MEDICA MEDICAID PRIOR AUTHORIZATION POLICY

POLICY: Cialis® (tadalafil tablets – Eli Lilly)

OVERVIEW

Cialis, a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5), is indicated for the treatment of erectile dysfunction (ED), the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH), and for the treatment of ED and the signs and symptoms of BPH (ED/BPH).[1] If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks. This is because the incremental benefit of Cialis decreases from 4 weeks to 26 weeks, and the benefit beyond 26 weeks is unknown.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Cialis. All approvals are provided for the duration noted below.

Note: PDE5 inhibitors should not be administered, either regularly or intermittently, with concomitant nitrate therapy. Patients will be informed of the consequences should they initiate nitrate therapy while taking a PDE5 inhibitor.

Benefit information: Drugs used for the treatment of erectile dysfunction, regardless of the cause, are excluded under the Minnesota Medicaid plan. Cialis when used for erectile dysfunction is not eligible for coverage.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cialis is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Benign Prostatic Hyperplasia (BPH).** Approve 2.5 mg or 5 mg tablets ONLY for **up to maximum of #30/30 day supply for** 1 year if the patient meets ONE of the following criteria (A or B):
   - **A)** Patient has tried an α_1-blocker (e.g., Cardura® XL [doxazosin extended-release tablets], terazosin tablets/capsules, tamsulosin capsules, alfuzosin extended-release tablets); OR
   - **B)** Patient has tried a 5α-reductase inhibitor (e.g., finasteride, dutasteride).

   Cialis 2.5mg and 5mg strength tablets are indicated for the treatment of the signs and symptoms of BPH.[1]

Other Uses with Supportive Evidence

2. **Raynaud's Phenomenon.** Approve for 1 year up to maximum of #30/30 day supply if the patient meets ONE of the following criteria (A or B):

A) Patient has tried at least TWO of the following therapies: calcium channel blockers (e.g., amlodipine, felodipine, nifedipine), α-adrenergic blockers (e.g., prazosin), nitroglycerin, losartan, fluoxetine, or angiotensin converting enzyme (ACE) inhibitors; OR

B) Patient has tried one vasodilator (e.g., Flolan® [epoprostenol for injection], Edex® [alprostadil for injection], Tracleer® [bosentan tablets]).

Limited information is available with the use of Cialis in Raynaud disease.[6-8]

A small prospective, randomized, double-blind, placebo-controlled, crossover study evaluated Cialis at a dose of 20 mg QD for 4 weeks compared with placebo in women with Raynaud disease secondary to systemic scleroderma.[8] A total of 45 women enrolled in the trial, and 39 women completed the study. Treatment with Cialis showed no statistically significant difference in RCS, Raynaud frequency, or Raynaud duration compared with placebo.

A double-blind, placebo-controlled, fixed-dose, crossover study evaluated the efficacy of Cialis in patients with scleroderma or mixed connective tissue disease (MCTD).[9] Patients experienced ≥ four Raynaud's attacks per week in the 2 weeks before study inclusion, despite treatment with vasodilators for ≥ 3 months. Patients were randomized to receive either Cialis 20 mg or matching placebo every other day for 6 weeks. All the patients were receiving calcium channel blockers; 18 patients were also on other vasodilators. A total of 24 patients completed the study. Cialis significantly improved the mean daily frequency and mean daily duration of Raynaud's phenomenon as compared with placebo and baseline, respectively. About 67% of the patients had > 25% improvement in the mean daily duration of Raynaud's phenomenon while receiving Cialis as compared with 25% of the patients who had > 25% improvement during placebo therapy. Cialis healed existing digital lesions and prevented development of new digital lesions. It also improved quality of life measures in patients with resistant secondary Raynaud's phenomenon.

A consensus document published by the systemic sclerosis experts notes that for secondary Raynaud's phenomenon (i.e., due to systemic sclerosis) calcium channel blockers were the recommended first-line treatment in patients with mild (about 5 attacks/week) or more severe (about 25 attacks/week) attacks.[10] Consensus was not obtained for further treatment; however 35% of the surveyed experts' recommended PDE5 inhibitors as second-line treatment for mild attacks and 45% of experts would recommend Cialis for more severe attacks. A meta-analysis of six trials assessing the efficacy of PDE5 inhibitors in secondary Raynaud's phenomenon showed moderate clinical benefit on Raynaud's Condition Score (RCS), frequency, and duration of attacks.[11] PDE5 inhibitors reduced the frequency of attacks by ~0.5/day compared with placebo, which is comparable reduction to calcium channel blockers (~0.6/day).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Cialis has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.
2. Coverage for Erectile Dysfunction (ED) is not allowed for members in Minnesota Medicaid plans because coverage of drugs for the treatment of erectile dysfunction is excluded from the benefit.
3. Prophylaxis After Radical Prostatectomy is only allowed for Commercial plans which allow for erectile dysfunction coverage. Minnesota Medicaid plans excludes coverage of Cialis for erectile or sexual dysfunction so coverage is not allowed for this indication.

REFERENCES

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