Effective Date **11/15/2022**
Next Review Date **11/15/2023**
Coverage Policy Number **IP0456**

Clonidine Extended-Release

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Related Coverage Resources

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. 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.

Overview

This policy supports medical necessity review for the following clonidine extended-release products:

- **clonidine 0.17 mg extended-release** tablet
- **Nexiclon XR™** (clonidine 0.17 mg extended-release tablet)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Clonidine extended-release products in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and the Preferred Covered Alternatives:

Non-Covered Product	Criteria
clonidine 0.17 mg extended-release tablet **Nexiclon XR** (clonidine 0.17 mg extended-release tablets)	Individual meets the following (1): **1. Hypertension.** Individual meets **ALL** of the following criteria (A, B, and C): A. Individual is 18 years of age or older B. There is documentation of **EITHER** of the following: i. Inability to achieve dose with **BOTH** clonidine immediate-release tablets AND clonidine transdermal patches ii. Significant intolerance to **BOTH** clonidine immediate-release tablets AND clonidine transdermal patches (difference in the inactive ingredient(s), dyes, fillers, preservatives) C. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **THREE** covered formulary alternatives from ANY of the following classes: i. thiazide-like or thiazide-type diuretics [chlorthalidone, indapamide, hydrochlorothiazide] ii. angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs) [captopril, enalapril, lisinopril, ramipril, candesartan, losartan, valsartan] iii. dihydropyridine-type calcium channel blockers [amlodipine, nifedipine, nicardipine]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Clonidine extended-release products are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial and reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered not medically necessary.

Background

OVERVIEW
Nexiclon XR is indicated in the treatment of hypertension. Nexiclon XR may be employed alone or concomitantly with other antihypertensive agents.

Nexiclon XR (clonidine) Extended-Release Tablets are available for oral administration in two dose strengths: 0.17 mg and 0.26 mg. The 0.17 mg and 0.26 mg tablets are equivalent to 0.2 mg and 0.3 mg of immediate-release clonidine hydrochloride, respectively.

References

1. Nexiclon XR (clonidine) [prescribing information]. Monmouth Junction, NJ: Tris Pharma Inc; August 2021.