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PHARMACY POLICY – 5.01.545

Tadalafil Products for Benign Prostatic Hyperplasia

Effective Date:	June 1, 2023	RELATED MEDICAL POLICIES:	
Last Revised:	May 22, 2023	5.01.522	Advanced Therapies for Pharmacological Treatment of Pulmonary Arterial Hypertension
Replaces:	N/A		

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Introduction

Benign prostatic hyperplasia (BPH) is the medical term for an enlarged prostate. BPH is a noncancerous condition caused by prostate cells that keep multiplying. Over time, the excess prostate tissue puts pressure on the tube that carries urine and semen out of the body. As more pressure is applied, urinary difficulties often develop. These can include a weak or slow stream, a sense that the bladder isn't completely empty, and/or needing to urinate frequently and urgently. Cialis® (tadalafil) was originally developed to treat erectile dysfunction (difficulty in achieving and keeping an erection). However, it was discovered that Cialis also addresses symptoms of BPH. This policy describes when Cialis and a combination product with tadalafil called Entadfi™ may be approved for BPH. Using Cialis for erectile dysfunction is not covered.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Documentation in the form of chart notes/medical records must be provided with prior authorization review for the agents described below.

Indication	Medical Necessity
Treatment for symptoms of benign prostatic hyperplasia (BPH)	**Cialis® (tadalafil) and generic tadalafil may be considered medically necessary as second line treatment for symptoms of benign prostatic hyperplasia (BPH) when ALL the following conditions are met:** • Individual has a diagnosis of benign prostatic hyperplasia (BPH) **AND** • Individual has tried a generic alpha blocker (terazosin, tamsulosin, doxazosin, or alfuzosin) first and had an inadequate response or intolerance to the alpha blocker **OR** • has tried generic finasteride, dutasteride, or silodosin first and had an inadequate response or intolerance to finasteride, dutasteride, or silodosin **AND** • Prescription is for either 2.5mg or 5mg taken once daily. **Note:** Cialis (tadalafil) and generic tadalafil are also available in 10mg and 20mg tablets for use as needed. These are indicated ONLY for treatment of erectile dysfunction, not BPH. **Entadfi™ (finasteride and tadalafil) may be considered medically necessary for the treatment of symptoms of benign prostatic hyperplasia (BPH) when ALL the following conditions are met:** • Individual has a diagnosis of benign prostatic hyperplasia (BPH) **AND** • Individual has tried generic finasteride 5 mg and generic tadalafil 5 mg separately **AND** • There is a documented specific rationale for why the individual is not able to continue to use generic finasteride 5 mg and generic tadalafil 5 mg separately **AND**

Indication	Medical Necessity
	• Prescription is limited to one capsule (containing finasteride 5 mg and tadalafil 5 mg) once daily **AND** • The duration of treatment is for ≤ 26 weeks

Indication	Contract Exclusion
Erectile dysfunction in individuals without BPH	**Use of Cialis® (tadalafil) and generic tadalafil for erectile dysfunction in individuals without BPH is considered a contract exclusion.**

Indication	Investigational
All other indications	**Use of Cialis® (tadalafil), generic tadalafil, and Entadfi™ (finasteride and tadalafil) for all other indications is considered investigational.** **Use of Entadfi™ (finasteride and tadalafil) for > 26 weeks treatment duration is considered investigational.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Cialis® (tadalafil) and generic tadalafil may be approved up to 12 months.** **Entadfi™ (finasteride and tadalafil) may be approved up to 26 weeks.**
Re-authorization criteria	**Future re-authorization of Cialis® (tadalafil) and generic tadalafil may be approved up to 12 months as long as the drug-specific coverage criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.** **Future re-authorization of Entadfi™ (finasteride and tadalafil) for > 26 weeks treatment duration is considered investigational.**

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the diagnosis, relevant history, physical evaluation, and medication history

Note: Tadalafil is available as Adcirca® in different strengths for the treatment of pulmonary arterial hypertension (PAH). For these individuals, refer to the pulmonary arterial hypertension guidelines contained in a separate medical policy (see **Related Policies**).

Coding

N/A

Related Information

Benefit Application

This policy applies to all lines of business. Language pertaining specifically to contractual exclusion of tadalafil is applicable only to benefits that exclude coverage for treatment of erectile dysfunction.

