

**Regence BlueCross BlueShield of Oregon • Regence BlueShield
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Medication Policy Manual

Policy No: dru099

Topic: Cialis[®], tadalafil 2.5 mg, 5 mg, 10 mg,
and 20 mg

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Next Review Date: July 2010

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Administration of Contract

Cialis[®] (tadalafil) for impotence is generally a benefit not covered by member contracts regardless of medical necessity.

If Cialis (tadalafil) for impotence is a covered benefit, contract language will be applied to determine coverage (see Appendix I). Generally, contract language specifies one of the following types of coverage to determine when this medication policy is applicable.

Coverage Type	Maximum Quantity Already defined by Contract Language	Coverage is based on Medical Necessity	Medication Policy Applies
1.	Yes	No	No
2.	Yes	Yes	Yes
3.*	No	Yes	Yes

* This applies, but is not limited to benefit plans where contracts are silent on coverage of impotence treatments and/or impotence medications.

Description

Cialis (tadalafil) is a medication used for erectile dysfunction. Tadalafil is the same active ingredient in Adcirca™, which is used to improve exercise capacity in pulmonary arterial hypertension.

Policy/Criteria

I. Most contracts require prior authorization approval of Cialis (tadalafil) for coverage. Cialis (tadalafil) may be considered medically necessary for erectile dysfunction in men when the following criteria A and B below are met:

A. There is documented diagnosis of organic impotence (ICD-9 - 607.84).

AND

B. There is clinical documentation that includes an evaluation of reversible causes of impotence.

II. Administration, Quantity Limitations, and Authorization Period

A. Regence considers Cialis (tadalafil) to be a self-administered medication.

B. When prior authorization is approved, Cialis (tadalafil) may be authorized in quantities of up to six tablets per month (or the maximum quantity specified in the contract).

C. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

- III.** Cialis (tadalafil) is considered not medically necessary when used for the following conditions:
- A.** Psychogenic impotence.
 - B.** Impotence resulting from medication use.
 - C.** Lower urinary tract symptoms (LUTS) resulting from benign prostatic hypertrophy.
- IV.** Cialis (tadalafil) is considered investigational when used for all other conditions, including, but not limited to:
- A.** Achalasia.
 - B.** Enhancing exercise performance.
 - C.** Female arousal disorders.
 - D.** Heart failure.
 - E.** Males with a functioning penile prosthesis or post removal of a prosthesis.
 - F.** Patients on nitrates.
 - G.** Preservation of penile function after radical prostatectomy.
 - H.** Raynaud's phenomenon.

Position Statement

Summary

- The PDE-5 inhibitors [Viagra (sildenafil), Cialis[®] (tadalafil), and Levitra[®] (vardenafil)] are used to treat erectile dysfunction (ED).^[28, 34, 35]
- There is no reliable evidence of any difference in efficacy among the PDE-5 inhibitors in improving the quality or duration of erection in men with erectile dysfunction due to organic, psychogenic, or mixed causes, including diabetes mellitus.^[1-4, 20-33, 52]
- Viagra (sildenafil) has gained the most clinical data to support efficacy in many different patient subgroups, such as erectile dysfunction associated with angina, parkinsonism, spina bifida, spinal cord injury, ischemic heart disease, multiple sclerosis, kidney transplant recipients or chronic dialysis.^[24-26, 39, 53] Tadalafil^[57, 60-61] and vardenafil^[29, 31, 40] are also being studied in different subpopulations.
- Sildenafil, available as Revatio[®], and tadalafil, available as Adcirca[™], are also FDA-approved for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability.^[38]
- Daily dosing of PDE-5 inhibitors has not been shown to be superior to as needed dosing in the treatment of erectile dysfunction.

Several studies demonstrate the efficacy of PDE-5 inhibitors in drug-induced (antidepressant and antipsychotic) erectile dysfunction.^[43, 44] This use is considered not medically necessary as treatment of the underlying cause of erectile dysfunction is the first-line of treatment (reversible cause).

- PDE-5 inhibitors are considered investigational when used for conditions for which there is poor to no available evidence of efficacy.

Clinical Efficacy

ERECTILE DYSFUNCTION (ED)

- Efficacy of PDE-5 inhibitors was based on ability to achieve and maintain erection sufficient for sexual activity.^[28, 34-35]
- Assessments were made by patients from 4 weeks to 3 months.^[28, 34-35]
- Overall, success rates with PDE-5 inhibitors were better than those achieved with placebo.^[28, 34-35]
- Better results were generally achieved in patients with less impairment at baseline.^[28]

PULMONARY ARTERIAL HYPERTENSION (PAH)

