Hemlibra (emicizumab-kxwh)

Policy Number: 5.02.551  Last Review: 04/2018
Origination: 03/2018  Next Review: 04/2019

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Hemlibra (emicizumab-kxwh) when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Hemlibra may be considered medically necessary when all of the following criteria are met:

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; AND
- Confirmation the patient has inhibitors to factor VIII; AND
- Patient has used routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
- Hemlibra is not used in combination with Immune Tolerance Induction (ITI); AND
  - Patient has ≥ 2 documented episodes of spontaneous bleeding into joints; OR
  - Patient has documented trial and failure of Immune Tolerance Induction (ITI); OR
  - Patient has documented trial and failure of or is currently on routine prophylaxis with a bypassing agent (e.g., NovoSeven, Feiba)

When Policy Topic is not covered
Hemlibra is considered investigational when the above criteria are not met and for all other uses.

Considerations
Hemlibra requires prior authorization through the pharmacy services department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty...
guidelines, local medical policies of other health plans, Medicare (CMS), local
providers.

**Description of Procedure or Service**

Hemlibra (emicizumab-kxwh) is a bispecific factor IXa- and factor X-directed monoclonal antibody that is indicated for routine prophylaxis for the prevention or reduction in the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.

Hemlibra (emicizumab-kxwh) represents the first non-factor product available to treat hemophilia patients with inhibitors. It should be noted that Hemlibra (emicizumab-kxwh) is not indicated for on-demand treatment and control of bleeding episodes as well as perioperative management of bleeds in patients with hemophilia A with or without inhibitors.

Hemlibra (emicizumab-kxwh) is the first hemophilia product available for weekly SC self-administration. Patient selection will be key along with use of improved testing methodologies. Hemlibra (emicizumab-kxwh) offers a new opportunity for treatment of hemophilia A inhibitor patients who have had poor response to available therapies and have not responded to immune tolerance induction (ITI) therapy.

**Rationale**

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Hemlibra (emicizumab-kxwh) while maintaining optimal therapeutic outcomes.

**References**


**Billing Coding/Physician Documentation Information**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>Q9995</td>
<td>Injection, emicizumab-kxwh, 0.5mg</td>
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**Additional Policy Key Words**

Policy Number 5.02.551

**Policy Implementation/Update Information**
State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.