MDWISE PRIOR AUTHORIZATION CRITERIA

NIFEDIPINE EXTENDED-RELEASE Tablet: 30mg, 60mg, 90mg
FORMULARY STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

Vasospastic Angina, Chronic Stable Angina, or Hypertension:
- Diagnosis of vasospastic angina, chronic stable angina, or hypertension.
- Documented trial and failure or intolerance with therapeutic doses with at least three preferred alternatives.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, then based on professional judgment, the Pharmacist reviewer will issue a denial for the medication requested.

Hypertension in Pregnancy:
- Diagnosis of hypertension.
- Patient is pregnant.

If the above conditions are met, the request will be approved with a 9 month duration; if the above conditions are not met, then based on professional judgment, the Pharmacist reviewer will issue a denial for the medication requested.

FDA INDICATIONS

- Extended-release nifedipine is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation, 2) angina or coronary artery spasm provoked by ergonovine, or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. Extended-release nifedipine may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

- Extended-release nifedipine, such as Procardia XL is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents. In chronic stable angina (effort-associated angina) nifedipine has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in these patients is incomplete. Controlled studies in small numbers of patients suggest concomitant use of nifedipine and beta-blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs.

- Extended-release nifedipine, such as Procardia XL is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

DOSAGE AND ADMINISTRATION

Dosage must be adjusted according to each patient’s needs. Therapy for either hypertension or angina should be initiated with 30 or 60 mg once daily. Extended-release nifedipine should be swallowed whole and should not be bitten or divided. In general, titration should proceed over a 7-14 day period so that the physician can fully assess the response to each dose level and monitor blood pressure before proceeding to higher doses. Since steady-state plasma levels are achieved on the second day of dosing, if symptoms so warrant, titration may proceed more rapidly provided the patient is assessed frequently. Titrations to doses above 120mg are not recommended. Angina patients controlled on immediate-release capsules alone or in combination with other antianginal medications may be safely switched to extended-release nifedipine at the nearest equivalent total daily dose (e.g., 30mg t.i.d. of Procardia capsules may be changed to 90 mg once daily of Procardia XL Extended Release Tablets). Subsequent titration to higher or lower doses may be necessary and should be initiated as clinically warranted. Experience with doses greater than 90mg in patients with angina is limited. Therefore, doses greater than 90mg should be used with caution and only when clinically warranted. No “rebound effect” has been observed upon discontinuation of extended-release
nifedipine. However, if discontinuation of nifedipine is necessary, sound clinical practice suggests that the dosage should be decreased gradually with close physician supervision. Care should be taken when dispensing nifedipine products such as Procardia XL to assure that the extended release dosage form has been prescribed.

REFERENCES

Revision/Review Date: MAC 10/12/2011
Associated Policy: Prior Authorization of Medications 236.200