Erectile Dysfunction - Phosphodiesterase Type 5 Inhibitors, Topical Prostaglandin Prior Authorization with Quantity Limit Program Summary

The prior authorization with quantity limit program applies to Health Insurance Marketplace formularies and targets Cialis/tadalafil 2.5 mg and 5 mg only.

The quantity limit only program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, and KeyRx formularies.

This is a FlexRx standard and GenRx standard quantity limit program.

The BCBS MN Step Therapy Supplement also applies to this program for HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
7/1/2023	8/1/2019

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Cialis® * (tadalafil) Tablet	Treatment of erectile dysfunction (ED) Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH)^ Treatment of ED and the signs and symptoms of BPH (ED/BPH) ^Limitation of Use: If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.	* generic available	1
Levitra®* (vardenafil) Tablet	Treatment of erectile dysfunction (ED)	* generic available	2
Staxyn®* (vardenafil) Orally Disintegrating Tablet	Treatment of erectile dysfunction (ED)	* generic available	4
Stendra® (avanafil) Tablet	Treatment of erectile dysfunction (ED)		7

Agent(s)	FDA Indication(s)	Notes	Ref#
Viagra®* (sildenafil) Tablet	Treatment of erectile dysfunction (ED)	* generic available	3

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Erectile Dysfunction (ED)	Erectile Dysfunction (ED) is defined as the inability to attain and/or maintain penile erection sufficient for satisfactory sexual performance. The Panel also endorses the Fourth International Consultation on Sexual Medicine's ED definition as the consistent or recurrent inability to attain and/or maintain penile erection sufficient for sexual satisfaction.(5) The American Urological Association (AUA) guideline on ED (2018) states the following:(5) • There is insufficient literature to constitute an evidence base for diagnosis of ED in clinical practice • Any type of treatment for ED is a valid choice • Oral medications are the least invasive option. Oral phosphodiesterase type 5 inhibitors (PDE5i) have the highest graded level evidence (Grade B) for recommendation in use of ED treatment • PDE5i's have similar efficacy in the general ED population The American Family Physician guideline on the management of ED states the following:(6) • There is no preferred, first-line diagnostic test for ED, and routine screening is not recommended • History and physical examination are sufficient in making an accurate diagnosis of ED in most cases • PDE5i's are the most effective oral drugs in the treatment of ED and should be considered first-line therapy • PDE5i's are considered to be relatively similar in effectiveness and there is no rigorous data to suggest that one is superior to another Sexual behavior studies indicate that commonly prescribed PDE5 inhibitor quantities range from 3 to 6 tablets per patient per month.(5)
Efficacy	PDE5i have similar efficacy in the general ED population. Examination of data reported by trials that evaluated PDE5i revealed that these medications had similar efficacy among men in the general ED population, defined as men with a variety of underlying conditions that potentially contributed to ED symptoms.(5)
Benign Prostatic Hyperplasia (BPH)	As men age, benign prostatic hyperplasia (BPH) becomes increasingly common. BPH can lead to urinary symptoms of increased frequency of urination, nocturia, hesitancy, urgency, and weak urinary stream. Symptomatic patients may benefit from medical or surgical treatment. The American Urological Association Symptom Index (AUA-SI) and the International Prostate Symptom Score (I-PSS) are nearly identical, validated short, self-administered questionnaires, used to assess the severity of three storage symptoms (frequency, nocturia, urgency) and four voiding symptoms (feeling of incomplete emptying, intermittency, straining, and a weak stream). The scores range from 0 to 35 with higher numeric scores representing greater severity. In patients with mild (AUA-SI/I-PSS <8) to moderate (AUA-SI/I-PSS 8-19) symptoms of BPH, the suggested initial treatment is alpha-1-adrenergic antagonist monotherapy. Alpha-1-adrenergic antagonists provide immediate therapeutic benefits. Alternative agents that

