Mass General Brigham
Health Plan

Orladeyo (berotralstat)
Effective 01/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Orladeyo (berotralstat) is a plasma kallikrein inhibitor that inhibits plasma kallikrein proteolytic activity, controlling excess bradykinin generation to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with Orladeyo, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. The member will be using Orladeyo for the prevention of hereditary angioedema attacks
2. Orladeyo will not be used in combination with any medication used for the prophylaxis of HAE attacks.
3. Member meets ONE of the following:
    a. Member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets BOTH of the following criteria:
        i. Member has a C4 level below the lower limit of normal as defined by the laboratory performing the test
        ii. Member meets ONE of the following criteria:
            (a) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test
            (b) 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).
    b. Member has normal C1 inhibitor as confirmed by laboratory testing and meets ONE of the following criteria:
        i. Member has an F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing

ii. 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.

4. Member has adverse effect or contraindication to icatibant (generic for Firazyr)

Continuation of Therapy

Reauthorization may be granted for members when ALL of the following are met, and documentation is provided:

1. Member meets all initial approval criteria.
2. Member has experienced a significant reduction in frequency of attacks (e.g. ≥ 50%) since starting treatment.
3. Member has reduced the use of medications to treat acute attacks.

Limitations

1. Initial approvals and reauthorizations will be for 6 months.
2. The following quantity limits apply:

Oraldeyo capsules	30 capsules per 30 days

References

1. Orladeyo [package insert]. Durham, NC: BioCryst Pharmaceuticals, Inc.; December 2020.
2. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema – the 2017 revision and update. Allergy. 2018;00:1-22.
3. Henao MP, Kraschnewski J, Kelbel T, Craig T. Diagnosis and screening of patients with hereditary angioedema in primary care. Therapeutics and Clin Risk Management. 2016; 12: 701-711.
4. Zuraw B, Lumry WR, Johnston DT, et al. Oral once-daily berotralstat for the prevention of hereditary angioedema attacks: A randomized, double-blind, placebo-controlled phase 3 trial. J Allergy Clin Immunol. 2020;S0091-6749(20)31484-6.

Review History

05/19/2021 – Created and Reviewed May P&T. Effective 07/01/2021.
9/21/2022 – Reviewed and Updated for Sept P&T; added requirement of adverse effect or contraindication to icatibant (generic for Firazyr). Separated out MH vs. Comm/Exch. Effective 1/1/2023.