



Drug Coverage Policy

Effective Date6/15/2026
Coverage Policy Number..... DQM017
Policy Title.....Erectile Dysfunction
Agents Drug Quantity Management
Policy – Per Days

Erectile Dysfunction Agents Drug Quantity Management Policy – Per Days

- Cialis® (tadalafil tablets – Eli Lilly, generic)
- Stendra® (avanafil tablets – Metuchen, generic)
- Vardenafil orally disintegrating tablets (generic only)
- Vardenafil tablets (generic only)
- Viagra® (sildenafil citrate tablets – Pfizer, generic)
- Caverject® and Caverject Impulse® dual chamber system (alprostadil injection [in lyophilized powder and aqueous forms] – Pfizer)
- Edex® (alprostadil injection – Auxilium)
- Muse® (alprostadil urethral suppository – Meda [obsolete 6/2024])

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not

covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Stendra, tadalafil (Cialis, generic), vardenafil tablets (generic only), vardenafil orally disintegrating tablets (generic only), sildenafil (Viagra, generic), and Vybriq are oral phosphodiesterase type 5 (PDE₅) inhibitors, which are all indicated for the treatment of erectile dysfunction (ED).^{1-5, 41} Tadalafil is also indicated for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) and BPH/ED.³ If tadalafil is used with finasteride to initiate BPH treatment, it is recommended to limit therapy at 26 weeks. This is because the incremental benefit of tadalafil decreases from 4 weeks to 26 weeks and the benefit beyond 26 weeks is unknown.

Alprostadil, administered either by intracavernosal injection (Caverject/Caverject Impulse, Edex) or as an intraurethral suppository (Muse), is indicated for the treatment of ED.³⁰⁻³³ Caverject and Caverject Impulse are additionally indicated as an adjunct to other diagnostic tests in the diagnosis of erectile dysfunction.

Dosing/Availability

Table 1. Recommended Dosing of the ED Agents.^{1-5, 30-33,41}

Brand (generic)	Recommended Dose	Availability
Oral PDE₅ inhibitors		
Cialis® (tadalafil tablets, generic)	<ul style="list-style-type: none"> • <u>As needed ED dosing</u>, the recommended starting dose is 10 mg; may be increased to 20 mg or decreased to 5 mg. Maximum recommended frequency is once per day. • <u>QD ED dosing</u>, the recommended starting dose is 2.5 mg QD and can be increased to 5 mg QD. • <u>BPH or ED/BPH</u>, the recommended dose is 5 mg QD. When used with finasteride for BPH, the combined use is limited for up to 26 weeks. • Dose reductions/less frequent dosing may be needed for certain patients based on renal function, hepatic function, or to manage drug interactions. 	2.5 mg, 5 mg, 10 mg, and 20 mg tablets
Stendra® (avanafil tablets)	<ul style="list-style-type: none"> • Starting dose is 100 mg taken as early as approximately 15 minutes before sexual activity, as needed. • Maximum frequency is once per day for ED. • Stendra should not be used in patients taking strong CYP3A4 inhibitors and dose reductions are needed to manage drug interactions. 	50 mg, 100 mg, and 200 mg tablets
Vardenafil orally disintegrating tablets (generic only)	<ul style="list-style-type: none"> • Starting dose is 10 mg taken approximately 60 minutes prior to sexual activity, as needed. • Maximum frequency is once per day for ED. 	10 mg orally disintegrating tablets

