Pharmacy Medical Necessity Guidelines: Bylvay™ (odevixibat)

Effective: June 13, 2023

Guideline Type
☒ Prior Authorization
☐ Non-Formulary
☐ Step-Therapy
☐ Administrative

Applies to:

Commercial Products
☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988
☒ Tufts Health Plan Commercial products; Fax: 617-673-0988
CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products
☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications
Bylvay (odevixibat) is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis.

Bylvay (odevixibat) 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).

Clinical Guideline Coverage Criteria

The plan may authorization coverage of Bylvay for Members when all of the following criteria are met:

Initial Authorization

1. Documented diagnosis of progressive familial intrahepatic cholestasis

2. Documentation of molecular genetic testing that does not indicate progressive familial intrahepatic cholestasis type 2 with ABCB11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3)

3. Prescribed by or in consultation with a hepatologist, gastroenterologist, or a provider who specializes in progressive familial intrahepatic cholestasis

4. The patient is 3 months of age or older

5. Documentation of pruritus

6. Documentation of trial and failure with at least one (1) systemic medication considered standard of care for progressive familial intrahepatic cholestasis, unless contraindicated (e.g., antihistamines, cholestyramine, rifampicin, ursodiol)

7. Documentation the patient has not had a liver transplant
Reauthorization Criteria

1. Documented diagnosis of progressive familial intrahepatic cholestasis

AND

2. Documentation of molecular genetic testing that does not indicate progressive familial intrahepatic cholestasis type 2 with ABCB11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3)

AND

3. Prescribed by or in consultation with a hepatologist, gastroenterologist, or a provider who specializes in progressive familial intrahepatic cholestasis

AND

4. The patient is 3 months of age or older

AND

5. Documentation of a positive clinical response as evidence by one (1) of the following:
   a. Improvement in severity of pruritus
   b. Reduction in serum bile acid from baseline

AND

6. Documentation the patient has not had a liver transplantation

Limitations

1. Initial coverage of Bylvay will be authorized for 6 months. Reauthorization of Bylvay will be provided in 12-month intervals.

2. Members new to the plan stable on Bylvay (odevixibat) should be reviewed against Reauthorization Criteria.

3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes
None

References


Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- June 13, 2023: No changes

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates
Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.