Criteria Checklist for Cilostazol (Pletal®)

VHA Pharmacy Benefits Management Services and the Medical Advisory Panel

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient situation.

EXCLUSION CRITERIA ***(If one is selected, patient is NOT eligible)***

Patient with one of the following conditions:

- ❑ Congestive heart failure
- ❑ Diagnosis of neurogenic claudication
- ❑ Active bleeding disorder (i.e.; peptic ulcer)
- ❑ Hypersensitivity to cilostazol
- ❑ Severe liver failure (enzymes 3 times upper limit)

INCLUSION CRITERIA ***(Both must be selected for patient to be eligible)***

- ❑ Patient with moderate to severe intermittent claudication
- ❑ Patient is not a candidate for surgical or catheter based interventions

NON-PHARMACOLOGIC MANAGEMENT ***(It is strongly recommended that patient be evaluated and an attempt made at risk factor reduction prior to cilostazol initiation)***

- ❑ Exercise therapy program www.prevention.va.gov/January_2008.asp
- ❑ Smoking cessation program as outlined in the VA/DoD Clinical Practice Guidelines at www.oqp.med.va.gov/cpg/TUC3/TUC_Base.htm
- ❑ Weight management http://www.move.va.gov/
- ❑ Control of diabetes, blood pressure, lipids as outlined in the VA/DoD Clinical Practice Guidelines at www.oqp.med.va.gov/cpg/cpg.htm

DOSING GUIDELINES

- Patient receiving therapy with an inhibitor of the CYP3A4 system (i.e.; erythromycin, ketoconazole, diltiazem, itraconazole). Cilostazol dose is 50 mg orally, twice daily
- Patient receiving therapy with an inhibitor of the CYP2C19 system (i.e.; omeprazole) Cilostazol dose is 50 mg orally, twice daily
- Patient on no interacting drug therapy. Cilostazol dose is 100 mg orally, twice daily.
- Cilostazol dose should be taken 30 minutes before or 2 hours after a meal

MONITORING ***(Therapy should be discontinued if no improvement noted)***

- ❑ Patient should be reevaluated at 6 months to document any symptomatic improvement

SPECIAL CONSIDERATIONS

Patients with a creatinine clearance <25 ml/min: Severe renal impairment increases metabolite levels and alters protein binding of cilostazol. However, the estimated pharmacological activity appears to be similar to that of patients with normal renal function based on a pharmacokinetic study.[1] It is unlikely that hemodialysis would effectively remove cilostazol given its high protein binding, although no studies have been conducted. The manufacturer recommends caution with the use of cilostazol in patients with severe renal impairment.

[1]Mallikaarjun S et al. Clin Pharmacokinet. 1999;37 Suppl.2:33-40.

See Cilostazol Drug Monograph for more information at: http://www.pbm.va.gov/monograph/76et16cilostazol.pdf

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