GARADACIMAB

Included Products: Andembry (garadacimab-gxii)

Created: 11/13/2025 Revised: 11/13/2025 *Reviewed*: 11/13/2025 *Updated*: 12/01/2025

All Diagnoses			
Initial Criteria: All Diagnoses		**If yes**	**If no**
1.	Does the member have a diagnosis of hereditary angioedema (HAE) confirmed by one of the following: • C1-INH antigenic level below the lower limit of normal; OR • C1-INH functional level below the lower limit of normal; OR • Normal C1-INH levels and one of the following: ○ Confirmed presence of variant(s) in the gene(s) for factor XII (F12), angiopoietin-1 (ANGPT1), plasminogen (PLG), kininogen-1 (KNG1), myoferlin (MYOF), and heparan sulfate-glucosamine 3-Osulfotransferase 6 (HS3ST6); OR ○ Recurring angioedema attacks that are refractory to high-dose antihistamines	Continue to #2.	Do not approve.
2.	Does the member have a history of attacks that are considered severe with swelling of the face, throat or gastrointestinal tract that significantly interrupts usual daily activity despite short-term symptomatic treatment?	Continue to #3.	Do not approve.
3.	Has the member been evaluated for triggers of HAE attacks and is maximally managed for avoidance of those triggers (such as stress, hormonal changes, dental surgery, trauma, medications including ACE inhibitors and estrogen)?	Continue to #4.	Do not approve.

4.	Is treatment with acute, abortive therapy an option for this member (Firazyr, Berinert)?	Do not approve.	Continue to #5.
5.	All approvals subject to medical director review. Initial approval duration of 6 months.		
Renewal Criteria		If yes	If no
1.	Has the patient been attack free for greater than 6 months?	Continue to #2.	Continue to #3.
3.	Has there been at least a 50% reduction in the number of angioedema attacks, significant improvement in the severity of attacks, and clinical documentation of functional improvement?	Approve for 6 months.	Do not approve.