DRUG DETERMINATION POLICY

Title: DDP-02 Formulary Alternatives and Exclusions

Effective Date: 01/14/2022

Physicians Health Plan

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the process for coverage of formulary alternative drugs and excluded drugs.

This policy does not guarantee or approve Benefits. Coverage depends on the specific Benefit plan. Pharmacy Benefit Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Health Plan covers medications requiring prior approval through the medical or outpatient Prescription Drug benefits using the following determination guidelines.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. General

A. Medication trial [must meet all listed below]:

1. No Pharmaceutical sample use: the Plan does not recognize samples as a medication trial or for continuation of therapy.

2. Trial timeline [must meet all listed below]:

a. Duration: continuous use of a medication for four months at therapeutic doses (exceptions can be made for fast onset medications).

b. Timeframe: within an acceptable time range (e.g., how long ago) relevant to disease state.

3. Medical condition: specifically prescribed and monitored for the treatment of the same medical condition.

B. Diagnosis: meets standard diagnostic criteria that designates signs, symptoms and test results to support the specific diagnosis.

C. Single medication authorization/approval: only one medication is prior authorized/approved for the same medical condition in the same timeframe (to assess single product trial outcome).

D. Contraindications and black box warnings determination [must meet both listed below]

1. Published in the Food and Drug Administration approved product Package Insert (PI).

2. Verifies a documented "contraindication" to a preferred product.

E. Site of care: preferred site of care determined by the Health Plan.

II. Formulary Designation.

A. Excluded drugs: determined not to be a covered benefit [must meet one below]

1. Traditional drugs as designated by Health Plan [must meet one listed below]:

a. Contraindicated, inadequate response or significant adverse effects to all preferred products.

2. Specialty drugs as designated by Health Plan: exceptions can be made to cover the excluded drug [must meet one listed below]:

a. Contraindicated, inadequate response or significant adverse effects to all preferred products.

b. Continuation of long-term stable therapy established for at least six months.

3. Compounded drugs (see Appendix II): individual review of cases.

4. OTC (over-the-counter) products and equivalents: OTC or chemical equivalent products to prescription drug including combination agents.

5. New-to-market block: new medication introduced to the market that has not yet been reviewed at the Pharmacy and Therapeutics (P & T) Committee and therefore blocked from coverage [must meet one listed below]:

a. Contraindicated, inadequate response or significant adverse effects to all preferred products.

b. At least two supporting articles from major peer-reviewed medical journals that support a significant advantage (safety or efficacy) compared to formulary drugs.

B. Utilization management edits [must meet preferred alternative/step therapy AND therapeutic edits listed below]

1. Preferred alternative: contraindicated, inadequate response or significant adverse effects to one listed below:

a. At least two preferred therapeutically equivalent alternative medication trials plus the generic if available; or

b. At least two preferred medically appropriate medications, if no preferred therapeutic equivalent exists.

2. Step therapy: designated preferred or generic formulary medication trial(s) [must meet one listed below]:

a. Contraindicated, inadequate response or significant adverse effects to designated step therapy medication trial(s).

3. Therapeutic edits

a. Supply limits: within the supply limit (day's supply or quantity limit) established by the Plan

b. Other edits (e.g. age, gender): meets the pertinent edits established by the Plan

C. Appropriate medication use [must meet both listed below]:

1. FDA approval status [must meet one listed below]:

a. FDA approved: product, indication, and/or dosage regimen.

b. Non-FDA approved: compendium support (Lexicomp™) for use of a drug for a non-FDA approved indication or dosage regimen.

2. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

III. Medication Trial Outcome.

A. Inadequate response [must meet both listed below]:

1. Fill history [must meet both listed below]:

a. Consistent fill history electronically or verbally from pharmacy.

b. Physician attestation of medication use if no fill history as above.

2. Documentation: chart note indicating inadequate response with objective data.

B. Clinically significant adverse drug effect or reaction [must meet all listed below]:

1. Fill history [must meet one listed below]:

a. Fill history electronically or verbally from pharmacy.

b. Physician attestation of medication use if no fill history as above.

2. Documentation: chart note indicating clinically significant adverse drug effect with objective data.

3. Causality supported: consistent time course and literature support for adverse drug reaction.

4.0 Unique Configuration/Prior Approval/Coverage Details:

None.

5.0 References, Citations & Resources:

1. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology https://www.nccn.org/professionals/physician_gls/default.aspx accessed December 2020.
2. http://online.factsandcomparisons.com/MonoDisp.aspx?monoID=fandc-hcp15420&quick=430846%7c14&search=430846%7c14&isstemmed=true - #FDA "Compounded Menopausal Hormone therapy: Questions and Answers.

6.0 Appendices:

See page 5.

7.0 Revision History:

Original Effective Date: June 24, 2014

Next Review Date: 01/27/2023

Revision Date	Reason for Revision
2/19	Transitioned to new format
4/19	Modified I. General A-D and IIB1 Preferred alternative
9/19	Opened for off cycle review; replaced abbreviations, reformatted med use by diagnosis to Appropriate Medication Usage added place in therapy, clarified step therapy; removed COC citation
4/20	Annual review; changed excluded drug /utilization management (UM) verbiage, clarified choice instructions, added generic to UM 1a; replaced abbreviations
12/20	Annual review, changed trial duration from 3 to 4 months, added NCCN category 2A to place in therapy, clarified instructions; added diagnosis statement under general section, approved by P&T 2/24/21
5/21	Off cycle review, added compendium support for non-FDA approved indication
12/21	Annual review added quantity limit under appropriate use section, clarification or OTC exclusions

Appendix I: Risks associated with compounded drugs

A. Compounded drugs can pose direct and indirect health risks:
   - Direct health risks: poor quality compounding practices resulting in sub- or super-potent, contaminated, or otherwise adulterated unsafe products.
   - Indirect health risks: use of ineffective compounded drugs instead of FDA-approved drugs shown to be safe and effective.

B. Pharmacists may not be well-trained/well-equipped to compound certain medications safely:
   - Various levels of compounding skills and equipment; some drugs may be inappropriate for compounding.
   - Lack of sufficient controls (e.g., equipment, training, testing, or facilities) to ensure compounded product quality for complex drugs like sterile or extended-release drugs.
   - Unknown quality of compounded drugs can pose potential risks to the patients.

C. Pharmacy compounders with high-volume distribution increase the risk of patient harm.

   FDA warning examples:
   - December 2006: five firms were warned about their standardized compounded high-strength topical anesthetic creams. Two deaths connected to the anesthetics compounded by two pharmacies.
   - August 2006: three firms were warned to stop manufacturing & distributing thousands of doses of unapproved "compounded" inhalation drugs. Serious concerns sited included inadequate quality control, variable potency and compounding copies of FDA-approved drugs.
   - March 2006: Maryland firm was warned regarding contaminated compounded of cardioplegia solutions used in open-heart surgeries; 5 serious systemic infections in five hospitalized patients resulted in three deaths.