	may be used to treat lower urinary tract symptoms (LUTS) associated with BPH include 5-alpha-reductase inhibitors (5-ARIs), anticholinergics, and phosphodiesterase-5 inhibitors (PDE5i).(9) The AUA guideline on BPH (2021) states that more recently, treatment has also been focused on the alteration of disease progression and prevention of complications that can be associated with BPH/LUTS. The pharmacologic classes used to treat LUTS attributed to BPH include alpha-adrenergic antagonists (alpha-blockers), beta adrenergic agonists, 5-ARIs, anticholinergics, vasopressin analogs, and PDE-5 inhibitors.(9) Alpha-adrenergic receptor blockers are use as initial pharmacologic agents in most patients with BPH/LUTS. Treatment effects are seen within days. Bladder outlet obstruction (BOO) is primarily mediated by alpha-1 adrenergic receptors located on prostatic smooth muscle, which are upregulated in the stromal glandular hyperplasia seen in BPH. Blocking signaling through the alpha-adrenergic receptors leads to relaxation of the smooth muscle of the bladder neck and the prostatic urethra.(12) PDE5 inhibitors have been shown in several randomized trials to be beneficial in improving symptom scores in patients with LUTS/BPH, although no significant changes in urine flow rates have been demonstrated.(12)
Efficacy	The efficacy and safety of Cialis (tadalafil) for once daily use for the treatment of the signs and symptoms of BPH was evaluated in 3 randomized, double-blinded, placebo-controlled, efficacy and safety studies of 12 weeks duration. Two of these studies were in men with BPH and one study was specific to men with both ED and BPH. The first study randomized 1058 patients to receive either Cialis 2.5 mg, 5 mg, 10 mg or 20 mg for once daily use or placebo. The second study randomized 325 patients to receive either Cialis 5 mg for once daily use or placebo. The primary efficacy endpoint in the two studies that evaluated the effect of Cialis on lower urinary tract symptoms (LUTS) of BPH was the International Prostate Symptom Score (IPSS), a four week recall questionnaire that was administered at the beginning and end of a placebo run-in period and subsequently at follow-up visits after randomization. The IPSS assesses the severity of irritative (frequency, urgency, nocturia) and obstructive symptoms (incomplete emptying, stopping and starting, weak stream, and pushing or straining), with scores ranging from 0 to 35; higher numeric scores representing greater severity. In each of these 2 trials, Cialis 5 mg for once daily use resulted in statistically significant improvement in the total IPSS compared to placebo.(1,5)
Preservation of Erectile Function following Prostatectomy	Sexual dysfunction associated with radical retropubic prostatectomy (RRP) may start before the surgery. Men undergoing RRP frequently have some degree of sexual dysfunction. In addition to the psychological stress of the diagnosis, the biopsy may itself have a detrimental effect. After surgery, all men will experience loss of ejaculate, because the organ responsible for ejaculate has been removed. Penile sensation and the ability to have an orgasm are preserved even if the erectile nerves are removed during radical prostatectomy, leaving several options for treatment of erectile dysfunction. These include the use of oral phosphodiesterase-5 inhibitors, vacuum-assisted erection devices, penile self-injection (prostaglandin E1, papaverine, phentolamine), and intraurethral alprostadil. Phosphodiesterase inhibitors are most helpful in men who have undergone a nerve-sparing procedure.(10)
Efficacy	In one study of 91 men presenting with erectile dysfunction following radical prostatectomy, the response rates to sildenafil in men who had undergone bilateral nerve-sparing, unilateral nerve-sparing, and a non-nerve sparing approach were 72, 50, and 15 percent, respectively. The response to sildenafil increases with time following radical prostatectomy. In a study in which 95 percent of men had undergone nerve-sparing procedures, 60 percent reported benefit from sildenafil at 18 to 24 months after surgery, significantly higher than the 29 percent who reported benefit in the first six months after surgery.(10) A study of 174 men showed a response rate to sildenafil in men who had undergone bilateral nerve-sparing, unilateral nerve-sparing, and non-nerve-sparing were 76%, 53.5%, and 14.2% respectively. The recovery of erectile function can require as long

	as 18 to 24 months. Initial failures of therapy might be followed by successful re-challenge at 18 to 24 months postoperatively.(11)
Safety	Cialis is contraindicated in the following:(1) • Administration of Cialis to patients using any form of organic nitrate is contraindicated. Cialis was shown to potentiate the hypotensive effect of nitrates. • History of known serious hypersensitivity reaction to Cialis or Adcirca • Administration with guanylate cyclase (GC) stimulators, such as riociguat Levitra is contraindicated in the following:(2) • Administration with nitrates and nitric oxide donors • Administration with guanylate cyclase (GC) stimulators, such as riociguat Staxyn is contraindicated in the following:(4) • Administration with nitrates and nitric oxide donors • Administration with guanylate cyclase (GC) stimulators, such as riociguat Stendra is contraindicated in the following:(7) • Administration of Stendra to patients using any form of organic nitrate is contraindicated • Hypersensitivity to any component of the Stendra tablet • Administration with guanylate cyclase (GC) stimulators, such as riociguat Viagra is contraindicated in the following:(3) • Administration of Viagra to patients using nitric oxide donors, such as organic nitrates or organic nitrites in any form. Viagra was shown to potentiate the hypotensive effect of nitrates. • Known hypersensitivity to sildenafil or any component of tablet • Administration with guanylate cyclase (GC) stimulators, such as riociguat

