

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Hepatology – Bylvay Drug Quantity Management Policy – Per Rx

- Bylvay™ (odevixibat capsules and oral pellets – Albireo Pharma)

REVIEW DATE: 09/21/2022

OVERVIEW

Bylvay, an ileal bile acid transporter (IBAT) inhibitor, is indicated for the treatment of pruritus in patients ≥ 3 months of age with **progressive familial intrahepatic cholestasis (PFIC)**.¹

Dosing

The recommended dosage of Bylvay is 40 mcg/kg once daily (QD) in the morning with a meal.¹ If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg QD, not to exceed a total daily dose of 6 mg daily. Table 1 below shows the recommended weight-based total daily doses needed for the recommended dose.

Bylvay oral pellets are intended for use by patients < 19.5 kg.¹ The capsules are intended for use by patients weighing ≥ 19.5 kg.

The oral pellets should be placed in a small amount of food (up to 30 mL [2 tablespoons] of apple sauce, oatmeal, banana or carrot puree, chocolate or rice pudding) and gently mix until well dispersed.¹ The oral capsules can either be swallowed whole with a glass of water, or may be opened, and sprinkled and mixed with a small amount of soft food.

Table 1. Recommended Weight-Based Total Daily Dosage.

Body Weight (kg)	Total Daily Dose 40 mcg/kg	Total Daily Dose 80 mcg/kg	Total Daily Dose 120 mcg/kg
≤ 7.4 kg	200 mcg (1 x 200 mcg pellet)	400 mcg (2 x 200 mcg pellets)	600 mcg (3 x 200 mcg pellets OR 1 x 600 mcg pellets)
7.5 kg to 12.4 kg	400 mcg (2 x 200 mcg pellets)	800 mcg (4 x 200 mcg pellets)	1,200 mcg (2 x 600 mcg pellets OR 1 x 1,200 mcg capsule)
12.5 kg to 17.4 kg	600mcg (3 x 200 mcg pellets OR 1 x 600 mcg pellets)	1,200 mcg (2 x 600 mcg pellets OR 1 x 1,200 mcg capsule)	1,800 mcg (9 x 200 mcg pellets OR 3 x 600 mcg pellets)
17.5 kg to 19.4 kg	800 mcg (4 x 200 mcg pellets)	1,600 mcg (8 x 200 mcg pellets)	2,400 mcg (4 x 600 mcg pellets OR 2 x 1,200 mcg capsules)
19.5 kg to 25.4 kg	800 mcg (2 x 400 mcg capsules)	1,600 mcg (4 x 400 mcg capsules)	2,400 mcg (2 x 1,200 mcg capsules)
25.5 kg to 35.4 kg	1,200 mcg (1 x 1200 mcg capsule)	2,400 mcg (2 x 1200 mcg capsules)	3,600 mcg (3 x 1,200 mcg capsules)
35.5 kg to 45.4 kg	1,600 mcg (4 x 400 mcg capsules)	3,200 mcg (8 x 400 mcg capsules)	4,800 mcg (4 x 1,200 mcg capsules)
45.5 kg to 55.4 kg	2,000 mcg (5 x 400 mcg capsules)	4,000 mcg (10 x 400 mcg capsules)	6,000 mcg (5 x 1,200 mcg capsules)
≥ 55.5 kg	2,400 mcg (2 x 1,200 mcg capsules)	4,800 mcg (4 x 1,200 mcg capsules)	6,000 mcg (5 x 1,200 mcg capsules)

Availability

09/21/2022

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Bylvay is available as a 400 and 1,200 mg capsules and 200 and 600 mg pellets in dispensing capsules.¹
All dosage forms are supplied in bottles of 30.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the dose consolidation, prevent stockpiling and waste, and address potential order entry error of Bylvay. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx*	Home Delivery Maximum Quantity per Rx
Bylvay™ (odevixibat capsules and oral pellets)	200 mcg oral pellets (in dispensing capsules)	120 oral pellets (in dispensing capsules)	360 oral pellets (in dispensing capsules)
	400 mcg capsules	150 capsules	450 capsules
	600 mcg oral pellets (in dispensing capsules)	30 oral pellets (in dispensing capsules)	90 oral pellets (in dispensing capsules)
	1,200 mcg capsules	60 capsules	180 capsules

*This is enough drug for a 30-day supply at 40 mcg/kg per day dosing (up to 4 x 200 mcg pellets in dispensing capsules, up to 3 x 400 mcg capsules, 1 x 600 mcg pellets in dispensing capsules, and up to 2 x 1,200 mcg capsules) . Additional quantities for dose titration can be made available through coverage review.

