Commercial/Healthcare Exchange PA Criteria

Effective: 6/9/2021

Prior Authorization: CONJUPRI™ (Levamlodipine)

Products Affected: CONJUPRI™ (Levamlodipine) tablets, for oral use.

Medication Description:
Amlodipine is a dihydropyridine calcium antagonist (calcium ion antagonist or slow-channel blocker) that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Experimental data suggest that amlodipine binds to both dihydropyridine and nondihydropyridine binding sites. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Negative inotropic effects can be detected *in vitro* but such effects have not been seen in intact animals at therapeutic doses. Serum calcium concentration is not affected by amlodipine. Within the physiologic pH range, amlodipine is an ionized compound (pKa=8.6), and its kinetic interaction with the calcium channel receptor is characterized by a gradual rate of association and dissociation with the receptor binding site, resulting in a gradual onset of effect.
Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

Amlodipine is a 1:1 racemic mixture of Levamlodipine and dextro amlodipine, it has been demonstrated that Levamlodipine is the pharmacologically active, anti-hypertensive isomer.

Covered Uses: Hypertension

Exclusion Criteria:
Levamlodipine is contraindicated in patients with known sensitivity to amlodipine.

Required Medical Information:
1. Diagnosis
2. Medications tried and failed

Age Restrictions: 6 years of age or older.

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

I. Initial Approval Criteria
(must meet all):

1. Patient has diagnosis of hypertension; AND
2. Patient is 6 years of age or older; AND
3. The medication will be used alone or in combination with other antihypertensive agents; AND
4. A patient-specific, clinically significant reason why the member cannot use amlodipine oral tablets (or another generic calcium channel blocker), is provided; AND
5. The dose does not exceed 5 mg orally once daily for adults and 2.5 mg once daily for pediatrics.

II. Continued Therapy
1. Member is responding positively to therapy; AND
2. Member has not experienced unacceptable toxicity from the drug (e.g. hypotension, increased angina or myocardial. etc)

References:
1.CONJUPRI™ (levamlodipine) tablets [Package Insert]. Hot Springs, AR, Burke Therapeutics, LLC. Updated October 14, 2020. Accessed April 29, 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d1c7a0f2-9b6c-44a2-9e8c-70c3ce8a2aa8

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New policy	New policy	All	6/9/2021