This policy is managed through the Pharmacy benefit.

Evidence Review

Description

Benign prostatic hyperplasia (BPH) is a condition characterized by epithelial and stromal cell proliferation (enlargement) of the prostate gland. BPH and BPH-related lower urinary tract symptoms (LUTS) are age-dependent, with BPH being one of the top 10 most commonly diagnosed conditions in men over 50 years of age. The estimated prevalence of LUTS secondary to BPH in Caucasian Americans between the ages of 50 and 79 in 2000 was 42%. In a European cross-sectional study of men >40 years of age attending urology clinics, the prevalence of LUTS secondary to BPH was 56% and erectile dysfunction was 40%. These conditions are also frequently comorbid in the same men. In BPH, as the prostate gland enlarges it may constrict the urethra and/or the bladder wall may thicken and become irritable resulting in lower urinary tract symptoms such as diminished urine stream, intermittency, straining, polyuria, nocturia, urinary urgency, and inability to empty the bladder.

The American Urological Association (AUA) recommends for the treatment of BPH: alpha adrenergic antagonists, 5-alpha reductase inhibitors, anticholinergics, and PDE5 inhibitors. However, the AUA does note the combination of low-dose daily 5mg tadalafil with alpha adrenergic antagonists for the treatment of LUTS/BPH as it offers no advantages in symptom improvement over either agent alone. The mechanism of action of alpha-adrenergic antagonists is blockade of alpha-1 receptors in the prostate, bladder, and urethra which relaxes smooth muscle in these tissues and improves urine flow and symptoms associated with BPH. It is important to note that drugs in this class do not reduce prostate size. 5-Alpha reductase inhibitors interfere with testosterone's stimulatory effect on prostate enlargement and therefore do reduce prostate size.

Cialis® (tadalafil)

The clinical efficacy of tadalafil 5 mg once daily for lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH) was primarily established in 3 similarly designed multinational, 12-week, randomized, double-blind, placebo-controlled trials. Two of these studies were conducted in men with LUTS suggestive of BPH (Porst, 2011 and Roehrborn, 2008) and one was specific to men with comorbid BPH and erectile dysfunction (Egerdie, 2011). The primary efficacy endpoint in all 3 trials was change from baseline in total International Prostate Symptom Score (IPSS). The IPSS assesses severity of the spectrum of symptoms associated with BPH. The comorbid ED study had a co-primary endpoint that was change from baseline in the erectile function domain score of International Index of Erectile Function (IIEF-EF). All 3 trials consistently showed a statistically and clinically significant improvement in these

surrogate outcomes after 12-weeks. While these studies were not specifically designed to evaluate the following endpoints, nocturia and objective urodynamic measures (peak urinary flow and postvoid residual volume) were consistently not improved.

A 1-year, open-label, safety extension of the registrational Roehrborn (2008) study suggests efficacy for LUTS secondary to BPH is maintained longer-term (Donatucci, 2011). Two other preliminary RCTs also consistently support the short-term (12-week) efficacy of tadalafil 5 mg once daily for LUTS secondary to BPH with or without comorbid ED.

Results from one unpublished, multinational, 12-week, randomized, double-blind, double dummy, placebo-controlled trial with a parallel tamsulosin 0.4 mg once daily arm were recently posted on **Clinicaltrials.gov** (NCT00970632). While this study was not designed to compare the two active drugs, tadalafil 5 mg once daily appeared to provide similar improvements to that of tamsulosin 0.4 mg in men with LUTS suggestive of BPH. As might be expected, tadalafil appeared superior to the alpha-blocker for treatment of comorbid erectile dysfunction.

One prospective, open-label, uncontrolled study was identified on literature search that examined the efficacy and safety of add-on tadalafil at the approved 5 mg daily dose combined with an alpha-blocker (tamsulosin 0.2 mg or alfuzosin 10 mg) for 12-weeks in 158 Korean men with concurrent LUTS-BPH and ED. Total IPSS and IIEF-5 were significantly ($p<0.001$) improved with combination therapy, but Qmax and PVR did not, compared to baseline low-dose alpha-blocker monotherapy.

