Mass General Brigham
Health Plan

Bylvay (odevixibat)
Effective 03/01/2025

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
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

Bylvay (odevixibat) is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of:

- Pruritis in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Limitations of use: May not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).
- Cholestatic pruritus in patients 12 months of age and older with Alagille syndrome (ALGS)

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted all of the following criteria are met:

Progressive Familial Intrahepatic Cholestasis (PFIC)

1. Member has a diagnosis of progressive familial intrahepatic cholestasis (PFIC)
2. Genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3)
3. Member is 3 months of age or older
4. Requested medication is being prescribed by or in consultation with a hepatologist, gastroenterologist or a provider who specializes in PFIC
5. Member has pruritis
6. Member has had an inadequate response, adverse reaction, or contraindication to at least ONE of the following:
    a. Ursodiol (UDCA)
    b. Antihistamine
    c. Rifampin
    d. Cholestyramine

e. Sertraline
f. Naltrexone

Cholestatic Pruritus in Alagille Syndrome

1. The member has a diagnosis of Alagille syndrome (ALGS) confirmed by ONE of the following:
    a. Documentation of genetic testing confirming mutations of the JAG1 or NOTCH2 genes
    b. Bile duct paucity
    c. THREE of the five major clinical features of ALGS:
        i. Cholestasis
        ii. Cardiac defect (e.g., stenosis of the peripheral pulmonary artery and its branches)
        iii. Skeletal abnormality (e.g., butterfly vertebrae)
        iv. Ophthalmologic abnormality (e.g., posterior embryotoxon)
        v. Characteristic facial features (e.g., triangular-shaped face with a broad forehead and a pointed chin, bulbous tip of the nose, deeply set eyes, and hypertelorism)
2. Member is 12 months of age or older
3. Requested medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or provider who specializes in treatment of Alagille Syndrome
4. Member has pruritus
5. Member has had an inadequate response, adverse reaction, or contraindication to at least ONE of the following:
    a. Ursodiol (UDCA)
    b. Antihistamine
    c. Rifampin
    d. Cholestyramine
    e. Sertraline
    f. Naltrexone

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Prescriber submits documentation of positive clinical response as evidenced by improvement in severity of pruritis

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months
2. The following quantity limits apply:

Drug Name	Quantity Limit
Bylvay 400mcg and 1200mcg oral capsule	60 capsules per 30 days
Bylvay (pellets) 200mcg oral capsule sprinkles	60 capsules per 30 days
Bylvay (pellets) 600mcg oral capsule sprinkles	30 capsules per 30 days

References

1. Bylvay (odevixibat) [prescribing information]. Boston, MA: Ipsen Biopharmaceuticals, Inc; February 2024.

Review History

03/16/2022 – Created for March P&T Effective 05/01/2022.

12/11/2024 – Reviewed and updated at December P&T. Added criteria for Alagille syndrome. Updated PFIC criteria to require step through with one alternative agent. Effective 3/1/2025.