- Pharmacologic treatment of PAH includes oral anticoagulants, diuretics, oxygen, inotropic agents (digoxin and dobutamine), calcium channel blockers, prostacyclin and prostacyclin analogs (epoprostenol, treprostinil, and iloprost), endothelin-receptor antagonists (ETAs) (ambrisentan, bosentan), and type 5 phosphodiesterase inhibitors (sildenafil, tadalafil).
- In early disease or with less severe symptoms, oral therapies may be used. As symptoms progress, injectable therapies, such as epoprostenol and treprostinil, become necessary.
- Revatio (sildenafil) 20 mg, and Adcirca (tadalafil) 40 mg are used for the treatment pulmonary arterial hypertension (PAH) to improve exercise ability. ^[38]
 - * Both were found to improve performance on the 6-minute walk test relative to placebo. The six-minute walk test is a measure of exercise tolerance and measures the distance that is covered in a 6-minute timeframe. Improvements in this test have been correlated to improved survival in PAH patients.
 - * There are currently no well-done trials that compare these medications to other PAH therapies, such as bosentan (Tracleer), ambrisentan (Letairis) or inhaled iloprost (Ventavis).
- There are several studies that evaluate Viagra (sildenafil) in doses ranging from 25-100 mg three times daily in adults and children with PAH; however, results from these studies are of uncertain clinical relevance or are not useful in demonstrating gains in functional improvement. ^[13-14, 36]
- There are no trials with sildenafil in patients with PAH that are adequately designed or of sufficient duration to determine the long-term safety or survival benefit with treatment.
- There are no trials with Revatio (sildenafil) 20 mg or Adcirca (tadalafil) 40mg that establish the safety and efficacy of these doses in the treatment of erectile dysfunction.

OTHER CONDITIONS

- PDE-5 inhibitors are considered investigational when used in conditions for which there is poor or no available evidence of efficacy:
 - * There is no reliable evidence to support the efficacy of PDE-5 inhibitors in the treatment of achalasia or female arousal disorders.

- * Studies in men with benign prostatic hyperplasia (BPH) treated with tadalafil^[58, 70], vardenafil^[66] or sildenafil^[59] reported statistical improvement in lower urinary tract symptoms (LUTS) based on placebo-corrected changes in the International Prostate Symptom Score (I-PSS). The clinical relevance of a 2- to 4-point change (out of a possible 35 points) in the I-PSS is not known. It is also not known how these drugs compare with alpha₁-blockers (e.g., doxazosin, prazosin) in the treatment of LUTS.
- * Although one small study in healthy adults suggests potential efficacy of sildenafil to enhance exercise performance in otherwise healthy individuals at low or high altitude, this use is considered not medically necessary.^[37]
- * In a small trial in 46 patients, sildenafil was studied in the management of heart failure.^[62] Potential benefit was based on cardiopulmonary exercise testing parameters (intermediate endpoints) and not clinical outcomes. Additional trials are needed to establish benefit in this setting.
- * PDE-5 inhibitors have been used in a small number of patients with Raynaud's phenomenon to improve peripheral blood flow. Evidence is preliminary. Larger, well-controlled trials are necessary to establish the efficacy and safety of these medications in this disease.^[41, 42]
 - - One small study evaluated 18 patients with Raynaud's phenomenon that was resistant to conventional vasodilatory treatment.^[42] Frequency and duration of attacks was significantly lower in the sildenafil treatment group. There was also improvement in digital ulcerations in several of the patients. Larger, well-controlled trials are needed to establish the safety and effectiveness of sildenafil in the treatment of Raynaud's.
- * In a small (n = 42) exploratory study, vardenafil was not found to improve symptoms of tinnitus when compared with placebo.^[67]
- Several studies support the efficacy of PDE-5 inhibitors in men with erectile dysfunction after undergoing bilateral nerve sparing radical retropubic prostatectomy.^[45-49, 50, 51, 56, 63-64] Although some patients were able to achieve an erection with these agents, there is no reliable evidence that these agents preserve penile erectile function after prostate resection.
 - * Evidence was not reliable due to flaws that included: retrospective design; lack of randomization, control groups, blinding, and/or intent-to-treat analysis; small numbers of patients, and short duration of study.
 - * In a study that compared continuous vardenafil with "on-demand" vardenafil, no difference was demonstrated between the two regimens in the proportion of subjects that achieved an erectile function (IIEF-EF) score of at least 22 after 9 months. The quality of evidence is unreliable because not all randomized patients were evaluated for efficacy and more than 30% of subjects did not complete the study.^[69]

Safety

- All PDE-5 products carry similar product safety labeling that includes the contraindication for use in patients on nitrates and warnings about their use in patients on nitrates and alpha-adrenergic inhibitors. ^[28, 34-35, 38]
 - * Patients on nitrates were excluded from the clinical trials because of an interaction with Viagra (sildenafil) that results in hypotension.
- Headache, dyspepsia and back pain are the predominant adverse effects reported among all PDE-5 inhibitors. ^[28, 34-35, 38]

Dosing and administration

- Both Viagra (sildenafil) and vardenafil doses need to be given 0.4-4 hours and 1 hour, respectively, prior to sexual intercourse to be effective. ^[28, 34]
- Tadalafil has a longer half-life and in clinical trials has shown to improve erectile dysfunction compared to placebo up to 36 hours following dosing, allowing a longer window (36 hours) opportunity or "full day" coverage for intercourse to occur. ^[1-4]

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Cross References
Treatment of pulmonary hypertension with prostacyclin analogues, endothelin receptor antagonists, or phosphodiesterase inhibitors, BlueCross BlueShield Association Medical Policy, 5.01.09, Issue 4.2009.
Adcirca™, tadalafil dru184
Levitra® , vardenafil dru099
Revatio® , sildenafil 20mg dru117
Viagra® , sildenafil dru024

Codes	Number	Description
N/A		

Appendix 1

Impotence Medications - Administration of Contract Language and Medication Policy