REFERENCES

Number	Reference
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3	Viagra prescribing information. Pfizer Inc. December 2017.
4	Staxyn prescribing information. Bayer HealthCare Pharmaceuticals Inc. August 2017.
5	Erectile Dysfunction: American Urological Association (AUA) Guideline (2018). Available at https://www.auanet.org/guidelines-and-quality/guidelines/erectile-dysfunction-(ed)-guideline.
6	Heidelbaugh JJ. Management of Erectile Dysfunction. Am Fam Physician 2010;81(3):305-312. Available at https://www.aafp.org/pubs/afp/issues/2010/0201/p305.html
7	Stendra prescribing information. Metuchen Pharmaceuticals, LLC. October 2022.
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9	American Urological Association Guidelines. Management of Benign Prostatic Hyperplasia/ Lower Urinary Tract Symptoms: American Urological Association (AUA) Guideline (2021). Published

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	2021. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-(bph)-guideline
10	McCullough AR. Sexual dysfunction after radical prostatectomy. Rev Urol. 2005;7 Suppl 2(Suppl 2):S3-S10. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1477599/.
11	Raina R, Lakin MM, Agarwal A, et al. Efficacy and factors associated with successful outcome of sildenafil citrate use for erectile dysfunction after radical prostatectomy. *Urol J* 2004;63(5):960-966.
12	McVary K. Medical Treatment of Benign Prostatic Hyperplasia. UpToDate. Last updated August 2022. Literature review current through October 2022.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Cialis	Tadalafil Tab 2.5 MG	2.5 MG	M ; N ; O ; Y	O ; Y		
Cialis	Tadalafil Tab 5 MG	5 MG	M ; N ; O ; Y	O ; Y		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	Vardenafil HCl Orally Disintegrating Tab 10 MG	10 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
	Vardenafil HCl Tab 2.5 MG	2.5 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
	Vardenafil HCl Tab 5 MG	5 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
							and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
Cialis	Tadalafil Tab 10 MG	10 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
Cialis	Tadalafil Tab 2.5 MG	2.5 MG	30	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
Cialis	Tadalafil Tab 20 MG	20 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
Cialis	Tadalafil Tab 5 MG	5 MG	30	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
							for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
Levitra	Vardenafil HCl Tab 10 MG	10 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
Levitra	Vardenafil HCl Tab 20 MG	20 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
Stendra	avanafil tab	100 MG ; 200 MG ; 50 MG	6	Tablets	30	DAYS			
Viagra	Sildenafil Citrate Tab 100 MG	100 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
							and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
Viagra	Sildenafil Citrate Tab 25 MG	25 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		
Viagra	Sildenafil Citrate Tab 50 MG	50 MG	6	Tablets	30	DAYS	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Cialis	Tadalafil Tab 2.5 MG	2.5 MG	Health Insurance Marketplace/BasicRx
Cialis	Tadalafil Tab 5 MG	5 MG	Health Insurance Marketplace/BasicRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Vardenafil HCl Orally Disintegrating Tab 10 MG	10 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Vardenafil HCl Tab 2.5 MG	2.5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Vardenafil HCl Tab 5 MG	5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cialis	Tadalafil Tab 10 MG	10 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cialis	Tadalafil Tab 2.5 MG	2.5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cialis	Tadalafil Tab 20 MG	20 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Cialis	Tadalafil Tab 5 MG	5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Levitra	Vardenafil HCl Tab 10 MG	10 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Levitra	Vardenafil HCl Tab 20 MG	20 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Stendra	avanafil tab	100 MG ; 200 MG ; 50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Viagra	Sildenafil Citrate Tab 100 MG	100 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Viagra	Sildenafil Citrate Tab 25 MG	25 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Viagra	Sildenafil Citrate Tab 50 MG	50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA QL	**Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested agent is a phosphodiesterase 5 (PDE5) inhibitor and ONE of the following: A. The patient's diagnosis is erectile dysfunction (ED) and ALL of the following: 1. The patient's benefit plan covers agents for treatment of erectile dysfunction **AND** 2. The patient is 18 years of age or over **AND** 3. The patient will NOT be using the requested agent in combination with a nitrate or nitric oxide **AND** 4. The patient will NOT be using the requested agent in combination with another ED agent (e.g., oral, injectable, or suppository) **AND** 5. ONE of the following: A. The requested agent is a generic phosphodiesterase type 5 inhibitor **OR** B. The requested agent is for one of the following phosphodiesterase type 5 inhibitor brand agents with an available generic equivalent (listed below), then ONE of the following: 1. The patient has tried and had an inadequate response to the required generic equivalent **OR** 2. The patient has an intolerance or hypersensitivity to the required generic equivalent **OR** 3. The patient has an FDA labeled contraindication to the required generic equivalent **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that the required generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** **Brand** / **Generic Equivalent** Cialis — tadalafil tablets Levitra — vardenafil tablets Staxyn — vardenafil orally disintegrating tablets Viagra — sildenafil tablets C. The requested agent is Stendra and ONE of the following: 1. The patient has tried and had an inadequate response to ONE generic phosphodiesterase type 5 inhibitor **OR** 2. The patient has an intolerance or hypersensitivity to ONE generic phosphodiesterase type 5 inhibitor **OR** 3. The patient has an FDA labeled contraindication to ALL generic phosphodiesterase type 5 inhibitor **OR**

