Coagulants / Anti-Inhibitor

Hemlibra (emicizumab-kxwh) J7170, Hemgenix (Etranacogene Dezaparvovec-drlb) J1411, Coagulant Complex J7198

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	Date Requested _____
	Requestor _____ Clinic name: _____ Phone / Fax

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug ☐ Self-administered	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).

Prior Authorization Group – Coagulants PA

Drug Name(s):

ANTI-INHIBITOR COAGULANT COMPLEX

HEMLIBRA	**EMICIZUMAB-KXWH**
HEMGENIX	**ETRANACOGENE DEZAPARVOVEC-DRLB**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. **Drug meets the following utilization management criteria:**
    a. A negative Factor IX inhibitor test result within the past 30 days: OR
    b. If member has a positive Factor IX inhibitor test result within the past 30 days, there must be a negative test result within 2 weeks of the initial positive result. AND
    c. Members has severe or moderately severe Factor IX deficiency (less than or equal to 2% of normal circulating Factor IX) AND
    d. Currently using Factor IX prophylactic therapy AND
    e. Current or history of a life-threatening hemorrhage OR
    f. History of repeated, serious spontaneous bleeding episodes or Has not previously received gene therapy treatment.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Anti-Inhibitor Coagulant Complex

- Hemorrhage, Routine prophylaxis - Hereditary factor IX deficiency disease with inhibitor - Hereditary factor VIII deficiency disease with inhibitor
- Hemorrhage - Hereditary factor IX deficiency disease with inhibitor - Hereditary factor VIII deficiency disease with inhibitor
- Hemorrhage - Hereditary factor IX deficiency disease with inhibitor - Hereditary factor VIII deficiency disease with inhibitor - Surgical procedure

Hemlibra

- Hemophilia A, Patients with or without Factor VIII inhibitors - Hemorrhage; Prophylaxis

Hemgenix

- Hemophilia B, Patients without Factor IX inhibitors - Hemorrhage; Prophylaxis

Off-Label Uses:
N/A

Age Restrictions:
AICC: Safety and efficacy not evaluated in neonates
Hemlibra: 12 years or older
Hemgenix: Safety and efficacy have not been established in pediatric patients

Other Clinical Considerations:
AICC: Acute thrombosis or embolism, including myocardial infarction
Hemlibra: Cases of thrombotic microangiopathy and thrombotic events were reported when on average a cumulative amount of greater than 100 units/kg/24 hours of activated prothrombin complex concentrate (aPCC) was administered for 24 hours or more to patients receiving emicizumab-kxwh prophylaxis.

Resources:
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