RiaSTAP® (fibrinogen)

Last Review Date: July 15, 2019
Number: MG.MM.PH.145

Medical Guideline Disclaimer

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Definition

RiaSTAP (coagulation factor I) is a soluble plasma glycoprotein and a physiological substrate of 3 enzymes: thrombin, factor XIIIa, and plasmin. Thrombin converts fibrinogen into fibrin. Fibrin is stabilized in the presence of calcium ions and by activated Factor XIII. Factor XIIIa induces cross-linking of fibrin polymers which result in the fibrin clot being more elastic and more resistant to fibrinolysis. The cross-linked fibrin is the end result of the coagulation cascade.

RiaSTAP is FDA-labeled for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

I. INITIAL APPROVAL CRITERIA

RiaSTAP may be considered medically necessary if the below condition is met AND use is consistent with the medical necessity criteria that follows:

1. Fibrigenous Deficiency (Factor I deficiency)
   a. Diagnosis of congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia; AND
   b. One of the following:
      i. Routine prophylactic treatment; OR
      ii. Peri-operative management of surgical bleeding; OR
      iii. Treatment of bleeding episodes.

Limitations/Exclusions

1) Indications not supported by CMS recognized compendia or acceptable peer reviewed
literature may be deemed as not approvable and therefore not reimbursable.

II. **RENEWAL CRITERIA**

- Patient continues to meet INITIAL APPROVAL CRITERIA.

**Dosage/Administration**

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<tr>
<th>Indication</th>
<th>Dose</th>
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| Fibrinogen Deficiency    | - **Baseline fibrinogen level known:** dose = (target level (mg/dL) - measured level (mg/dL)) divided by 1.7 (mg/dL per mg/kg body weight) IV not exceeding 5 ml/min.  
                        | - **Baseline fibrinogen level unknown:** 70 mg/kg IV not exceeding 5 ml/min.                                      |

* Maintain fibrinogen level of 100 mg/dL until hemostasis is obtained.*

**Applicable Procedure Codes**

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J7178</td>
<td>Injection, human fibrinogen concentrate (RiaSTAP), 1 mg, 1 billable unit = 1 mg</td>
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**Applicable NDCs**

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>63833-0891-51</td>
<td>RiaSTAP single use vial; powder for injection</td>
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**Applicable Diagnosis Codes**

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<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tr>
<td>D68.2</td>
<td>Hereditary deficiency of other clotting factors [congenital fibrinogen deficiency]</td>
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**References**