

**HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES**

PHOSPHODIESTERASE 5 INHIBITOR (PDE5I) AGENTS

Generic	Brand	HICL	GCN	Exception/Other
AVANAFIL	STENDRA	40798		
SILDENAFIL	VIAGRA		57901 57902 57903	
TADALAFIL	CIALIS		18995 18996 20736 99409	
VARDENAFIL HCL	LEVITRA	25035	19326 19327 19328 20258	
VARDENAFIL HCL	STAXYN	25035	29673	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a female or a patient under 18 years of age?

If yes, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, **[DRUG]** is not covered when prescribed for females or for males under 18 years of age because this medication is not approved by the Food and Drug Administration for females or males under 18 years of age. Your provider indicated that you are [female or under 18 years of age] and therefore your request was not approved.

If no, continue to #2.

2. Does the member have a diagnosis of Benign Prostatic Hyperplasia (BPH)?

If yes, continue to #3.

If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

3. Is the request for tadalafil (Cialis) 2.5mg or 5mg?

If yes, **approve Cialis 2.5mg or 5mg for 12 months by GPID with a quantity limit of 30 tablets per 30 days.** Please use status code #056 and the approval text provided.

APPROVAL TEXT: Your request for **[DRUG]** has been approved for 30 tablets per 30-day supply for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT (Cialis 10 mg or 20 mg): Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, tadalafil (Cialis) is only covered for the treatment of Benign Prostatic Hyperplasia (BPH) in a dose up to 5mg per day. The requested dosage exceeds the FDA-approved recommended dose for the treatment of BPH and therefore your request was not approved.

DENIAL TEXT (non-Cialis requests): Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, **[DRUG]** is not covered for the treatment of Benign Prostatic Hyperplasia (BPH). Your provider indicated you would be taking this medication for the treatment of BPH and therefore your request was not approved.

4. Is the member being treated for penile rehabilitation due to a recent (within the previous 3 months) prostatectomy?

If yes, continue to #5.

If no, continue to #10.

5. Has the member previously received approval for a 6 month course of an additional quantity of sildenafil (Viagra), tadalafil (Cialis), Levitra, Staxyn, or Stendra?

If yes, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, your plan covers additional quantities of **[DRUG]** for up to 180 days post-prostatectomy. Your additional coverage of **[DRUG]** was used on **[DATES]**. Therefore, the request for additional dosages was not approved.

If no, continue to #6.

6. Is the member taking nitrates or a non-selective alpha blocker (doxazosin, prazosin, or terazosin)?

If yes, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per FDA-approved product information, this drug is associated with significant risk when taken with nitrates and/or other cardiovascular drugs. Your doctor has indicated that you are currently taking one or more of these medications and therefore your request was not approved.

If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

7. Is the request for a non-formulary medication?

If yes, continue to #8.

If no, continue to #9.

8. Has the member tried and failed tadalafil (Cialis) and sildenafil (Viagra)?

If yes, **approve for 6 months by GPID for the quantity requested by the ordering provider up to a maximum quantity of 30 tablets per 30 days.** Please use status code #056 and the approval text provided.

APPROVAL TEXT: Your request for [DRUG] has been approved with a quantity limit of _____ per 30 days for a 6-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, your plan only covers [DRUG] after you have tried tadalafil (Cialis) and sildenafil (Viagra). Your provider did not indicate that you have tried tadalafil (Cialis) and sildenafil (Viagra), and therefore your request was not approved.

9. **Approve for 6 months by GPID for the quantity requested by the ordering provider, up to a maximum of the quantity limit listed below.** Please use status code #056 and the approval text provided.

- **Tadalafil (Cialis) 2.5mg or 5mg: 30 tablets per 30 days**
- **Tadalafil (Cialis) 10mg or 20mg: 10 tablets per 30 days**
- **Sildenafil (Viagra): 30 tablets per 30 days**
- **Levitra: 30 tablets per 30 days**
- **Staxyn: 30 tablets per 30 days**
- **Stendra: 30 tablets per 30 days**

APPROVAL TEXT: Your request for [DRUG] has been approved for [###] tablets per 30-day supply for a six-month period.

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INITIAL CRITERIA (CONTINUED)

10. Does the member have a diagnosis of Erectile Dysfunction (ED)?

If yes, continue to #11.

If no, do not approve. Please use status code #238 and the denial text provided.

TADALAFIL (CIALIS) DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, Cialis is only covered when prescribed for erectile dysfunction, rehabilitation after recent prostate surgery (within the previous three months), or for the treatment of Benign Prostatic Hyperplasia (BPH). Your physician did not indicate that you are being treated for any of these conditions and therefore your request was not approved.

SILDENAFIL (VIAGRA)/ LEVITRA/STAXYN/STENDRA DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, **[DRUG]** is only covered when prescribed for erectile dysfunction or rehabilitation after recent prostate surgery (within the previous three months). Your provider did not indicate that you are being treated for either condition and therefore your request was not approved.

11. Is the request for a non-formulary medication?

If yes, continue to #12.

If no, continue to #14.

