



DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Erectile Dysfunction Agents Drug Quantity Management Policy – Per Rx
- Cialis® (tadalafil tablets – Eli Lilly, generic)
 - Vardenafil orally disintegrating tablets (generic only)
 - Vardenafil tablets (generic only)
 - Viagra® (sildenafil citrate tablets – Pfizer, generic)

REVIEW DATE: 04/23/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tadalafil (Cialis, generic), vardenafil tablets (generic only), vardenafil orally disintegrating tablets (generic only), and sildenafil (Viagra, generic) are oral phosphodiesterase type 5 (PDE₅) inhibitors, which are all indicated for the treatment of erectile dysfunction (ED).¹⁻⁴ Tadalafil is also indicated for the treatment of the 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. Of note, Stendra® (avanafil tablets) is another PDE₅ inhibitor that is subject to Per Rx quantity limitations.⁵ However, there are no overrides to the Stendra quantity limit and therefore, it is not included in this policy. Additionally, Caverject® and Caverject Impulse® dual chamber system (alprostadil injection), Edex® (alprostadil injection), and Muse® (alprostadil urethral suppository) are other ED agents that are also subject to Per Rx quantity limitations. However, there are

no overrides to these quantity limits and therefore, they are not included in this policy.

Dosing/Availability

Table 1. Recommended Dosing of the ED Agents.¹⁻⁴

Brand (generic)	Recommended Dose	Availability
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. 	2.5 mg, 5 mg, 10 mg, and 20 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. • 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 tablets and Vardenafil ODT are not interchangeable. 	10 mg orally disintegrating tablets
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. 	2.5 mg, 5 mg, 10 mg, and 20 mg tablets

Table 1 (continued). Recommended Dosing of the ED Agents.¹⁻⁴

Brand (generic)	Recommended Dose	Availability
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

ED – Erectile dysfunction; QD – Once daily; BPH – Benign prostatic hyperplasia; CYP – Cytochrome P450.

Off-label Dosing

Benign Prostatic Hyperplasia

The 2.5 mg and 5 mg strengths of tadalafil are FDA-approved for daily use in treating benign prostatic hyperplasia (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.^{8,9,31-35}

Prevention and Treatment of Erectile Dysfunction following Radical Prostatectomy

PDE₅ inhibitors, primarily sildenafil, vardenafil, and tadalafil, 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}

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.^{20-22,30} A dose of 20 mg of tadalafil administered every other day (e.g., two to three times per week) has been used as has 10 mg QD dosing. Vardenafil at a dose of 10 mg BID has been shown to reduce the number of attacks per day in patients with Raynaud 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 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.

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.

Drug Quantity Limits

Product	Strength/Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Cialis® (tadalafil tablets, generic)	2.5 mg tablets (generic only)	30 tablets	90 tablets
	5 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets
	10 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets
	20 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets
Vardenafil orally disintegrating tablets (generic only)	10 mg tablets	6 tablets – OR – 8 tablets ^{a,β}	18 tablets – OR – 24 tablets
Vardenafil tablets (generic only)	2.5 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets
	5 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets
	10 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets
	20 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets
Viagra® (sildenafil citrate tablets, generic)	25 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets
	50 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets
	100 mg tablets	6 tablets – OR – 8 tablets ^a	18 tablets – OR – 24 tablets

^a Quantity limit of 6 or 8 tablets is based on choice of client plan design. If additional medication is needed, the patient would need to pay an additional co-pay or meet one of the override criteria below;

^β Vardenafil orally disintegrating tablets are supplied in blister packs containing 4 tablets each, so dispensing 6 or 18 tablets would require a partial blister pack to be dispensed.

Erectile Dysfunction Agents Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Tadalafil 2.5 mg tablets (Cialis, generic)

No overrides recommended.

Tadalafil 5 mg tablets (Cialis, generic)

1. If the patient is treating erectile dysfunction and has been taking tadalafil 2.5 mg once daily and is increasing the dose to 5 mg once daily, without regard to timing of sexual activity, approve 30 tablets per dispensing at retail or 90 tablets per dispensing at home delivery.
2. If the patient has a diagnosis of benign prostatic hyperplasia (BPH) with or without erectile dysfunction, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.
3. If the patient is using tadalafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 30 tablets per dispensing at retail or 90 tablets per dispensing at home delivery.
4. If the patient has a diagnosis of Raynaud’s phenomenon, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.
5. 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.
6. If the patient has a diagnosis of pulmonary arterial hypertension (PAH), approve the requested quantity, not to exceed 60 tablets per dispensing at retail or 180 tablets per dispensing 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 dispensing at retail or 90 tablets per dispensing at home delivery.
2. If the patient is using tadalafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 13 tablets per dispensing at retail or 39 tablets per dispensing at home delivery.
3. If the patient has a diagnosis of Raynaud’s phenomenon, approve 30 tablets per dispensing at retail or 90 tablets per dispensing 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 dispensing at retail or 90 tablets per dispensing 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 dispensing at retail or 90 tablets per dispensing at home delivery.
2. If the patient is using tadalafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 13 tablets per dispensing at retail or 39 tablets per dispensing at home delivery.
3. If the patient has a diagnosis of Raynaud's phenomenon, approve 15 tablets per dispensing at retail or 45 tablets per dispensing 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 dispensing at retail or 90 tablets per dispensing 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 dispensing at retail or 180 tablets per dispensing at home delivery.
2. If the patient is using vardenafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 30 tablets per dispensing at retail or 90 tablets per dispensing at home delivery.
3. If the patient has a diagnosis of Raynaud's phenomenon, approve the requested quantity, not to exceed 60 tablets per dispensing at retail or 180 tablets per dispensing 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 dispensing at retail or 90 tablets per dispensing at home delivery.

2. If the patient is using sildenafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 30 tablets per dispensing at retail or 90 tablets per dispensing at home delivery.
3. If the patient has a diagnosis of Raynaud's phenomenon, approve the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing 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 dispensing at retail or 450 tablets per dispensing 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 dispensing at retail or 90 tablets per dispensing at home delivery.
2. If the patient is using sildenafil for prevention or treatment of erectile dysfunction after radical prostatectomy, approve 30 tablets per dispensing at retail or 90 tablets per dispensing at home delivery.
3. If the patient has a diagnosis of Raynaud's phenomenon, approve the requested quantity, not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing 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 dispensing at retail or 450 tablets per dispensing at home delivery.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	04/19/2023
Annual Revision	Brand Levitra and Brand Staxyn were removed from the policy (obsolete).	04/23/2024

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