Criteria for Non-Formulary Use of Tamsulosin in VA Patients with Benign Prostatic Hyperplasia

Of the available alpha-adrenergic antagonists, prazosin and terazosin are listed on the VA National Formulary. If clinically necessary, doxazosin may be obtained by non-formulary request. Tamsulosin is a selective $alpha_{1A}$ adrenergic antagonist that has been shown to improve symptoms and urinary flow rate in patients with benign prostatic hyperplasia (BPH). There is no evidence that tamsulosin provides any benefit in patients who have not responded to an adequate trial with prazosin, terazosin, or doxazosin.[a] Tamsulosin is not listed on the VA National Formulary but may be considered for use in patients with BPH under selected circumstances (see below). These criteria are not intended to dictate therapy in all instances, but are developed to promote appropriate use of tamsulosin in veteran patients based on available medical evidence.

Tamsulosin may be used when an alpha-blocker is considered necessary for treatment of BPH (refer to VHA Clinical Practice Guideline to Promote The Management of Benign Prostatic Hyperplasia in Primary Care @ http://vaww.webdev.med.va.gov/quality/) AND when a patient has or develops:

- Significant symptomatic hypotension[b] while receiving treatment with prazosin or terazosin[c]
- Significant orthostatic hypotension[d] or postural symptoms while receiving treatment with prazosin or terazosin,[c] or at baseline
- Syncope or near syncope symptoms after initiation of prazosin, terazosin, or doxazosin[c] (not related to inappropriate initiation of therapy)
- Significant adverse drug event (ADE),[c] as documented in the medical record while on prazosin, terazosin, or doxazosin (a lower dose may be considered to minimize ADEs; reevaluate efficacy on the lower dose;[a] consider trial of another formulary alpha-blocker). Most common ADEs include dizziness (10-20%), headache (7.8-16.2%), asthenia (1-12%). Postural hypotension has been reported in 0.3-1.3% patients. If selected, tamsulosin should be used with caution in these patients since these are also potential side effects with tamsulosin.

In addition, use of tamsulosin may be applicable in patients with BPH and hypertension (HTN) in the following situations:

- Monotherapy with doxazosin (or possibly prazosin or terazosin): The ALLHAT hypertension study recently found increased cardiac complications in patients treated with doxazosin compared to those treated with chlorthalidone[1] (refer to *Statement on the Use of α-Adrenergic Blockers in the Management of Patients with Hypertension* at www.vapbm.org or http://vaww.pbm.med.va.gov). For patients with concomitant BPH and HTN, the drug regimen should be reviewed for consideration of addition of another antihypertensive agent. If the patient develops symptomatic hypotension after addition of another antihypertensive agent and symptoms persist on the lowest effective dose of the alpha-antagonist for obstructive urinary symptoms, then tamsulosin may be considered.[c,e]
- Normotensive on current antihypertensive therapy (not including an alpha-antagonist): Adjust antihypertensive therapy upon initiation of prazosin or terazosin. If the patient develops symptomatic hypotension after adjustment of antihypertensive therapy, tamsulosin may be considered to replace the current alpha-antagonist therapy.[c,e]

Recommendations for Monitoring: The most frequently reported side effects with tamsulosin 0.4mg include headache (19.3%), dizziness (14.9%), rhinitis (13.1%), infection (9%), and abnormal ejaculation (8.4%). Symptomatic postural hypotension and syncope were both reported in 0.2% patients receiving tamsulosin 0.4mg. Patients should be instructed to avoid situations where injury may result if syncope occurs upon initiation of therapy with tamsulosin.

Dosing Recommendations: Tamsulosin is available as a 0.4mg capsule. The initial dose is 0.4mg once daily administered 30 minutes after the same meal each day. The capsule should not be opened, chewed, or crushed. Two to four weeks may be necessary before patient response can be assessed. An increase in dose has not been found to be consistently more effective, however manufacturer information states the dose may be increased to 0.8mg once daily. If the dose is increased, the patient should be reassessed and the dose decreased or discontinued if inadequate response since higher doses are associated with increased side effects.

[a] Recommended doses for BPH are prazosin 2mg bid, terazosin 5 to 10mg qd, doxazosin 4 to 8mg qd (although lower doses have been effective)

[b] For patients with significant baseline hypotension (not receiving antihypertensive medication), use of alpha-antagonists should be at the clinician's discretion

[c] Complete ADE report and forward to VISN and National PBM

[d] Defined as a ↓ SBP ≥ 20 mm Hg upon standing from the supine position; ↓ DBP ≥ 10 mm Hg upon standing with DBP < 65 mm Hg; ↑ pulse of ≥ 20 bpm upon standing with a standing pulse ≥ 100 bpm

[e] The change in blood pressure with terazosin has been found to be clinically insignificant in BPH patients who are either normotensive or have HTN that is well-controlled with pharmacologic agents[2]

References:

[1] The ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group. Major cardiovascular events in hypertensive patients randomized to doxazosin vs chlorthalidone: the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). JAMA 2000;283:1967-75.

[2] Lowe FC, Olson PJ, Padley RJ. Effects of terazosin therapy on blood pressure in men with benign prostatic hyperplasia concurrently treated with other antihypertensive medications. Urology 1999;54:81-5.