

Hereditary Angioedema (HAE) Drug Products

Approved July 2019

Preferred Agents for Prophylaxis:

Haegarda® (C1 inhibitor)

Takhzyro® (lanadelumab)

Non-Preferred Agent for Prophylaxis:

Cinryze® (C1 inhibitor)

Andembry (garadacimab-gxii) (Reference the ABH Andembry Guideline)

Dawnzera (donidalorsen) (Reference the ABH Dawnzera Guideline)

Orladeyo (berotralstat) (Reference the Global Exception Guideline)

Criteria for approval:

1. The patient unable to take the preferred agents Haegarda and Takhzyro, for the given diagnosis, due to a trial and inadequate treatment response or intolerance, or a contraindication.
2. Medication is requested for prophylaxis against hereditary angioedema (HAE); AND
3. The patient is within the FDA-approved age range for the medication requested; AND
4. Medication is prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders; AND
5. Medications known to cause angioedema (for example, ACE-Inhibitors, estrogen-containing medications, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate; AND
6. Not used in combination with other approved treatments for prophylaxis against HAE attacks; AND
7. Weight must be received for drugs that have weight-based dosing

Approval Duration: 6 months

Preferred Agents for Acute treatment:

Berinert® (C1 inhibitor)

Icatibant

Sajazir (icatibant)

Non-Preferred Agents for Acute treatment:

Firazyr® (icatibant)

Kalbitor® (ecallantide)

Ruconest® (C1 inhibitor)

Ekterly (sebetralstat) (Reference the ABH Ekterly Guideline)

Criteria for approval:

1. Medication is requested for the acute management of HAE attack; AND

2. The patient is within the FDA-approved age range for the medication requested; AND
3. Medication is prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders; AND
4. Medications known to cause angioedema (for example, ACE-Inhibitors, estrogen-containing medications, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate; AND
5. Not used in combination with other approved treatments for acute HAE attacks (listed); AND
6. Weight must be received for drugs that have weight-based dosing

Approval Duration: 6 months

References:

1. Cinryze [prescribing information]. Lexington, MA. Shire ViroPharma, Inc. June 2018
2. Haegarda [prescribing information]. Kankakee, IL. CSL Behring LLC. October 2017.
3. Takhzyro [prescribing information]. Lexington, MA. Dyax Corporation. August 2018
4. Firazyr [prescribing information]. Lexington, MA. Dyax Corporation. August 2018
5. Kalbitor [prescribing information]. Burlington, MA. Dyax Corporation. March 2015
6. Berinert [prescribing information]. Kankakee, IL. CSL Behring. September 2016
7. Ruconest [package insert]. Bridgewater, NJ. Pharming Healthcare Inc. November 2017
8. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2018. Available at 9. Cicardi B, et al. Evidence-based recommendations for the therapeutic management of angioedema owing to hereditary C1 inhibitor
9. deficiency; consensus report of an International Working Group. *Allergy* 2012;67:147-157
10. Zuraw BL, et al. A focused parameter update: hereditary angioedema, acquired C1 inhibitor deficiency, and angiotensin -converting enzyme inhibitor-associated angioedema. *J Allergy Clin Immunol* 2013; 131:1491.