DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Hypertension – Clonidine Patches Drug Quantity Management Policy – Per Days
- Catapres TTS (clonidine transdermal system [patch] – Boehringer Ingelheim, generic)

REVIEW DATE: 06/02/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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

Clonidine transdermal therapeutic system (TTS) [Catapres-TTS, generic], a centrally acting alpha-agonist, is indicated for the treatment of **hypertension**.[1] It may be used alone or in combination with other antihypertensive agents.

Dosing

Clonidine TTS is applied once every 7 days to a hairless area of intact skin on the upper outer arm or chest.[1] Each new patch should be applied on a different skin site from the previous location. If the system loosens during 7-day wearing, the adhesive cover should be applied directly over the system to ensure good adhesion. There have been rare reports of the need for patch changes prior to 7 days to maintain blood pressure control.

To initiate therapy, the clonidine patch dosage should be titrated according to individual therapeutic requirements, starting with clonidine TTS-1 patch (delivers 0.1 mg clonidine/day for 1 week).[1] If after 1 or 2 weeks the desired reduction in blood pressure is not achieved, increase the dosage by adding another clonidine TTS-1 patch or changing to a higher strength patch. An increase in dosage above two clonidine TTS-3 patches (2 x 0.3 mg clonidine/day for 1 week) is usually not associated with additional efficacy.

When substituting clonidine patches for oral clonidine or for other antihypertensive drugs, prescribers should be aware that the antihypertensive effect of clonidine patches may not commence until 2 to 3 days after initial application.[1] Therefore, gradual reduction of prior drug dosage is advised. Some or all previous antihypertensive treatment may have to be continued, particularly in patients with more severe forms of hypertension.

Availability

Clonidine TTS (Catapres TTS, generic) is available in three strengths: 0.1 mg/day for 1 week (clonidine TTS-1), 0.2 mg/day for 1 week (clonidine TTS-2), and 0.3 mg/day for 1 week (clonidine TTS-3).[1] Each strength is supplied in cartons containing 4 packets (1 patch/packet) and 4 adhesive covers. Generic patches are also available as single packets (1 patch).

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of clonidine transdermal therapeutic system. 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
Catapres-TTS® (clonidine transdermal system [patch], generic)	0.1 mg/day patch	4 patches	12 patches
	0.2 mg/day patch	4 patches	12 patches
	0.3 mg/day patch	4 patches	12 patches

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Clonidine 0.1 mg/day patch (Catapres TTS-1, generic)
No overrides recommended

Clonidine 0.2 mg/day patch (Catapres TTS-2, generic)

1. If the patient requires two of the clonidine 0.2 mg/day patches be applied simultaneously, approve 8 patches per 28 days at retail or 24 patches per 84 days at home delivery.
Note: Overrides are not recommended for patients changing the patch more frequently than every 7 days.

Clonidine 0.3 mg/day patch (Catapres TTS-3, generic)

1. If the patient requires two of the clonidine 0.3 mg/day patches be applied simultaneously, approve 8 patches per 28 days at retail or 24 patches per 84 days at home delivery.
Note: Overrides are not recommended for patients changing the patch more frequently than every 7 days.

REFERENCES

1. Catapres-TTS® transdermal therapeutic system [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; February 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	06/08/2023
Annual Revision	No criteria changes.	06/19/2024
Annual Revision	No criteria changes.	06/02/2025