

# Pharmacy Management Drug Policy

**SUBJECT: PDE-5 Inhibitor Drugs-Medical Necessity Review (MMC & HARP)**

**POLICY NUMBER: PHARMACY-81**

**EFFECTIVE DATE: 6/1/2019**

**LAST REVIEW DATE: 12/15/2019**

*If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.*

## **DESCRIPTION:**

The New York State Department of Health (NYSDOH) has indicated that the PDE-5 inhibitor class of drugs **are not covered** by the Medicaid program when prescribed to treat sexual or erectile dysfunction. Pursuant to Appendix K, Section 10 (c)(vi)(5) of the Medicaid Managed Care/Family Health Plus/HIV Special needs Plan/Health and Recovery Plan (Model Contract), such drugs are not covered unless prescribed to treat a condition other than sexual or erectile dysfunction for which the drug has been approved by the FDA, as identified in Social Security Law, Section 1927 (g)(1)(B)(i).

This policy applies to both male and female members of all ages.

This policy applies only to Managed Medicaid and HARP members.

## **POLICY:**

1. Requests received for PDE-5 inhibitor medications, where the requesting provider indicates a diagnosis of sexual or erectile dysfunction, **cannot be covered**. The PDE-5 inhibitors are excluded from coverage when requested to treat sexual or erectile dysfunction. A benefit denial will be issued for any request for erectile dysfunction.

Requests received for PDE-5 inhibitors, for any FDA approved diagnosis other than sexual or erectile dysfunction (such as benign prostatic hyperplasia (BPH) or pulmonary arterial hypertension (PAH)), will be reviewed for medical necessity. The clinical criteria applied to the review will depend on the drug and diagnosis that is being requested (see "Review Process" below). Prior to doing the medical necessity review, the Erectile Dysfunction Verification System (EDVS) will be checked to determine the member's sex offender status and documented in the review case notes.

2. If the member is **not** on the sex offender list, the review will proceed per the Plan drug policy, and the request will be reviewed for medical necessity.
3. If the member **is found** on the sex offender list, the Plan pharmacist will outreach to the requesting provider to discuss alternative medically appropriate treatment options. If the provider is agreeable to an alternative treatment option, the information will be documented in the case notes and the review will proceed per the Plan's drug policy.
4. If the member **is found** on the sex offender list, and the requesting provider insists that the requested PDE-5 medication is medically necessary and declines other non-PDE-5 alternatives as not medically appropriate, the Plan medical director will outreach to the provider to engage in a peer to peer review of the case.

## Pharmacy Management Drug Policy

### PDE-5 Inhibitor Drugs-Medical Necessity Review (MMC & HARP)

- A. The Plan medical director will confirm that other alternative treatment options to treat the enrollee's health condition were considered as part of the decision-making process, and that the prescribing provider has clarified rationale to support the prescribed PDE5 inhibitor drug as medically appropriate and necessary to treat the health condition.

5. Based on the outcome of the peer to peer discussion, the following process will be followed:

**Approvals:** Approval will be granted upon verification with the prescribing provider that alternative treatment options were considered as part of the decision making process to prescribe a PDE5 inhibitor medication. The approval will be limited to a maximum of 30-day supply. The prescriber will need to confirm every 30 days that the medication is still necessary and is still the only medically appropriate treatment. If the member is on the sex offender list and the member requires long-term therapy with a PDE5 inhibitor medication an authorization request must be submitted by the member's prescribing provider every 30 days for review by the Plans' medical director. The provider will need to confirm that the medication is still necessary and continues to be the only medically appropriate treatment.

**Adverse Determinations:** An adverse determination for a prescribed PDE5 inhibitor medication will be issued after the Plan has made reasonable attempts to engage in a peer-to-peer discussion with the member's prescribing provider to understand the reasons behind the need for prescribing the requested PDE5 inhibitor medication. Per NYS DOH guidance, the time frame to issue a determination begins when all the information needed to complete the review is submitted to the plan. For the review of a PDE5 medication, this includes a response from the EDVS system and contact with the prescriber to discuss alternative treatment options.

6. In the event that the above process cannot be completed during normal business hours (due to after hours, holiday, or weekend requests, where the EDVS system is not available to report search results for the sex offender registry list), the plan can authorize a 72 hour emergency supply of a PDE-5 inhibitor medication, provided that the diagnosis being treated is confirmed to be an FDA approved diagnosis **other than sexual or erectile dysfunction** (such as BPH or PAH). When this occurs, the Plan should check the EDVS system as soon as possible on the first business day following this emergency supply being granted. If the member **is found** on the sex offender registry at that time, the Plan pharmacist and medical director must work with the member's provider to conduct a medical necessity review, including consideration of other alternative treatments in place of the PDE-5 medication, as described above.