The registrational RCTs show tadalafil 5 mg once daily to be well tolerated for the short-term treatment of LUTS suggestive of BPH with or without comorbid ED. Overall, adverse events were infrequent and the majority (>95%) were mild to moderate in severity. No unexpected adverse events occurred. No clinically significant changes in vitals or electrocardiogram were observed. Rates of myocardial infarction appeared similar to that of placebo in the same population, with the caveat that these trials were of short duration (12 weeks). In short-term (12-week) clinical trials, incidence of a positive orthostatic test was similar in tadalafil-treated and placebo-treated LUTS-BHP individuals, about 20%. No priapism was reported.

A long-term (1-year) safety extension in the target population found no new or greater frequency of any adverse events, serious adverse events, or discontinuation for adverse events compared to double-blind short-term (12-week) treatment (Donatucci, 2011).

Two open-label safety extension trials of tadalafil 5 mg once daily in men with ED also showed the drug to be well tolerated for up to 2 years. No unexpected adverse events were observed. No deaths or serious adverse events, cardiovascular or otherwise, were attributed to study drug.

No sudden hearing or vision losses (non-arteritic anterior ischemic optic neuropathy [NAION]) were reported in short- or long-term clinical trials for LUTS secondary to BPH.

In the unpublished, multinational, 12-week, randomized, double-blind, double dummy, placebo-controlled trial with the parallel tamsulosin 0.4 mg once daily arm (NCT00970632), incidence of adverse events, serious adverse events, and discontinuation for adverse events appeared similar between tadalafil 5 mg, tamsulosin 0.4 mg, and placebo once daily in men with LUTS-BPH with or without ED.

A prospective, multicenter, randomized, open-label, parallel-group study (Yoshida et al. 2017) compared the efficacy and safety of silodosin versus tadalafil in 192 individuals with LUTS-BPH. The primary efficacy endpoint was change in IPSS total symptom score before and after Period 1 treatment (Week 4). Both silodosin and tadalafil demonstrated statistically significant improvement from baseline (Week 0) IPSS total symptom score, with a mean ± SD change of -10.1 ±6.4 (P<0.0001) and -8.0±6.3 (<0.0001), respectively. The difference between silodosin and tadalafil was statistically significant (P=0.0277). In addition, silodosin demonstrated a significantly greater decrease in symptoms of incomplete emptying, weak stream, and nocturia than tadalafil (P=0.0254, P=0.0067, and P=0.0387). Adverse drug reactions occurred more frequently with silodosin (23.4%) than tadalafil (8.4%), but no serious adverse reactions were observed in both arms. Nervous system disorders (i.e., dizziness and headache) and gastrointestinal disorders (i.e., soft feces) were reported in both arms, but orthostatic hypotension (n=2), nasal congestion (n=4), ejaculation disorder (n=6), and retrograde ejaculation (n=5) were only reported in the silodosin arm.

Entadfi™ (finasteride and tadalafil)

The efficacy of Entadfi is based on an adequate and well-controlled study of tadalafil co-administered with finasteride. Tadalafil for once daily use initiated together with finasteride was shown to be effective in treating the signs and symptoms of BPH in men with an enlarged prostate (>30 cc) for up to 26 weeks. A double-blinded, parallel-design study of 26 weeks duration randomized 696 men to initiate either tadalafil 5 mg with finasteride 5 mg or placebo with finasteride 5 mg. The study population had a mean age of 64 years (range 46-86). Individuals with multiple co-morbid conditions such as erectile dysfunction, diabetes mellitus, hypertension, and other cardiovascular disease were included.

Tadalafil and finasteride administered together demonstrated statistically significant improvement in the signs and symptoms of BPH compared to placebo with finasteride, as measured by the total symptom score (IPSS) at 12 weeks, the primary study endpoint. Key

secondary endpoints demonstrated improvement in total IPSS starting at the first scheduled observation at week 4 (tadalafil -4.0, placebo -2.3: p<.001) and the score remained decreased through 26 weeks (tadalafil -5.5, placebo -4.5; p=.022). However, the magnitude of the treatment difference between placebo/finasteride and tadalafil/finasteride decreased from 1.7 points at Week 4 to 1.0 point at Week 26. Entadfi is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown.

2014 Update

Updated per literature search 7/1/13 to 10/31/14. No changes required.

