

KALBITOR (ecallantide)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 12 years of age and older

Diagnosis

Patient must have the following:

- 1. Hereditary Angioedema (HAE) with **ONE** of the following:
 - Patient has a C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing AND ALL of the following:
 - C4 level below the lower limit of normal as defined by the laboratory performing the test
 - ii. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test **OR** normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)
 - Patient has normal C1 inhibitor as confirmed by laboratory testing
 AND ONE of the following:
 - i. F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing
 - ii. Documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine (e.g., cetirizine) for at least one month

AND ALL of the following:

- 1. Used for acute attacks of hereditary angioedema
- 2. **NOT** being used for the routine prevention of hereditary angioedema attacks
- 3. Will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema
- 4. **NO** dual therapy with another agent for treating acute attacks of hereditary angioedema (e.g., Berinert, Firazyr/Sajazir, Ruconest)



KALBITOR (ecallantide)

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Requirements

Age 12 years of age and older

Diagnosis

Patient must have the following:

Hereditary Angioedema (HAE)

AND ALL of the following:

- 1. Used for acute attacks of hereditary angioedema
- 2. **NOT** being used for the routine prevention of hereditary angioedema attacks
- 3. Patient has experienced a reduction in severity and/or duration of hereditary angioedema attacks
- 4. Will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema
- 5. **NO** dual therapy with another agent for treating acute attacks of hereditary angioedema (e.g., Berinert, Firazyr/Sajazir, Ruconest)

Prior - Approval Renewal Limits

Same as above