Policy Title:	Kalbitor (ecallantide) (Subcutaneous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	10/02/19, 12/18/19, 1/22/20, 5/06/21, 2/10/2022, 3/16/2023		
Revision Date:	10/02/19, 12/18/19, 1/22/20, 5/06/21		

Purpose: To support safe, effective and appropriate use of Kalbitor (ecallantide).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Kalbitor (ecallantide) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Kalbitor (ecallantide) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Member is 12 years of age or older; AND
- Kalbitor is being used for treatment of acute hereditary angioedema (HAE) attacks
- Medication is prescribed by, or in consultation with allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders; AND
- Member has history of moderate to severe cutaneous attacks (without concomitant hives) OR abdominal attacks OR mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling); AND
- Patient has documented diagnosis of HAE type I or type II and meets one of the following:
    - Member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets both of the following criteria:
        - Member has a C4 level below the lower limit of normal as defined by the laboratory performing the test, AND
        - Member meets one of the following criteria:
            - 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); OR

- Member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
    - Member has an F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing, OR
    - Member has a 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.
- Dose does not exceed FDA approved labeling; AND
- The requested medication will not be used in combination with other products indicated for acute treatment of HAE attacks (e.g., Ruconest, Haegarda, or Icatibant)
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria; AND
- Patient has experienced reduction in severity and duration of attacks since starting treatment; AND
- Documentation supporting a positive clinical response to therapy with Kalbitor (e.g., chart notes, medical records)

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = 1 mg)**
HAE	30 mg injected subcutaneously by a health care professional in three 10 mg injections. An additional dose of 30 mg may be administered if the attack persists. Not to exceed a total of two 30 mg doses (60 mg) in 24 hours	240 billable units per 28 days

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J1290	Injection, ecallantide, 1 mg

References:

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7. Lang DM, Aberer W, Bernstein JA, et al. International consensus on hereditary and acquired angioedema. Ann Allergy Asthma Immunol. 2012; 109:395-202.
8. Cicardi M, Aberer W, Banerji A, et al. Classification, diagnosis, and approach to treatment for angioedema: consensus report from the Hereditary Angioedema International Working Group. Allergy. 2014;69: 602-616.
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10. Bernstein J. Update on angioedema: Evaluation, diagnosis, and treatment. Allergy and Asthma Proceedings. 2011;32(6):408-412.
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