2015 Update

Updated per literature search 11/1/14 to 9/15/15. There was no information which prompted a change in the policy statements. Rapaflo was added as a qualifier to coverage of Cialis along with Proscar and Avodart. Verbiage also updated to call them out separately from the generic alpha blockers.

2016 Update

A literature search was conducted between 04/01/15 and 12/06/16. No information was found which would prompt a change in the existing policy statements.

2017 Update

A literature search was conducted between 07/01/16 and 11/01/17. No information was found which would prompt a change in the existing policy statements.

2018 Update

A literature search was conducted between 11/01/17 and 10/31/18. No information was found which would prompt a change in the existing policy statements. Tadalafil was studied in a

placebo-controlled phase 3 RCT in individuals 7-14 years of age with Duchenne Muscular Dystrophy. Tadalafil failed to show benefit in reducing rate of ambulatory decline.

2019 Update

Reviewed Cialis® (tadalafil) prescribing information and conducted a literature search from 11/1/18 through 11/30/19. No new information was identified that would require changes to this policy. Added generic tadalafil name to policy.

2020 Update

Reviewed Cialis® (tadalafil) prescribing information and conducted a literature search from 12/1/19 through 9/30/20. No new information was identified that would require changes to this policy. Updated criteria to reflect that Proscar® (finasteride), Avodart®, (dutasteride), and Rapaflo® (silodosin) are now all available as generics and removed reference to the brand name medications from coverage criteria.

2021 Update

Reviewed Cialis® (tadalafil) prescribing information and the 2021 on the Management of Benign Prostatic Hyperplasia/ Lower Urinary Tract Symptoms. No new information was identified that would require changes to this policy.

2022 Update

Reviewed Cialis® (tadalafil) prescribing information and checked for updated American Urological Association (AUA) Guidelines. The 2021 AUA Guidelines remain the most recent version of guidelines. Added coverage criteria for Entadfi™ (finasteride and tadalafil) for the treatment of symptoms of BPH. Entadfi™ is a combination of finasteride, a 5α-reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor. Entadfi™ is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown.

2023 Update

Reviewed Cialis® (tadalafil) prescribing information and Entadfi™ (finasteride and tadalafil) prescribing information. No new information was identified that would require changes to this policy.

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History

Date	Comments
08/12/13	New policy. Add to Prescription Drug section.
12/17/14	Annual Review. Policy updated with literature review. No change in policy statements.
10/13/15	Annual Review. Added Rapaflo as a qualifier to coverage of Cialis along with Proscar and Avodart. Verbiage also updated to call them out separately from the generic alpha blockers. Policy statements unchanged.
01/01/17	Annual Review, approved December 13, 2016. No changes to Policy Criteria.
12/01/17	Annual Review, approved November 21, 2017. No changes to the Policy Criteria. One study was added to the Reference List.
07/01/18	Interim Review, approved June 5, 2018. Added requirement of documentation in the form of chart notes/medical records for medical necessity review of medications within this policy.
12/01/18	Annual Review, approved November 21, 2018. No changes. Added reference to a failed trial in patients with DMD.
01/01/20	Annual Review, approved December 10, 2019. Added generic tadalafil to policy. No changes to policy statement.
12/01/20	Annual Review, approved November 3, 2020. No changes to policy statement. Updated criteria to reflect that Proscar (finasteride), Avodart, (dutasteride), and Rapaflo (silodosin) are now all available as generics and removed reference to the brand name medications from coverage criteria.
10/01/21	Annual Review, approved September 23, 2021. No changes to policy statement.
05/01/22	Annual Review, approved April 12, 2022. Added coverage criteria for Entadfi (finasteride and tadalafil) for the treatment of symptoms of BPH.
05/01/22	Interim Review, approved April 25, 2022. Updated title from "Cialis® (tadalafil) for Benign Prostatic Hyperplasia" to "Tadalafil Products for Benign Prostatic Hyperplasia".

Date	Comments
06/01/23	Annual Review, approved May 22, 2023. Updated “patient” to “individual” for the process of standardization. Reviewed Cialis® (tadalafil) prescribing information and Entadfi™ (finasteride and tadalafil) prescribing information. No new information was identified that would require changes to this policy.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2023 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

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УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው፡ 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.