CRITERIA

Bylvay 200 mcg oral pellets (in dispensing capsules)

1. If the patient's daily dose is 80 mcg/kg/day and the patient weighs < 19.5 kg, approve the requested quantity not to exceed 240 oral pellets (in dispensing capsules) per dispensing at retail or 720 oral pellets (in dispensing capsules) per dispensing at home delivery.

Note: This is a quantity sufficient for 80 mcg/kg/day dosing in patients who weigh < 19.5 kg and require a 1,600 mcg daily dose. For patients who weigh ≥ 19.5 kg and require a dose of 80 mcg/kg/day refer the patient to the 400 mcg capsules or 1,200 mcg capsules.

2. If the patient's daily dose is 120 mcg/kg/day and the patient weighs < 17.5 kg, approve the requested quantity not to exceed 270 oral pellets (in dispensing capsules) per dispensing at retail or 810 oral pellets (in dispensing capsules) per dispensing at home delivery.

Note: This is a quantity sufficient for 120 mcg/kg/day per day dosing in patients who weigh < 17.5 kg and require an 1,800 mcg daily dose. For patients who weigh ≥ 17.5 kg and require a dose of 120 mcg/kg/day, refer the patient to the 600 mcg pellets (in dispensing capsules) [weight ≥ 17.5 kg to < 19.5 kg] or 1,200 mcg capsules (weight ≥ 19.5 kg).

Bylvay 600 mcg oral pellets (in dispensing capsules)

1. If the patient's daily dose is 80 mcg/kg/day and the patient weighs < 17.5 kg, approve the requested quantity not to exceed 60 oral pellets (in dispensing capsules) per dispensing at retail or 180 oral pellets (in dispensing capsules) per dispensing at home delivery.

Note: This is a quantity sufficient for 80 mcg/kg/day dosing in patients who weigh < 17.5 kg and require a 1,200 mcg daily dose. For patients who weigh \geq 17.5 kg and require a dose of 80 mcg/kg/day, refer the patient to the 200 mcg pellets (in dispensing capsules) [weight \geq 17.5 kg to < 19.5 kg] or 400 mcg capsules or 1,200 mcg capsules (weight \geq 19.5 kg).

2. If the patient's daily dose is 120 mcg/kg/day and the patient weighs < 19.5 kg, approve the requested quantity not to exceed 120 oral pellets (in dispensing capsules) per dispensing at retail or 360 oral pellets (in dispensing capsules) per dispensing at home delivery.

Note: This is a quantity sufficient for 120 mcg/kg/day dosing in patients who weigh < 19.5 kg and require a 2,400 mcg daily dose. For patients who weigh \geq 19.5 kg and require a dose of 120 mcg/kg/day, refer the patient to the 1,200 mcg capsules.

Bylvay 400 mcg capsules

1. If the patient's daily dose is 80 mcg/kg/day and the patient weighs \geq 19.5 kg, approve the requested quantity not to exceed 300 capsules per dispensing at retail or 900 capsules per dispensing at home delivery.

Note: This is a quantity sufficient for 80 mcg/kg/day dosing up to a 4,000 mcg daily dose. For doses \geq 4,000 mcg/day, refer the patient to the 1,200 mcg capsules.

Bylvay 1,200 mcg capsules

1. If the patient's daily dose is 80 mcg/kg/day and the patient weighs \geq 19.5 kg, approve the requested quantity not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

Note: This is a quantity sufficient for 80 mcg/kg/day dosing up to a 4,800 mcg daily dose.

2. If the patient's daily dose is 120 mcg/kg/day and the patient weighs \geq 17.5 kg, approve the requested quantity not to exceed 150 capsules per dispensing at retail or 450 capsules per dispensing at home delivery.

Note: This is a quantity sufficient for 120 mcg/kg per day up to the maximum daily dose of 6,000 mcg.

REFERENCES

1. Bylvay™ capsules and oral pellets [prescribing information]. Boston, MA: Albireo Pharma; July 2021.

