Coagulants / Anti-Inhibitor
Hemgenix (etranacogene dezaparvovec-drlb) J1411, Hemlibra (emicizumab-kxwh) J7170 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.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	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	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐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)

☐ 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. 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 12 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,

Off-Label Uses:

N/A

Age Restrictions:

AICC: Safety and efficacy not evaluated in neonates
Hemlibra: 12 years or older
Hemgenix: Safety and efficacy not 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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