Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2021**
Policy Number: PA.CP.PHAR.526	**Effective Date: 04/2021** **Revision Date: 04/2021**
Policy Name: Fibrinogen Concentrate [Human] (Fibryga, RiaSTAP)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Fibrinogen Concentrate [Human] (Fibryga, RiaSTAP)

Reference Number: PA.CP.PHAR.526
Effective Date: 04/2021
Last Review Date: 04/2021

Coding Implications
Revision Log

Description
The following are fibrinogen (coagulation factor I) concentrates requiring prior authorization: fibrinogen concentrate [human] (Fibryga® and RiaSTAP®).

FDA Approved Indication(s)
Fibryga and RiaSTAP are indicated for the treatment of acute bleeding episodes in patients (specified as adults and children for Fibryga) with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Limitation(s) of use: Fibryga is not indicated for dysfibrinogenemia.

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.

It is the policy of health plans affiliated with PA Health & Wellness® that Fibryga and RiaSTAP are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Fibrinogen Deficiency (must meet all)**:**

1. Diagnosis of congenital fibrinogen deficiency, including afibrinogenemia or hypofibrinogenemia;
2. Confirmation that the member does not have dysfibrinogenemia;
3. Prescribed by or in consultation with a hematologist;
4. Request is for treatment of acute bleeding episodes;
5. Documentation of both of the following (a and b):
   a. Plasma functional and immunoreactive fibrinogen levels are < 150 mg/dL;
   b. Prolonged prothrombin time and activated partial thromboplastin time as determined by laboratory-specific reference values;
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Congenital Fibrinogen Deficiency (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 3 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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

A. 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 – PA.CP.PMN.53;

B. Dysfibrinogenemia.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): individuals who have manifested severe immediate hypersensitivity reactions, including anaphylaxis, to Fibryga or its components (sodium citrate dihydrate; glycine; L-arginine hydrochloride); known anaphylactic or severe systemic reactions to human plasma-derived products (RiaSTAP)
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Fibrinogen concentrate (Fibryga)	The recommended target fibrinogen plasma level is 100 mg/dL for minor bleeding and 150 mg/dL for major bleeding. <u>When baseline fibrinogen level is known</u> • Age ≥ 12 years: [Target fibrinogen level (mg/dL) – measured fibrinogen level (mg/dL)]/1.8 (mg/dL per mg/kg body weight) by IV infusion	Individualized based on the extent of bleeding, laboratory values, and the clinical condition of the patient

Drug Name	Dosing Regimen	Maximum Dose
	• Age < 12 years: [Target fibrinogen level (mg/dL) – measured fibrinogen level (mg/dL)]/1.4 (mg/dL per mg/kg body weight) by IV infusion When baseline fibrinogen level is not known 70 mg/kg/dose by IV infusion	
Fibrinogen concentrate (RiaSTAP)	When baseline fibrinogen level is known [Target fibrinogen level (mg/dL) – measured fibrinogen level (mg/dL)]/1.7 (mg/dL per mg/kg body weight) by IV infusion When baseline fibrinogen level is not known 70 mg/kg/dose by IV infusion	Individualized based on the extent of bleeding, laboratory values, and the clinical condition of the patient

VI. Product Availability

Drug Name	Availability
Fibrinogen concentrate (Fibryga)	Lyophilized powder for reconstitution in a single-dose bottle: approximately 1 gram
Fibrinogen concentrate (RiaSTAP)	Lyophilized powder for reconstitution in a single-dose vial: 900-1,300 mg

VII. References

1. Fibryga Prescribing Information. Paramus, NJ: Octapharma USA, Inc.; December 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo. Accessed February 3, 2021.
2. RiaSTAP Prescribing Information. Kankakee, IL: CSL Behring LLC; July 2020. Available at: https://www.riastap.com. Accessed February 3, 2021.
3. De Moerloose P, Casini A, Neerman-Arbez M. Congenital fibrinogen disorders: an update. Semin Thromb Hemost 2013;39:585-95.
4. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders (revised August 2020). Available at: https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf. Accessed February 3, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7177	Injection, human fibrinogen concentrate (Fibryga), 1 mg
J7178	Injection, human fibrinogen concentrate, not otherwise specified, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04/2021	