	<ul style="list-style-type: none"> • Vardenafil ODT is not recommended for use in patients with moderate or severe hepatic impairment, patients on renal dialysis, or patients who are taking moderate to strong CYP3A4 inhibitors. • Vardenafil ODT and vardenafil tablets are not interchangeable. 	
Vardenafil tablets (generic only)	<ul style="list-style-type: none"> • Starting dose is 10 mg taken approximately 60 minutes prior to sexual activity, as needed. • Dose may be increased to 20 mg or decreased to 5 mg. Maximum frequency is once per day for ED. • A starting dose of 5 mg is recommended in patients ≥ 65 years of age and in patients with moderate hepatic impairment. Maximum starting dose in patients with moderate hepatic impairment is 10 mg. • Dose reductions/less frequent dosing may be needed for certain patients to manage drug interactions. 	2.5 mg, 5 mg, 10 mg, and 20 mg tablets
Viagra® (sildenafil citrate tablets, generic)	<ul style="list-style-type: none"> • Recommended starting dose is 50 mg taken approximately 60 minutes prior to sexual activity, as needed. It may be taken anywhere from 30 minutes to 4 hours before sexual activity. • The dose may be increased to 100 mg or decreased to 25 mg based on efficacy and tolerability. • The maximum recommended frequency is once per day. 	25 mg, 50 mg, and 100 mg tablets
Non-Oral ED Agents		
Caverject® (alprostadil injection)	<ul style="list-style-type: none"> • Dosing should be individualized. In clinical studies, doses ranged from 0.2 to 140 mcg; however, 99% of patients received doses of 60 mcg or less and therefore, doses greater than 60 mcg are not recommended. • Patients with ED due to vasculogenic, psychogenic, or mixed etiology should initiate therapy at 2.5 mcg, while those with pure neurogenic etiology (spinal cord injury) should initiate at 1.25 mcg; titrate doses as needed. • Caverject is injected intracavernosally, as needed before sexual activity; it should produce an erection in 5 to 20 minutes after administration. After reconstituted, use within 24 hours. • The recommended frequency of use is no more than 3 times a week, with at least 24 hours between each use. 	20 and 40 mcg vials (lyophilized powder)
Caverject Impulse® dual chamber system (alprostadil injection)		10 and 20 mcg dual-chamber syringe systems
Edex® (alprostadil injection)	<ul style="list-style-type: none"> • Dosing should be individualized. The dosage range is 1 to 40 mcg. In clinical studies, mean doses ranged from 10.7 to 21.9 mcg. Doses > 40 mcg have not been studied. • Patients with ED due to vasculogenic, psychogenic, or mixed etiology should initiate therapy at 2.5 mcg, while those with pure neurogenic etiology (spinal cord injury) should initiate at 1.25 mcg. 	10, 20, and 40 mcg dual chamber cartridges

	<ul style="list-style-type: none"> • Edex is injected intracavernosally immediately after reconstitution, as needed prior to sexual activity. Edex should produce an erection in 5 to 20 min after administration. • The recommended frequency of injection is no more than 3 times weekly, with at least 24 hours between doses. 	
Muse® (alprostadil urethral suppository)	<ul style="list-style-type: none"> • The 125 and 250 mcg doses are recommended for initial therapy; dose titration should be done under the supervision of a physician to monitor for evidence of hypotension. • The maximum recommended frequency of use is two suppositories in a 24-hour period. • Onset of effect is 5 to 10 minutes following administration and a duration of effect is approximately 30 to 60 minutes. 	250, 500, and 1,000 mcg suppositories

ED – Erectile dysfunction; PDE₅ – Phosphodiesterase type 5; QD – Once daily; BPH – Benign prostatic hyperplasia; CYP – Cytochrome P450; ODT – Orally disintegrating tablet.

Off-label Dosing

Benign Prostatic Hyperplasia

The 2.5 mg and 5 mg strengths of tadalafil are FDA-approved for daily use in treating BPH.³ Several studies have also demonstrated the effects of daily tadalafil 10 mg or 20 mg on lower urinary tract symptoms (LUTS) due to BPH.⁶ Additionally, vardenafil 10 mg twice daily (BID) has been studied for the treatment of LUTS due to BPH.⁷ Daily sildenafil (25 mg to 100 mg) has been effective in men with symptoms of LUTS due to BPH as well.^{8,9,37-40}

Prevention and Treatment of Erectile Dysfunction following Radical Prostatectomy

PDE₅ inhibitors (primarily sildenafil, vardenafil, and tadalafil) and intracavernosal alprostadil are used for the management of erectile dysfunction following radical prostatectomy.^{10,11} Daily and on demand use have been studied and both have been found effective. For tadalafil, the most common dose is 5 mg once daily (QD). However, the 10 mg and 20 mg strengths have also been studied administered three days per week.¹²⁻¹⁶ Daily dosing with vardenafil or sildenafil has been found to be beneficial as well.^{11,17-19} Intracavernosal alprostadil has been administered two to three times per week in studies, both as monotherapy and in combination with sildenafil.^{34,35}

Raynaud's Phenomenon

Sildenafil, tadalafil, and vardenafil have also been used for the management of Raynaud's Phenomenon in patients who are unable to use calcium channel blockers.^{20-22,36} A dose of up to 20 mg of tadalafil administered QD has been used.³⁶ Vardenafil at a dose of 10 mg BID has been shown to reduce the number of attacks per day in patients with Raynaud's Phenomenon. With sildenafil, a dose of 20 mg QD or BID is generally used initially, and then based on response and tolerability, may be increased to 20 mg three times daily (TID) as needed. If lower doses are not effective, the dose may be increased to 40 mg TID, if tolerated. Additionally, doses of 50 mg BID or TID have been reported as well.

High-Altitude Pulmonary Edema

For prevention of high-altitude pulmonary edema (HAPE), the preferred pharmacologic option is nifedipine.²³ However, PDE₅ inhibitors, sildenafil or tadalafil, may also be used for prevention of HAPE in patients who are not candidates for nifedipine or for treatment of HAPE when descent is impossible or delayed. The recommended prevention or treatment dose of tadalafil is 10 mg once every 12 hours for prevention of HAPE. For sildenafil, the recommended dose is 50 mg once every 8 hours.

