® (factor VIII/Von Willebrand factor human) HUMATE-P® (factor VIII/Von Willebrand factor human)	

F. VON WILLEBRAND FACTOR/FACTOR VIII

1. FDA-Approved Indications: FDA-approved or supported by standard pharmacopeias
2. Member must meet labeled age requirements for the medication;
3. Documentation that there have been therapeutic failures to no less than a 30 day trial of at least one medication not requiring prior approval, when such agent exists, unless one of the following (a,b or c)
    a. Allergy to all medications not requiring prior approval
    b. Contraindication to all medications not requiring prior approval
    c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval Duration: 12months

MONOCLONAL MODIFIED IMMUNOGLOBULIN G4 ANTIBODY*

CLINICAL PA REQUIRED "PREFERRED"	REQUIRED "NON-PREFERRED"
HEMLIBRA (emicizumab-kxwh)	

G. HEMLIBRA (emicizumab-kxwh) (Monoclonal Modified Immunoglobulin G4 antibody)

1. **Diagnosis of Hemophilia A (factor VIII deficiency):** or hemophilia A without inhibitors with documented failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level previous history of inhibitors) after a trial of prophylactic factor VIII replacement products.
2. Member must meet labeled age requirements for the medication;
3. Patient will not use concurrently with activated prothrombin complex concentrate (aPCC)
4. Dose does not exceed 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly.
5. Documentation that there have been therapeutic failures to no less than a 30 day trial of at least one medication not requiring prior approval, when such agent exists, unless one of the following (a,b,or c)
    a. Allergy to all medications not requiring prior approval
    b. Contraindication to all medications not requiring prior approval
    c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval duration: 12 months.

II. Diagnoses/Indications for which coverage is NOT authorized:

Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

*****See above tables for preferred alternatives***** *Dosing varies by drug product. See FDA approved dosing and administration.*

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- *See package insert; clinical pharmacology or other appropriate clinical reference*

IV. Dosage and Administration: varies by drug product. See package insert; clinical pharmacology or other appropriate clinical reference for FDA approved dosing and administration

V. Product Availability: See package insert; clinical pharmacology or other appropriate clinical reference for product availability

I. References. Refer to package insert.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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