Module	Clinical Criteria for Approval
	4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL generic phosphodiesterase type 5 inhibitor cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The requested quantity does NOT exceed the program quantity limit **OR** B. The patient's diagnosis is benign prostatic hyperplasia (BPH) and ALL of the following: 1. The requested agent is Cialis or tadalafil 2.5 mg or 5 mg **AND** 2. The patient will NOT be using the requested agent in combination with a nitrate or nitric oxide **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to ONE generic alpha blocker **OR** B. The patient has an intolerance or hypersensitivity to ONE generic alpha blocker **OR** C. The patient has an FDA labeled contraindication to ALL generic alpha blockers **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL generic alpha blockers cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient will NOT be using the requested agent in combination with an alpha blocker for the requested indication **AND** 5. ONE of the following: A. The requested agent is generic tadalafil 2.5 mg or 5 mg **OR** B. If the request is for one of the following phosphodiesterase type 5 inhibitor brand agents with an available generic equivalent (listed below), then ONE of the following: 1. The patient has tried and had an inadequate response to the generic equivalent **OR** 2. The patient has an intolerance or hypersensitivity to the generic equivalent **OR** 3. The patient has an FDA labeled contraindication to the generic equivalent **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval

A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

5. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

Brand	Generic Equivalent
Cialis	tadalafil tablets

6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
7. The requested quantity does NOT exceed the program quantity limit **OR**

C. The patient's indication of use is for preservation of erectile function following a radical retropubic prostatectomy AND ALL of the following:
1. The patient will NOT be using the requested agent in combination with a nitrate or nitric oxide **AND**
2. ONE of the following:
A. The requested agent is a generic phosphodiesterase type 5 inhibitor **OR**
B. If the request is for one of the following phosphodiesterase type 5 inhibitor brand agents with an available generic equivalent (listed below), then ONE of the following:
1. The patient has tried and had an inadequate response to the required generic equivalent **OR**
2. The patient has an intolerance or hypersensitivity to the required generic equivalent **OR**
3. The patient has an FDA labeled contraindication to the required generic equivalent **OR**
4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
5. The prescriber has provided documentation that the required generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

Brand	Generic Equivalent
Cialis	tadalafil tablets
Levitra	vardenafil tablets
Staxyn	vardenafil orally disintegrating tablets

Module	Clinical Criteria for Approval

Viagra	sildenafil tablets

C. The requested agent is Stendra and ONE of the following:
   1. The patient has tried and had an inadequate response to ONE generic phosphodiesterase type 5 inhibitor **OR**
   2. The patient has an intolerance or hypersensitivity to ONE generic phosphodiesterase type 5 inhibitor **OR**
   3. The patient has an FDA labeled contraindication to ALL generic phosphodiesterase type 5 inhibitor **OR**
   4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   5. The prescriber has provided documentation that ALL generic phosphodiesterase type 5 inhibitor cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
4. The requested quantity does NOT exceed 30 tablets per month **OR**

2. The requested agent is NOT a PDE5 Inhibitor and ONE of the following:
   A. The patient's diagnosis is erectile dysfunction (ED) and ALL of the following:
      1. The patient's benefit plan covers agents for treatment of erectile dysfunction **AND**
      2. The patient is 18 years of age or over **AND**
      3. The patient will NOT be using the requested agent in combination with another ED agent (e.g., oral, injectable, or suppository) **AND**
      4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
      5. The requested quantity does NOT exceed the program quantity limit

Length of Approval:

Erectile dysfunction (ED) or benign prostatic hyperplasia (BPH) - 12 months

Preservation of erectile function following radical retropubic prostatectomy – 30 tablets per month for 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when the following is met: 1. The requested agent is a phosphodiesterase type 5 (PDE5) inhibitor and ALL of the following: A. The patient will NOT be using the requested agent in combination with another phosphodiesterase type 5 (PDE5) inhibitor for the requested indication **AND** B. The requested agent has been prescribed for preservation of erectile function following radical retropubic prostatectomy **AND** C. The quantity requested is less than or equal to 30 tablets per month

Module	Clinical Criteria for Approval
	Length of Approval: Preservation of erectile function following a radical retropubic prostatectomy – 30 tablets per month for 12 months