12. Has the member tried and failed tadalafil (Cialis) and sildenafil (Viagra)?

If yes, continue to #13.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, your plan only covers **[DRUG]** after you have tried tadalafil (Cialis) and sildenafil (Viagra). Tadalafil (Cialis) and sildenafil (generic Viagra) are covered with a quantity limit of 4 tablets per 30 days. Your provider did not indicate that you have tried tadalafil (Cialis) and sildenafil (Viagra), therefore your request was not approved.

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PHOSPHODIESTERASE 5 INHIBITOR (PDE5I) AGENTS

INITIAL CRITERIA (CONTINUED)

13. Does the request exceed 4 tablets per 30 days?

If yes, **partially deny and enter a proactive prior authorization for the requested drug for 12 months by GPID up to 4 tablets per 30 days.** Please use status code #238 and the partial denial text provided.

PARTIAL DENIAL TEXT: Your request for **[DRUG]** has been partially approved with a quantity limit of _____ per 30 days for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier. Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, your plan covers 4 tablets per 30-day supply. Additional doses are only covered when prescribed for rehabilitation after recent prostate surgery. Your provider did not indicate that you are being treated for this condition and therefore your request was approved for 4 tablets per 30-day supply for a twelve-month period.

If no, **approve the requested drug for 12 months by GPID up to 4 tablets per 30 days.** Please use status code #056 and the approval text provided.

APPROVAL TEXT: Your request for **[DRUG]** has been approved with a quantity limit of _____ per 30 days for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

14. Does the request exceed 4 tablets per 30 days?

If yes, do not approve. Please use status code #238 and the denial text provided.

TADALAFIL (CIALIS) DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, your plan covers tadalafil (Cialis) up to 4 tablets per 30-day supply. Additional doses of tadalafil (Cialis) are only covered when prescribed for rehabilitation after recent prostate surgery or for the treatment of Benign Prostatic Hyperplasia (BPH). Your provider did not indicate that you are being treated for either of these conditions and therefore your request was not approved.

SILDENAFIL (VIAGRA)/ LEVITRA/STAXYN/STENDRA DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, your plan covers 4 tablets per 30-day supply. Additional doses of **[DRUG]** are only covered when prescribed for rehabilitation after recent prostate surgery (within the previous three months). Your provider did not indicate that you are being treated for this condition and therefore your request was not approved.

If no, a prior authorization is not required if the request does not exceed #4 tablets per 30 days for drugs covered on the formulary.

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PHOSPHODIESTERASE 5 INHIBITOR (PDE5I) AGENTS**

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for a female or a patient under 18 years of age?

If yes, **defer to HPHC.**

If no, continue to #2.

2. Does the member have a diagnosis of Benign Prostatic Hyperplasia (BPH)?

If yes, continue to #3.

If no, continue to #5.

3. Has the patient shown improvement?

If yes, continue to #4.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, authorization for renewal requires documentation of improvement. Your provider did not indicate that your symptoms have improved and therefore your request was not approved.

4. Is the request for tadalafil (Cialis) 2.5mg or 5mg?

If yes, **approve tadalafil (Cialis) 2.5mg or 5mg for 12 months by GPID with a quantity limit of 30 tablets per 30 days.** Please use status code #056 and the approval text provided.

APPROVAL TEXT: Your request for _____ has been approved for 30 tablets per 30-day supply for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided. (**NOTE:** If the request was previously approved by HPHC, please defer to HPHC.)

DENIAL TEXT (tadalafil (Cialis) 10 mg or 20 mg): Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, tadalafil (Cialis) is only covered for the treatment of Benign Prostatic Hyperplasia (BPH) in a dose up to 5mg per day. The requested dosage exceeds the FDA-approved recommended dose for the treatment of BPH and therefore your request was not approved.

DENIAL TEXT (non-Cialis requests): Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, this medication is not covered for the treatment of Benign Prostatic Hyperplasia (BPH). Your provider indicated you would be taking this medication for the treatment of BPH and therefore your request was not approved.

5. Is the request for a member being treated for penile rehabilitation following prostatectomy?

If yes, continue to #6.

If no, continue to #8.

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RENEWAL CRITERIA (CONTINUED)

6. Has the member previously received a 6 month course of therapy with a PDE-5 Inhibitor post-prostatectomy?

If yes, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, your plan covers **[DRUG]** for up to 180 days post-prostatectomy. Our records indicate you have received 180 days of medication, and therefore the request for additional dosages was not approved.

If no, continue to #7.

7. Is the request for a non-covered medication (i.e., a rejection of 'Product Not in Formulary')?

If yes, **approve the requested medication by GPID to allow up to 180-days of therapy post-prostatectomy for the quantity requested, up to a maximum quantity of 30 tablets per 30 days.** Please use status code #056 and the approval text provided.

APPROVAL TEXT: Your request for **[DRUG]** has been approved with a quantity limit of _____ per 30 days for a 6-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

If no, **approve the requested medication by GPID to allow up to 180-days of therapy post-prostatectomy for the quantity requested, up to a maximum quantity limit listed below.**

Please use status code #056 and the approval text provided.