Pulmonary Arterial Hypertension

Adcirca® (tadalafil tablets, generic) contains the same active ingredient as Cialis (generic).²⁴ Adcirca (generic) is available as 20 mg tablets and is FDA-approved at a dose of 40 mg QD for the treatment of pulmonary arterial hypertension (PAH) [WHO Group 1] to improve exercise ability. However, other doses of tadalafil, including 10 mg QD, have been studied.^{25,26} Patients requiring doses of 20 mg or 40 mg of tadalafil for PAH should use Adcirca (generic).

Revatio® (sildenafil tablets and oral suspension, generic) contains the same active ingredient as Viagra (generic).²⁷ Revatio is FDA-approved for the treatment of PAH (WHO Group 1) in adults to improve exercise ability and delay clinical worsening. It is also FDA-approved in patients 1 to 17 years of age for the treatment of PAH (WHO Group 1) to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise. Revatio (generic) is available as 20 mg tablets and a 10 mg/mL oral suspension. Viagra (generic) has also been used for this diagnosis.^{28,29} Doses of Viagra (generic) that were used in these reports ranged from 25 mg BID to 100 mg five times daily. Patients will have usually been started on Revatio 20 mg TID.

Coverage Policy

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of erectile dysfunction agents. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below. "One-time" approvals are provided for 30 days in duration. Meeting Drug Quantity Management Program Criteria does not satisfy any other prior authorization or medical necessity criteria requirements.

Drug Quantity Limits

Product	Strength/ Dosage Form	Retail Maximum Quantity per 30 days	Home Delivery Maximum Quantity per 90 days
Cialis® (tadalafil tablets, generic)	2.5 mg tablets	30 tablets	90 tablets
	5 mg tablets	30 tablets	90 tablets
	10 mg tablets	8 tablets	24 tablets
	20 mg tablets	8 tablets	24 tablets
Stendra® (avanafil tablets, generic)	50 mg tablets	8 tablets	24 tablets
	100 mg tablets	8 tablets	24 tablets
	200 mg tablets	8 tablets	24 tablets
Vardenafil tablets (generic only)	2.5 mg tablets	8 tablets	24 tablets
	5 mg tablets	8 tablets	24 tablets
	10 mg tablets	8 tablets	24 tablets
	20 mg tablets	8 tablets	24 tablets
Vardenafil orally disintegrating tablets (generic only)	10 mg tablets	8 tablets	24 tablets
Viagra®	25 mg tablets	8 tablets	24 tablets

(sildenafil citrate tablets, generic)	50 mg tablets	8 tablets	24 tablets
	100 mg tablets	8 tablets	24 tablets
Caverject® (alprostadil injection)	20 mcg vials	6 vials	18 vials
	40 mcg vials	6 vials	18 vials
Caverject Impulse® dual chamber system (alprostadil injection)	10 mcg syringes	6 syringes	18 syringes
	20 mcg syringes	6 syringes	18 syringes
Edex® (alprostadil injection)	10 mcg cartridge	6 cartridges	18 cartridges
	20 mcg cartridge	6 cartridges	18 cartridges
	40 mcg cartridge	6 cartridges	18 cartridges
Muse® (alprostadil urethral suppository)	250 mcg urethral suppositories	6 suppositories	18 suppositories
	500 mcg urethral suppositories	6 suppositories	18 suppositories
	1,000 mcg urethral suppositories	6 suppositories	18 suppositories

Quantity limit may be rounded up to the nearest package size, if needed.

A total quantity of 8 doses of sildenafil, tadalafil, vardenafil, alprostadil injection, or alprostadil urethral suppositories will be covered per 30-day period. The quantity limit is specific to these individual drugs or any combination of them. For example, 8 tablets of sildenafil 100 mg would be covered in 30 days; 4 tablets of sildenafil 100 mg plus 4 tablets of sildenafil 50 mg would be covered per 30 days; or 4 tablets of sildenafil 100 mg plus 4 vials of alprostadil injection would be covered per 30 days. Edex comes in unbreakable package sizes of 2 and 6. Since the limit of 8 is not evenly divisible by the package of 6, the limit for *only* the package size 6 of Edex is 12 per month. Edex does not accumulate with all other ED agents.

Exceptions to the quantity limits listed above are covered as medically necessary when ONE of the following criteria is met. Any other exception is considered not medically necessary.

CRITERIA

Stendra 50 mg, 100 mg, and 200 mg tablets

No overrides recommended.

