

SPECIALTY QUANTITY LIMIT PROGRAM

PROCYSBI (cysteamine bitartrate)

I. PROGRAM DESCRIPTION

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

II. COVERED QUANTITIES

Medication	Standard Limit	FDA-recommended dosing
Procysbi (cysteamine bitartrate) 25 mg delayed release capsule	240 capsules per 30 days	<p>The maintenance dosage after initial dose escalation is 1.3 g/m² of body surface area per day divided into two doses given every 12 hours.</p> <p>The recommended maintenance dose for patients weighing 51 kg and greater is 1,000 mg every 12 hours.</p> <p>Round dose calculations to the nearest incremental dosage that can be administered using the available strengths of delayed-release capsules or packets of oral granules</p>
Procysbi (cysteamine bitartrate) 75 mg delayed release capsule	750 capsules per 30 days	
Procysbi (cysteamine bitartrate) 75 mg delayed release oral granules	180 packets per 30 days	
Procysbi (cysteamine bitartrate) 300 mg delayed release oral granules	180 packets per 30 days	

III. REFERENCES

1. Procysbi [package insert]. Lake Forest, IL: Horizon Pharma USA, Inc.; February 2020.