RiaSTAP® (fibrinogen)

**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. **Fibrinogen 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**

<table>
<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**

<table>
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<tr>
<th>NDC</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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<thead>
<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**