

DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY: Cabergoline Drug Quantity Management Policy – Per Days

Cabergoline tablets – generic only

REVIEW DATE: 07/03/2024

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

Cabergoline tablets are indicated for the treatment of **hyperprolactinemic disorders**, either idiopathic or due to pituitary adenomas.¹

Cabergoline has also been used off-label for the management of acromegaly, Parkinson's disease, and Cushing's syndrome.²⁻⁸

Dosina

The recommended dose of cabergoline for hyperprolactinemic disorder is 0.25 mg twice weekly. The dose may be increased by 0.25 mg twice weekly up to a maximum dose of 1 mg twice weekly (4 x 0.5 mg tablets/week). Dose adjustments should not occur more frequently than every 4 weeks. Some patients have required doses up to 11 mg/week to overcome resistance.

For acromegaly, cabergoline has been used at doses ranging from 0.3 mg/week to 7 mg/week.^{3,4} For Parkinson's disease, cabergoline has been used at doses up to 20 mg/day⁵ For Cushing's syndrome, cabergoline has been used at doses up to 7 mg/week.⁸

Availability

Cabergoline is available as 0.5 mg scored tablets in bottles containing 8 tablets.¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of cabergoline. 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 28 Days	Home Delivery Maximum Quantity per 84 Days
Cabergoline tablets	0.5 mg tablets	8 tablets*	24 tablets*

^{* 8} tablets provide adequate quantity of medication for 4 weeks of therapy at retail or 12 weeks of therapy at home delivery at a dose of 0.5 mg twice weekly.

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

CRITERIA

1. If the patient has hyperprolactinemia, approve the requested quantity not to exceed 88 tablets per 28 days at retail or 264 tablets per 84 days at home delivery.

Note: For hyperprolactinemic disorder, patients may require doses up to 11 mg per week to overcome resistance.²

- 2. If the patient has acromegaly, approve the requested quantity not to exceed 56 tablets per 28 days at retail or 168 tablets per 84 days at home delivery.

 Note: For acromegaly, cabergoline has been used at doses ranging from 0.3 mg/week to 7 mg/week.^{3,4}
- **3.** If the patient has Parkinson's disease, approve the requested quantity not to exceed 1,120 tablets per 28 days at retail or 3,360 tablets per 84 days at home delivery at home delivery.

<u>Note</u>: For Parkinson's disease, cabergoline has been used at doses up to 20 mg/day.⁵

4. If the patient has Cushing's syndrome, approve the requested quantity not to exceed 56 tablets per 28 days at retail or 168 tablets per 84 days at home delivery.

Note: For Cushing's syndrome, cabergoline has been used at doses up to 7 mg/week.⁷

REFERENCES

- 1. Cabergoline tablets [prescribing information]. Peapack, NJ: Greenstone; November 2022.
- 2. Melmed S, Casanueva FF, Hoffman AR, et al. Diagnosis and treatment of hyperprolactinemia: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2011;96(2):273–288. Available at: https://www.endocrine.org/clinical-practice-guidelines/hyperprolactinemia. Accessed on June 20, 2024.
- 3. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. *J Clin Endorinol Metab.* 2014;99(11)3933–3951. Available at: https://www.endocrine.org/clinical-practice-guidelines/acromegaly https://academic.oup.com/jcem/article/99/11/3933/2836347. Accessed on June 20, 2024.
- 4. Sandret L, Maison P, Chanson P. Place of cabergoline in acromegaly: a meta-analysis. *J Clin Endocrinol Metab.* 2011;96(5):1327-1335.
- 5. Pringsheim T, Day GS, Smith DB, et al. Dopaminergic therapy for motor symptoms in early Parkinson disease practice guideline. A report of the American Academy of Neurology subcommittee. *Neurology*. 2021;97(20):942-957. Available at: https://www.aan.com/Guidelines/home/GuidelineDetail/1043. Accessed on June 20, 2024.
- 6. Odin, P, Oehlwein C, Stoarch A, et al. Efficacy and safety of high-dose cabergoline in Parkinson's disease. *Acta Neurol Scand*. 2006;113(1):18-24.
- 7. L. Niemen, B. Biller, J. Findling, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8):2807–2831. Available at https://academic.oup.com/jcem/article/100/8/2807/2836065. Accessed June 20, 2024.
- 8. Silber MH, Buchfuhrer MJ, Earley CJ, et al. The management of restless legs syndrome: an updated algorithm. *Mayo Clin Proc.* 2021;96(7):1921-1937.

HISTORY

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Type of	Summary of Changes	Review		
Revision		Date		
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	06/14/2023		
	 The following changes were made to the override criteria: For a patient with acromegaly, override criteria were updated to approve the requested quantity not to exceed 56 tablets per 28 days at retail or 168 tablets per 84 days at home delivery. Previously, this criterion approved the requested quantity for a 28-day supply at retail or an 84-day supply at home delivery. For a patient with Parkinson's disease, override criteria were updated to approve the requested quantity not to exceed 1,120 tablets per 28 days at retail or 3,360 tablets per 84 days at home delivery. Previously, this criterion approved the requested quantity for a 28-day supply at retail or an 84-day supply at home delivery. For a patient with restless legs syndrome, override criteria were updated to approve the requested quantity not to exceed 168 tablets per 28 days at retail or 504 tablets per 84 days at home delivery. Previously, this criterion approved the requested quantity for a 28-day supply at retail or an 84-day supply at home delivery. For a patient with Cushing's syndrome, override criteria were updated to approve the requested quantity not to exceed 56 tablets per 28 days at retail or 168 tablets per 84 days at home delivery. Previously, this criterion approved the requested quantity for a 28-day supply at retail or an 84-day supply at home delivery. 			
Annual	Override for an additional quantity of cabergoline 0.5 mg tablets for	07/03/2024		
Revision	restless legs syndrome was removed.			

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