STEP THERAPY POLICY

POLICY: Calcium Channel Blockers – Verapamil Products Step Therapy Policy
- Verelan® PM (verapamil extended-release PM capsules, controlled onset – Kremers/Lannett, generic)
- verapamil immediate-release tablets (generic only)
- verapamil extended-release tablets (generic only)
- verapamil extended-release capsules (generic only)
- verapamil sustained-release capsules (generic only)

REVIEW DATE: 06/18/2025

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

All of the available verapamil formulations are indicated for the treatment of **hypertension**.[1,2] Verapamil immediate-release is also indicated for the treatment of angina and specific cardiac arrhythmias.[1] Verapamil has also been used for off-label conditions, such as adjunctive treatment of hypertrophic cardiomyopathy and prophylaxis of migraine and cluster headaches.

Verelan PM is an extended-release controlled onset (COER) formulations designed to release verapamil 4 to 5 hours after ingestion and should be administered once daily at bedtime.[2] COER formulations result in a maximum plasma concentration of

verapamil in the morning hours, approximately 11 hours after ingestion. It has been hypothesized that the COER verapamil formulations may be more safe and effective in patients with hypertension than other verapamil formulations because their concentrations during a 24-hour period are synchronized with biological rhythm (chronotherapy).[4-6] In theory, these formulations may have an advantage over other sustained-/extended-release verapamil formulations as they would attenuate the increase in blood pressure, heart rate, cardiac ischemia, and catecholamines that naturally occur upon awakening and they would not cause hypotension during sleep. However, the role of verapamil as it relates to chronotherapy in the primary prevention of cardiovascular (CV) morbidity and mortality (e.g., myocardial infarction [MI], stroke) has not been demonstrated in controlled, comparative clinical trials.[6,7] The Controlled ONset Verapamil InvestigatioN of Cardiovascular Endpoints (CONVINCE) trial, which was terminated two years early for commercial reasons, was conducted in part to determine if there is a difference in the incidence of fatal or nonfatal MI, fatal or nonfatal stroke, or CV-related death between extended-release controlled onset verapamil ± hydrochlorothiazide (HCTZ), HCTZ alone, atenolol alone, or HCTZ in combination with atenolol.[8] The trial results did not provide evidence to support the concept of chronotherapeutics. Also, one small study comparing the effects of COER verapamil on the diurnal pattern of forearm vascular resistance in hypertensive and normotensive patients noted that COER verapamil minimized the diurnal pattern in forearm vascular resistance, but it did not hinder the early morning rate of blood pressure rise, despite being at peak concentration.[9]

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: generic verapamil extended-release capsules, generic verapamil extended-release tablets, generic verapamil immediate-release tablets, generic verapamil sustained-release capsules

Step 2: Verelan PM (brand and generic)

Calcium Channel Blockers – Verapamil Products Step Therapy Policy
product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. Verapamil tablet [prescribing information]. Congers, NY: Chartwell; August 2023.
2. Verelan® PM extended-release capsules controlled-onset [prescribing information]. Philadelphia, PA, and Gainesville, GA: Lannett/Recro/Alkermes; October 2019.
3. Anwar YA, White WB. Chronotherapeutics for cardiovascular disease. *Drugs*. 1998;55:631-643.
4. Smolensky MH, Portaluppi F. Chronopharmacology and chronotherapy of cardiovascular medications: relevance to prevention and treatment of coronary heart disease. *Am Heart J*. 1999;137:S14-S24.
5. Carter BL. Optimizing delivery systems to tailor pharmacotherapy to cardiovascular circadian events. *Am J Health-Syst Pharm*. 1998;55(Suppl 3):17-23.
6. Conlin PR, Williams GH. Use of calcium channel blockers in hypertension. *Adv Intern Med*. 1998;43:533-562.
7. Black HR, Elliott WJ, Neaton JD, et al. Rationale and design for the Controlled Onset Verapamil Investigation of Cardiovascular Endpoints (CONVINCE) trial. *Control Clin Trials*. 1998;19(4):370-390.
8. Black HR, Elliott WJ, Grandits G, et al. Principal results of the Controlled Onset Verapamil Investigation of Cardiovascular Endpoints (CONVINCE) trial. *JAMA.* 2003;289(16):2073-82.
9. Nguyen BN, Parker RB, Noujedehi M, Sullivan JM, Johnson JA. Effects of COER-verapamil on circadian pattern of forearm vascular resistance and blood pressure. *J Clin Pharmacol*. 2000;40(12 Pt 2):1480-1487.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/28/2023
Annual Revision	**Calan (brand name product):** Removed from Step 2 as it is no longer available.	06/26/2024
Selected Revision	**Generic verapamil extended-release tablets and generic verapamil sustained-release capsules:** Added to Step 1. **Generic verapamil sustained-release tablets:** This agent was removed from the policy (obsolete); previously it was in Step 1. **Generic verapamil extended-release PM capsules:** Moved from Step 1 to Step 2.	02/26/2025
Annual Revision	**Calan SR (brand name product)** and **Verelan (brand name product):** Removed from Step 2 of the policy as they are no longer available.	06/18/2025