#### **REVIEW PROCESS: (the processes below apply to reviews where the patient IS FOUND on the sex offender registry, thru checking of the EDVS system.)**

##### **1. Medication reviews for Benign Prostatic Hyperplasia (BPH)**

- A. Cialis, and its generic, tadalafil, are FDA approved to treat BPH. Any request for this drug and diagnosis will be screened as outlined above with the EDVS system, prior to clinical review.
- B. Cialis and generic tadalafil, when requested for BPH, are considered non-formulary drugs. Coverage exceptions will only be granted in specific limited cases:

## Pharmacy Management Drug Policy

### PDE-5 Inhibitor Drugs-Medical Necessity Review (MMC & HARP)

1. Provider attests that all formulary drugs, both brand and generic (including the exact generic equivalent if available) from the same therapeutic drug class have been tried and failed **AND**

Medical documentation is submitted that supports at least one of the following for each of the failed products:

- Hypersensitivity (allergic reaction)
  - Severe indisputable drug intolerance
  - Clinical ineffectiveness
- C. Current formulary alternatives, to treat BPH, include finasteride, tamsulosin, Rapaflo (or generic silodosin), alfuzosin, terazosin, dutasteride, and dutasteride/tamsulosin.
  - D. If the member has not tried ALL formulary alternatives, and medical justification is not submitted to support a formulary exception, a denial for tadalafil will be issued.
  - E. If the requesting provider indicates that the requested PDE-5 drug is medically necessary, and the member cannot take the alternative treatment options, a Plan medical director will complete the review process, as outlined above (“POLICY” lines 4 and 5, above).

### 2. Medication reviews for Pulmonary Arterial Hypertension (PAH)

- A. Please refer to the Plan drug policy “Pharmacy-42: Pulmonary Arterial hypertension”, which lists clinical criteria that applies to all non-Medicare lines of business (including Managed Medicaid and HARP requests).

In addition to the clinical review for coverage per policy, any request for Revatio, generic sildenafil, Adcirca, and generic tadalafil, for a diagnosis of PAH, will be screened as outlined above with the EDVS system, prior to clinical review.

- B. Any request made for Revatio, generic sildenafil, Adcirca, or generic tadalafil for a member who **is registered** as a sex offender (confirmed in EDVS verification system as outlined above) will require the Plan pharmacist to outreach to the requesting provider, to discuss alternative treatment options. The Plan pharmacist will inform the requesting provider that the Plan will allow use of any alternative treatment options to treat PAH listed in our policy, such as Letairis, Opsumit, Tracleer, Uptravi, Orenitram, or Adempas (provided all other clinical criteria are met).
- C. If the requesting provider indicates that the requested PDE-5 medication is medically necessary, and the member cannot take the alternative treatment options, a Plan medical director will complete the review process, as outlined above (“POLICY” lines 4 and 5 above).

## Pharmacy Management Drug Policy

### PDE-5 Inhibitor Drugs-Medical Necessity Review (MMC & HARP)

#### 3. Osphena for women

- A. Drugs to treat sexual dysfunction in women **are not covered** unless they have an indication **unrelated** to sexual dysfunction. Currently Osphena is the only drug for use in females that has an indication for both dyspareunia and vaginal dryness, a symptom of vaginal atrophy. A request for Osphena can be approved if the **ONLY** diagnosis indicated is vaginal dryness (a symptom of vaginal atrophy). If the requesting provider indicates that the patient has a diagnosis of dyspareunia – the request **must be denied**. In cases where the request indicates that the patient has both diagnoses ( dyspareunia AND vaginal dryness ) – the request **must be denied**.

#### **GUIDELINES:**

1. Requests for PDE-5 medications will not be denied based solely on the requesting member being registered as a sex offender in the EDVS system. The review process (including all steps by the Plan medical director above) will result in the request being either approved or denied for medical necessity.
2. When discussing requests with providers, it is permissible to inform the requesting provider that the member is registered as a sex offender on the HCS EDVS system, when discussing medically acceptable treatment alternatives.

#### **UPDATES:**

| Date     | Revision |
|----------|----------|
| 12/2019  | Revised  |
| 5/2019   | Revised  |
| 4/1/2019 | Created  |