Tadalafil 5 mg tablets (Cialis, generic)

1. If the patient has a diagnosis of benign prostatic hyperplasia (BPH) with or without erectile dysfunction, approve 60 tablets per 30 days at retail or 180 tablets per 90 days at home delivery.

2. If the patient has a diagnosis of Raynaud's phenomenon, approve 60 tablets per 30 days at retail or 180 tablets per 90 days at home delivery.
3. If the patient is using tadalafil for prevention or treatment of high-altitude pulmonary edema (HAPE), approve a one-time override for the requested quantity, not to exceed 120 tablets at retail or home delivery.
4. If the patient has a diagnosis of pulmonary arterial hypertension (PAH), approve the requested quantity, not to exceed 60 tablets per 30 days at retail or 180 tablets per 90 days at home delivery.

Tadalafil 10 mg tablets (Cialis, generic)

1. If the patient has a diagnosis of benign prostatic hyperplasia (BPH) with or without erectile dysfunction, approve 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.
2. If the patient is using tadalafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 13 tablets per 30 days at retail or 36 tablets per 90 days at home delivery.
3. If the patient has a diagnosis of Raynaud's phenomenon, approve 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.
4. If the patient is using tadalafil for prevention or treatment of high-altitude pulmonary edema (HAPE), approve a one-time override for the requested quantity, not to exceed 60 tablets at retail or home delivery.
5. If the patient has a diagnosis of pulmonary arterial hypertension (PAH), approve the requested quantity, not to exceed 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.

Tadalafil 20 mg tablets (Cialis, generic)

1. If the patient has a diagnosis of benign prostatic hyperplasia (BPH) with or without erectile dysfunction, approve 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.
2. If the patient is using tadalafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 13 tablets per 30 days at retail or 36 tablets per 90 days at home delivery.
3. If the patient has a diagnosis of Raynaud's phenomenon, approve 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.
4. If the patient is using tadalafil for prevention or treatment of high-altitude pulmonary edema (HAPE), approve a one-time override for the requested quantity, not to exceed 30 tablets at retail or home delivery.

Vardenafil 2.5 mg, 5 mg, 20 mg tablets (generic only)

1. If the patient is using vardenafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.

Vardenafil 10 mg tablets (generic only) and Vardenafil 10 mg orally-disintegrating tablets (generic only)

1. If the patient has a diagnosis of benign prostatic hyperplasia (BPH) with or without erectile dysfunction, approve the requested quantity, not to exceed 60 tablets per 30 days at retail or 180 tablets per 90 days at home delivery.
2. If the patient is using vardenafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.
3. If the patient has a diagnosis of Raynaud's phenomenon, approve the requested quantity, not to exceed 60 tablets per 30 days at retail or 180 tablets per 90 days at home delivery.

Sildenafil 50 mg tablets (Viagra, generic)

1. If the patient has a diagnosis of benign prostatic hyperplasia (BPH) with or without erectile dysfunction, approve the requested quantity, not to exceed 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.
2. If the patient is using sildenafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.
3. If the patient has a diagnosis of Raynaud's phenomenon, approve the requested quantity, not to exceed 90 tablets per 30 days at retail or 270 tablets per 90 days at home delivery.
4. If the patient is using sildenafil for prevention or treatment of high-altitude pulmonary edema (HAPE), approve a one-time override for the requested quantity, not to exceed 90 tablets at retail or home delivery.
5. If the patient has a diagnosis of pulmonary arterial hypertension (PAH), approve the requested quantity, not to exceed 150 tablets per 30 days at retail or 450 tablets per 90 days at home delivery.

Sildenafil 25 mg and 100 mg tablets (Viagra, generic)

1. If the patient has a diagnosis of benign prostatic hyperplasia (BPH) with or without erectile dysfunction, approve the requested quantity, not to exceed 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.
2. If the patient is using sildenafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 30 tablets per 30 days at retail or 90 tablets per 90 days at home delivery.
3. If the patient has a diagnosis of Raynaud's phenomenon, approve the requested quantity, not to exceed 90 tablets per 30 days at retail or 270 tablets per 90 days at home delivery.
4. If the patient has a diagnosis of pulmonary arterial hypertension (PAH), approve the requested quantity, not to exceed 150 tablets per 30 days at retail or 450 tablets per 90 days at home delivery.

Caverject vials, Caverject Impulse syringes, Edex cartridges, Muse suppositories

1. If the patient is using Caverject, Caverject Impulse, Edex, or Muse for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 13 vials, syringes, cartridges, or

suppositories per 30 days at retail or 36 vials, syringes, cartridges, or suppositories per 90 days at home delivery.

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Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	4/16/2026	6/15/2026

The policy effective date is in force until updated or retired.

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