IOWA Health and Human Services

Request for Prior Authorization
Odevixibat (Bylvay)

FAX Completed Form To
1 (800) 574-2515
Provider Help Desk
1 (877) 776-1567

(PLEASE PRINT – ACCURACY IS IMPORTANT)

IA Medicaid Member ID #	Patient name	DOB
Patient address		
Provider NPI	Prescriber name	Phone
Prescriber address		Fax
Pharmacy name	Address	Phone
Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.		
Pharmacy NPI	Pharmacy fax	NDC

Prior authorization (PA) is required for odevixibat (Bylvay). Payment will be considered under the following conditions:

1. **Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings and precautions, and drug interactions; and**
2. **Patient has a diagnosis of genetically confirmed progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2; and**
    a. **Genetic testing does not indicate PFIC type 2 with ABCB 11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3); and**
    b. **Patient has moderate to severe pruritis associated with PFIC; or**
3. **Patient has a diagnosis of Alagille Syndrome (ALGS) confirmed by genetic testing demonstrating a JAGI or NOTCH2 mutation or deletion; and**
    a. **Patient has cholestasis with moderate to severe pruritis; and**
    b. **Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:**
        i. **Ursodeoxycholic acid (ursodiol)**
        ii. **Cholestyramine**
        iii. **Rifampin; and**
4. **Patient's current weight in kg is provided; and**
5. **Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in PFIC or ALGS..**

Initial authorizations will be approved for 3 months for initial treatment or after a dose increase. Additional authorizations will be considered when the following criteria are met:

1. **Patient's current weight in kg is provided; and**
2. **Documentation is provided the patient has responded to therapy and pruritis has improved. If there is no improvement in pruritis after 3 months of treatment with the maximum 120 mcg/kg/day dose, further approval of odevixibat will not be granted.**

Non-Preferred

☐ Bylvay

Strength	Dosage Instructions	Quantity	Days Supply

Diagnosis: _____

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☐ **PFIC Type 1 or 2**

Does genetic testing indicate PFIC type 2 with ABCB 11 variants for encoding for nonfunction or absence of bile salt export pump protein (BSEP-3) (attach supporting documentation)? ❑ Yes ❑ No

Does patient have moderate to severe pruritis associated with PFIC? ❑ Yes ❑ No

☐ **ALGS**

Does patient have cholestasis with moderate to severe pruritis? ☐ Yes ☐ No

Treatment failures:

Trial 1: Name/Dose:_____ Trial Dates:_____

Failure reason:_____

Trial 2: Name/Dose:_____ Trial Dates:_____

Failure reason:_____

Provide patient's current weight in kg:_____ **Date obtained:**_____

Prescriber Specialty: ❑ Hepatologist ❑ Gastroenterologist ❑ Prescriber who specializes in PFIC or ALGS
❑ Other (specify): _____

If other, note consultation with hepatologist or gastroenterologist:
Consultation date: _____
Physician name, specialty & phone: _____

Renewal Requests

Provide patient's current weight in kg:_____ **Date obtained:**_____

Has patient responded to therapy and pruritis improved? ❑ Yes ❑ No

Attach lab results and other documentation as necessary.

Prescriber signature (Must match prescriber listed above.)	Date of submission

IMPORTANT NOTE: *In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Health and Human Services, that the member continues to be eligible for Medicaid.*