SENTARA COMMUNITY PLAN
(MEDICAID)

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Bylvay™ (odevixibat)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Quantity Limits:

- ❑ NDC 74528-020-01: 200 mcg oral pellets: 8 per day; 240 per 30 days
- ❑ NDC 74528-040-01: 400 mcg capsule: 10 per day; 300 per 30 days
- ❑ NDC 74528-060-01: 600 mcg oral pellets: 4 per day; 120 per 30 days
- ❑ NDC 74528-120-01: 1,200 mcg capsule: 5 per day; 150 per 30 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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❑ **DIAGNOSIS: Progressive Familial Intrahepatic Cholestasis**

Recommended Dosage:

- ❑ 40 mcg/kg/day. If no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg/day not to exceed a total daily dose of 6 mg
- ❑ Bylvay oral pellets are for patients weighing <19.5 kg, while the capsules are intended for use by patients weighing ≥ 19.5 kg

Body weight (kg)	Total daily dose (mcg) for 40 mcg/kg/day	Total daily dose (mcg) for 80 mcg/kg/day	Total daily dose (mcg) for 120 mcg/kg/day
≤ 7.4	200 (1 oral pellet)	400 (2 oral pellets)	600 (1 oral pellet)
7.5-12.4	400 (2 oral pellets)	800 (4 oral pellets)	1200 (2 oral pellets)
12.5-17.4	600 (1 oral pellet)	1200 (2 oral pellets)	1,800 (3 oral pellets)
17.5-19.4	800 (4 oral pellets)	1600 (8 oral pellets)	2,400 (4 oral pellets)
19.5-25.4	800 (2 capsules)	1600 (4 capsules)	2,400 (2 capsules)
25.5-35.4	1,200 (1 capsule)	2,400 (2 capsules)	3,600 (3 capsules)
35.5-45.4	1,600 (4 capsules)	3,200 (8 capsules)	4,800 (4 capsules)
45.5-55.4	2,000 (5 capsules)	4,000 (10 capsules)	6,000 (5 capsules)
≥ 55.5	2,400 (2 capsules)	4,800 (4 capsules)	6,000 (5 capsules)

Length of Authorization: 12 months

- ❑ Member is 3 months of age or older
- ❑ Member has been diagnosed with progressive familial intrahepatic cholestasis (PFIC)

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❑ **DIAGNOSIS: Cholestatic pruritus due to Alagille syndrome**

Recommended Dosage:

- ❑ 120 mcg/kg/day
- ❑ Bylvay oral pellets are for patients weighing <19.5 kg, while the capsules are intended for use by patients weighing ≥ 19.5 kg

Body weight (kg)	Total daily dose (mcg) for 120 mcg/kg/day
< 7.4	600 (1 oral pellet)
7.5-12.4	1200 (2 oral pellets)
12.5-17.4	1,800 (3 oral pellets)
17.5-19.4	2,400 (4 oral pellets)
19.5-25.4	2,400 (2 capsules)
25.5-35.4	3,600 (3 capsules)
35.5-45.4	4,800 (4 capsules)
45.5-55.4	6,000 (5 capsules)
> 55.5	7,200 (6 capsules)

Length of Authorization: 12 months

- ❑ Member is 12 months of age or older
- ❑ Member has been diagnosed with Alagille syndrome (ALGS)

Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutic Committee:** 11/19/2020; **9/21/2023**
REVISED/UPDATED: ~~12/12/2021; 12/23/2021; 10/17/2023~~**, 7/2/2026**