Pharmacy Benefit Determination Policy

Policy Subject: Formulary Alternatives and Exclusions	**Dates:**
Policy Number: SHS PBD45	**Effective Date:** June 24, 2014
Category: Miscellaneous	**Revision Date** October 29, 2018
Policy Type: ☒ **Medical** ☒ **Pharmacy**	**Approval Date:** February 27, 2019
Department: Pharmacy	**Next Review Date:** December 2019
Line(s) of Business:	**Clinical Approval By:**
☒ Physicians Health Plan: HMO, POS	**Medical Directors**
☒ PHP Insurance Company: PPO	PHP: Peter Graham, MD
☒ PHP Service Company: TPA, Sparrow ASO	**Pharmacy and Therapeutics Committee**
☒ Sparrow PHP: Exchange	PHP: Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance and Service Company, and Sparrow PHP will cover medications requiring prior authorization through the Medical or Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:

J-code: various

Clinical Determination Guidelines:

Document the following with chart notes:

I. General
- A. Medication Trial:
  1. Pharmaceutical sample(s): Not recognized as a medication trial or continuation of therapy.
  2. Trial duration: Continuous use of a medication for 3 months.
- B. Contraindication and Black Box Warnings:
  1. Reference source: Identified in the drugs Package Insert (PI)
  2. Relevance to policy: Provides an exception for the use of a preferred agent
- C. 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.
  1. Traditional drugs (designated by health plan):
     a. All preferred products are contraindicated, failed or resulted in significant adverse effects
  2. Specialty drugs (designated by health plan): Exceptions can be made to cover the excluded drug (one below):
     a. All preferred products are contraindicated, failed or resulted in significant adverse effects
     b. Continuation of long-term stable therapy: Established for $\geq$ 6 months
  3. Compounded drugs (see Appendix II): Individual review of cases
  4. OTC equivalents: OTC chemical equivalent to prescription drug including combination agents.

B. Utilization Management Edits (one below)
1. Preferred alternative (AHFS Pharmacologic-Therapeutic Classification -Appendix I): One below
   a. AHFS tier 3 drug: ≥ 2 preferred agents from AHFS tier 3 including available generic.
   b. AHFS tier 2 drug: ≥ 2 preferred agents from AHFS tier 2 if there's not ≥ 2 preferred AHFS tier 3 drugs.
2. Step therapy: ≥1 designated preferred formulary medication trial for a specific medical condition.
3. New-to-market block: New medication introduced to the market that has not yet been reviewed at P & T Committee and therefore blocked from coverage (one below)
   a. All preferred products contraindicated, failed or resulted in significant adverse effects
   b. ≥ 2 supporting articles from major peer-reviewed medical journals that supports a significant advantage (safety or efficacy) compared to formulary drugs.
4. Medication-use by diagnosis (one below)
   a. FDA approved
   b. Off-label use: ≥ 2 supporting articles from major peer-reviewed medical journals that support the off-label use as safe and effective

III. Medication Trial Outcome

A. Lack of Efficacy (all below)
1. Trial duration: 3 months at therapeutic dosage (exception may be made for fast-onset meds.)
2. Fill history (one below)
   a. Consistent fill history electronically or verbally from pharmacy
   b. Physician attestation of medication use if no fill history as above
3. Documentation: Chart note on lack of efficacy with objective data

B. Clinically Significant Adverse Drug Effect or Reaction (ADR): (all below)
1. Fill history (one 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 on clinically significant ADR with objective data
3. Causality supported: Consistent time course and literature support for ADR

Appendix I – Example of American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification

Some classes, like 16:00 and 60:00, only have a first tier, but others continue down the hierarchy with more granularity the further they go.

Compare the class for celecoxib (28:08.04.08) with aspirin (28:08.04.24):

AHFS Class Number	AHFS Class Description
28:00.00.00	Central Nervous System Agents
28:08.00.00	Analgesics and Antipyretics
28:08.04.00	Nonsteroidal Anti-inflammatory Agents
28:08.04.08	Cyclooxygenase-2 (COX-2) Inhibitors
28:08.04.24	Salicylates

Top to bottom tiers: Tier 1, tier 2, tier 3, tier 4

Appendix II: Risks associated with compounded drugs[3]

A. Compounded drugs can pose direct & 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 & effective.

B. Pharmacists may not be well-trained/well-equipped to compound certain medications safely:
   - Various levels of compounding skills & 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 ↑ the risk of patient harm.
   FDA warning examples:
   - December 2006: 5 firms warned about their standardized compounded high-strength topical anesthetic creams. 2 deaths connected to the anesthetics compounded by 2 pharmacies.
   - August 2006: 3 firms warned to stop manufacturing & distributing thousands of doses of unapproved "compounded" inhalation drugs. Serious concerns sited included inadequate quality control, variable potency & compounding copies of FDA-approved drugs.
   - March 2006: Maryland firm warned regarding contaminated compounded of cardioplegia solutions used in open-heart surgeries; 5 serious systemic infections in 5 hospitalized patients resulted in 3 deaths.

References and Resources:

1. List of AHFS Pharmacologic-Therapeutic Classification(abbreviated) accessed at http://resourcecenter.ovid.com/site/products/fieldguide/ipab/List_of_AHFS_Pharmacologic-.jsp on 2/23/17
2. List of AHFS Pharmacologic-Therapeutic Classification(c) accessed at http://www.mgh.org/Content/Uploads/UP%20Health%20System%20-%20Marquette/files/formulary/AHFS%20Pharmacologic-Therapeutic%20Classification%20(2012).pdf on 2/23/17
3. 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
4. PHP Outpatient Prescription Rider Section 2:#5.

Approved By:

M.D. 2/27/19

Peter Graham, MD – PHP Executive Medical Director Date

KBatteen 2/27/19

Kurt Batteen - Human Resources Date