

When requesting Kalbitor® (ecallantide), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indication¹

- Kalbitor is indicated for treatment of acute attacks of hereditary angioedema (HAE) in patients 12 years of age and older.

Approved Off-label Compendial uses

- None

Coverage Guidelines

- Has a diagnosis of hereditary angioedema (HAE) confirmed by C4 and C1 inhibitor laboratory testing (i.e. low C4 levels, low C1 inhibitor antigenic protein levels, low C1 inhibitor functional levels)³
- Request is for the treatment of acute attacks of HAE^{1,2}
- Member is 12 years of age or older¹
- Kalbitor will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and HAE¹
- Kalbitor will not be used in combination with another agent for treating acute attacks of HAE (e.g., Berinert, Firazyr, Ruconest)^{3,4}

Additional Information for Prescribers¹

- Hypersensitivity reactions including anaphylaxis may occur. Kalbitor should be administered in a setting equipped to manage anaphylaxis and HAE.

References

1. Kalbitor prescribing information. Burlington, MA; Dyax Corporation. March 2015. Available at http://www.shirecontent.com/PI/PDFs/Kalbitor_USA_ENG.pdf. Accessed January 06, 2017.
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed January 06, 2017. <http://www.micromedexsolutions.com/home/dispatch>
3. Craig, T, Pursun E, Bork, K, et al. WAO Guideline for the Management of Hereditary Angioedema. *World Allergy Organization Journal*. 2012; 5:182–199.
4. Zuraw, B, Banerji, A, Bernstein J, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 Recommendations for the Management of Hereditary Angioedema Due to C1 Inhibitor Deficiency. *American Academy of Allergy, Asthma & Immunology*. 2013;1:458-67.