- **Tadalafil (Cialis) 2.5mg or 5mg: 30 tablets per 30 days**
- **Tadalafil (Cialis) 10mg or 20mg: 10 tablets per 30 days**
- **Sildenafil (Viagra): 30 tablets per 30 days**
- **Levitra: 30 tablets per 30 days**
- **Staxyn: 30 tablets per 30 days**
- **Stendra: 30 tablets per 30 days**

APPROVAL TEXT: Your request for **[DRUG]** has been approved for **[##]** tablets per 30-day supply for a _____ period.

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RENEWAL CRITERIA (CONTINUED)

8. Does the member have a diagnosis of Erectile Dysfunction (ED)?

If yes, continue to #9.

If no, do not approve. Please use status code #238 and the denial text provided.

TADALAFIL (CIALIS) DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, tadalafil (Cialis) is only covered for renewal when prescribed for erectile dysfunction, rehabilitation after recent prostate surgery or for the treatment of Benign Prostatic Hyperplasia (BPH). Your provider did not indicate that you are being treated for one of these conditions and therefore your request was not approved.

SILDENAFIL (VIAGRA)/ LEVITRA/STAXYN/STENDRA DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, **[DRUG]** is only covered for renewal when prescribed for erectile dysfunction or rehabilitation after recent prostate surgery. Your provider did not indicate that you are being treated for one of these conditions and therefore your request was not approved.

9. Has the patient shown improvement?

If yes, continue to #10.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, authorization for requires documentation of improvement. Your provider did not indicate that your symptoms have improved and therefore your request was not approved.

10. Is the request is for a non-formulary medication (i.e., a rejection of 'Product Not in Formulary')?

If yes, continue to #11.

If no, continue to #12.

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RENEWAL CRITERIA (CONTINUED)

11. Does the request exceed 4 tablets per day?

If yes, **partially deny and enter a proactive prior authorization for the requested drug for 12 months by GPID up to 4 tablets per 30 days.** Please use status code #238 and the partial denial text provided.

PARTIAL DENIAL TEXT: Your request for [DRUG] has been partially approved with a quantity limit of 4 tablets per 30 days for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier. Per your health plan's Erectile Dysfunction Agents guideline, your plan covers 4 tablets per 30-day supply. Additional doses of [DRUG] are only covered when prescribed for rehabilitation after recent prostate surgery. Your provider did not indicate that you are being treated for this condition and therefore your request was approved for 4 tablets per 30-day supply for a twelve-month period.

If no, **approve the requested drug for 12 months by GPID up to 4 tablets per 30 days** Please use status code #056 and the approval text provided.

APPROVAL TEXT: Your request for [DRUG] has been approved with a quantity limit of 4 tablets per 30 days for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

12. Does the request exceed 4 tablets per day?

If yes, **do not approve.** Please use status code #238 and the denial text provided.

TADALAFIL (CIALIS) DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, your plan covers tadalafil (Cialis) up to 4 tablets per 30-day supply. Additional doses of tadalafil (Cialis) are only covered when prescribed for rehabilitation after recent prostate surgery or for the treatment of Benign Prostatic Hyperplasia (BPH). Your provider did not indicate that you are being treated for either of these conditions and therefore your request was not approved.

SILDENAFIL (VIAGRA)/ LEVITRA/STAXYN/STENDRA DENIAL TEXT: Per your health plan's Phosphodiesterase 5 Inhibitor (PDE5I) Agents guideline, your plan covers 4 tablets per 30-day supply. Additional doses of [DRUG] are only covered when prescribed for rehabilitation after recent prostate surgery. Your provider did not indicate that you are being treated for this condition and therefore your request was not approved.

If no, a prior authorization is not required if the request does not exceed #4 tablets per 30 days for drugs covered on formulary.

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RATIONALE

Erectile Dysfunction agents are covered with quantity limits on the HPHC formulary. This guideline has been developed in order to address requests for quantities which exceed the quantity limits that are currently in place and is meant to ensure that patients with BPH are able to receive daily treatment with Cialis and that prostatectomy patients are able to receive an additional quantity of these agents within the first 3 months following surgery for a duration of up to 6 months post-surgery.

FDA APPROVED INDICATIONS

For the treatment of erectile dysfunction.

Cialis is also approved for the treatment of the signs and symptoms of Benign Prostatic Hyperplasia (BPH).

REFERENCES

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- Eli Lilly and Company. Cialis product information. Indianapolis, IN. May 2017.
- Schering-Plough Corporation. Levitra product information. Kenilworth, NJ. August 2017.
- GlaxoSmithKline. Staxyn product information. Research Triangle Park, NC. August 2017.
- Padma-Nathan H, McCullough AR, Levine LA, et al. Randomized, double-blind, placebo-controlled study of postoperative nightly sildenafil citrate for the prevention of erectile dysfunction after bilateral nerve-sparing radical prostatectomy. *Int J Impot Res* 2008;20:479–86.
- Montorsi F, Brock G, Lee J, et al. Effect of nightly versus on-demand vardenafil on recovery of erectile function in men following bilateral nerve-sparing radical prostatectomy. *Eur Urol* 2008;54:924-31.
- Vivus Inc. Stendra product information. Mountain View, CA. September 2017.

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