

**Blue Cross and Blue Shield of Vermont and The Vermont Health Plan
Prior Approval Guidelines
Exforge® (amlodipine and valsartan)**

Description: Exforge® is a fixed combination of amlodipine, a dihydropyridine calcium channel blocker (CCB) and valsartan, (an angiotensin₁ receptor blocker (ARB).)

Indications: Exforge ® is indicated for treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. It is indicated when hypertension is not adequately controlled with thiazide diuretics, ACE Inhibitors, B-blockers, amlodipine (or another DHP CCB) alone or with valsartan (or another ARB) alone or in combination.

**Warnings/
Precautions:** When used in pregnancy, drugs acting directly on the renin-angiotensin system can cause injury and even death to the developing fetus. Female patients of childbearing age should be told of the consequences of exposure to drugs acting on the renin-angiotensin system. When pregnancy is detected, Exforge® should be discontinued as soon as possible.

Dose adjustment in elderly patients and those with hepatic insufficiency may be required.

Reasons for Prior Authorization: Cost Potential for misuse Toxicity

Criteria for Approval:

- 1) Diagnosis is an FDA-Labeled Indication **and**
- 2) Patient has no contraindications to treatment **and**
- 3) Patient has had a 30 day trial of thiazide diuretics, plus either ACEI or, ARB or, B-Blocker, or CCB, or combination.

Reasons for Denial of Benefit:

- 1) Patient has hypersensitivity to Exforge ® or any of its components.
- 2) Patient does not meet above criteria

Benefit Approval Approval for one year.

References:

- 1) Package Insert, Exforge ® Novartis Pharmaceuticals, East Hanover, New Jersey 07936.
- 2) The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Aram, et al. JAMA. 2003;289:2560.

