Line of Business: Medicaid
P & T Approval Date: May 15, 2019  Effective Date: July 1, 2019

These criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Prior Authorization criteria is available for: Firazyr (icatibant), Haegarda (C1 esterase inhibitor)

FIRAZYR (icatibant)

Covered Uses: Acute Hereditary Angioedema (HAE) attacks
(Clinical Pharmacist review required)

Exclusion Criteria: N/A

Required Medical Information:
Must meet all of the following requirements:
  a. C4 level below the lower limit of normal laboratory range
  b. Must meet “1” of the following requirements:
     1. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal laboratory range
     2. C1-INH functional level below the lower limit of normal laboratory range
     3. Documented C1-INH mutation

Age Restrictions: Must be age of 18 years and older

Prescriber Restrictions: Immunologist, Allergist, Hematologist

Other Criteria: Reauthorization Criteria: Must meet the following requirement:
  a. Documentation of ongoing HAE attacks and response to medication
HAEGARDA (C1 esterase inhibitor)

Covered Uses: Routine prophylaxis of Hereditary Angioedema (HAE) attacks (Clinical Pharmacist review required)

Exclusion Criteria: N/A

Required Medical Information: Must meet all of the following requirements:
   a. C4 level below the lower limit of normal laboratory range
   b. Must meet “1” of the following requirements:
      1. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal laboratory range
      2. C1-INH functional level below the lower limit of normal laboratory range
      3. Documented C1-INH mutation
   c. Must meet “1” of the following requirements:
      1. Documented history of more than one severe HAE attacks per month
      2. Documented history of a laryngeal HAE attack or airway compromise;
   d. Inadequate response or clinically significant adverse effects to danazol

Age Restrictions: Must be age of 12 years and older

Prescriber Restrictions: Immunologist, Allergist, Hematologist

Other Criteria: Reauthorization Criteria: Must meet the following requirement:
   a. Documentation of clinical response to medication
<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
<th>RPH</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/15/2019</td>
<td>• Add Firazyr and Haegarda to the formulary with PA</td>
<td>ND</td>
</tr>
<tr>
<td></td>
<td>• Retire criteria for non-formulary agents: Berinert, Kalbitor, Ruconest, Cinryze</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Add age restrictions for Firazyr</td>
<td></td>
</tr>
<tr>
<td>06/29/2018</td>
<td>• Changed Format</td>
<td>IK</td>
</tr>
<tr>
<td>05/16/2018</td>
<td>• Reformatted document</td>
<td>HC</td>
</tr>
<tr>
<td></td>
<td>• Added Haegarda that was previously reviewed under new drug review (NME)</td>
<td></td>
</tr>
</tbody>
</table>