



DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

- Bylvay® (odevixibat capsules and oral pellets – Albireo)

REVIEW DATE: 09/24/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

- Pruritus in patients \geq 3 months of age with **progressive familial intrahepatic cholestasis (PFIC)**.¹
- Cholestatic pruritus in patients \geq 12 months of age with **Alagille syndrome (ALGS)**.¹

Dosing

The recommended dosage of Bylvay for PFIC 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 QD. The recommended dosage of Bylvay for ALGS is 120 mcg/kg QD in the morning with a meal. Table 1 below shows the recommended weight-based total daily doses needed for the recommended dose.

Table 1. Recommended Weight-Based Total Daily Dosage.

Body Weight (kg)	ALGS* or PFIC	PFIC	ALGS or PFIC
	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 (6 x 200 mcg pellets OR 2 x 600 mcg pellets)
12.5 kg to 17.4 kg	600mcg (3 x 200 mcg pellets OR 1 x 600 mcg pellets)	1,200 mcg (6 x 200 mcg pellets OR 2 x 600 mcg pellets)	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 OR 2 x 400 mcg capsules)	1,600 mcg (8 x 200 mcg pellets OR 4 x 400 mcg capsules)	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 1,200 mcg capsule)	2,400 mcg (2 x 1,200 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)	PFIC 6,000 mcg (5 x 1,200 mcg capsules) ALGS 7,200 mcg (6 x 1,200 mcg capsules)

* Dose modification to manage adverse events.

Availability

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

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 mixed 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.

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.

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	360 oral pellets
	400 mcg capsules	150 capsules	450 capsules
	600 mcg oral pellets (in dispensing capsules)	30 oral pellets	90 oral pellets
	1,200 mcg capsules	60 capsules	180 capsules

Hepatology – Bylvay Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

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 ≥ 17.5 kg and require a dose a dose of 80 mcg/kg/day, refer the patient to the 200 mcg pellets (in dispensing capsules) [weight ≥ 17.5 kg to < 19.5 kg] or 400 mcg capsules or 1,200 mcg capsules (weight ≥ 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 ≥ 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 ≥ 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 ≥ 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 ≥ 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 ≥ 17.5 kg, approve the requested quantity not to exceed 180 capsules per dispensing at retail or 540 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 7,200 mcg.

REFERENCES

1. Bylvay™ capsules and oral pellets [prescribing information]. Boston, MA: Albireo; June 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Bylvay 1,200 mcg capsules: Criteria for patients taking a dose of 120 mcg/kg/day and weighing ≥ 17.5 kg were updated to approve the requested quantity, not to exceed 180 capsules per dispensing at retail or 540 capsules per dispensing at home delivery. Previously,	09/20/2023

	criteria approved for a quantity not to exceed 150 capsules per dispensing at retail or 450 capsules per dispensing at home delivery.	
Annual Revision	No criteria changes.	09/24/2024

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.