PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY / PROCEDURE

`Policy/Procedure Number: MPRP4033 (previously RP100433)			**Lead Department: Health Services**	
Policy/Procedure Title: Brand Name Drug Requests			☒ **External Policy** ☐ **Internal Policy**	
Original Date: 01/15/2004 – Medi-Cal		**Next Review Date:** **Last Review Date: 05/12/2021**		
Applies to:	☒ **Medi-Cal**		☐ **Employees**	
Reviewing Entities:	☒ **IQI**	☒ **P & T**	☐ **QUAC**	
	☐ **OPERATIONS**	☐ **EXECUTIVE**	☐ **COMPLIANCE**	☐ **DEPARTMENT**
Approving Entities:	☐ **BOARD**	☐ **COMPLIANCE**	☐ **FINANCE**	☒ **P&C**
	☐ **CEO** ☐ **COO**	☐ **CREDENTIALING**	☐ **DEPT. DIRECTOR/OFFICER**	
Approval Signature: *Robert Moore, MD, MPH, MBA*			**Archived vs. DHCS Carve-Out** **Effective Date: 01/01/2022**	

I. RELATED POLICIES:

A. MPRP4059 - Formulary Utilization Management for Managing Pain Safely program
B. MCRO4018 - Pharmacy TAR Procedure
C. MPRP4001 - Pharmacy & Therapeutics (P&T) Committee
D. MCRP4064 - Continuation of Prescription Drugs
E. MPRP4063 - Designated Specialty Drugs

II. IMPACTED DEPTS.:

N/A

III. DEFINITIONS:

N/A

IV. ATTACHMENTS:

A. Med Watch form

V. PURPOSE:

Partnership HealthPlan of California (PHC) requires generic substitution when an equivalent generic product is available. This policy & procedure describes the guidelines for authorizing pharmacy Treatment Authorization Requests (TARs) for brand name drugs when an equivalent generic product is available.

VI. POLICY / PROCEDURE:

A. Title 22 Prior Authorization Adherence
   1. PHC adheres to Title 22 of the California Code of Regulations 51003: Authorization may be granted only for the lowest cost item or service covered by the program that meets the patient's medical needs.
   2. TITLE 22. Social Security, Division 3. Health Care Services, Subdivision 1. California Medical Assistance Program, Chapter 3. Health Care Services, Article 1.3. General Provisions, §51003. Prior Authorization.

B. Continuity of Care Legislation for Pharmacy
   1. PHC's policy of requiring a generic substitution when a member has previously received a brand name product, either by prescription or via sample from a clinician, does not violate the Continuity of Care legislation for pharmacy. The Continuity of Care bill, AB974, for those Health Plans who are Knox-Keene licensed and under the jurisdiction of the Department of Managed Healthcare (DMHC), specifically states that it prohibits "construing the provision to prohibit generic drug substitutions, pursuant to specified existing law".

C. Maximum Allowable Cost (MAC) List
   1. MAC pricing lists are reimbursement schedules currently developed by PHC's Pharmacy Benefit Manager (PBM) that determines both the ingredient cost used to calculate reimbursement to the dispensing pharmacy and the rate PHC pays to the PBM for generic pharmaceutical products. The PBM enforces the following criteria for a drug to be added to the MAC list:
      a. The drug must be a Multi-Source product with a generic available
      b. The generic product must be manufactured by at least one nationally marketed company
      c. At least one of the generic manufacturers must have an "A" or "Z" rating
      d. A significant price spread must exist between the brand and the generic product
      e. A product must be approved for generic substitution by the PBM's Pharmacy & Therapeutics Committee.

D. Food & Drug Administration (FDA) Ratings
   1. The US FDA has rated all generic drugs "A" or "B" (www.fda.gov/cder/ob/default.htm). "A" rated drugs are considered bioequivalent to the brand-name original. They either have been demonstrated to be so by human bioavailability study ("AB"), or are considered inherently unlikely to have bioavailability problems ("AA"); "AA" drugs are usually oral solutions or oral drugs that dissolve readily in water. Other "A" designations (AN, AO, AP, AT) refer to non-oral formulations considered bioequivalent by the FDA. Only "A" rated products are interchangeable with their brand-name equivalents by the FDA.
   2. "B" drugs have not been demonstrated to be bioequivalent by an *in vivo* test. These tend to be drugs that were approved by the FDA on the basis of chemistry, manufacturing controls and *in vitro* dissolution tests.

E. First Data Bank "Z" Rating
   1. "Z" rating is not an official rating by the FDA, but through First Data Bank, which supports databases for drugs. "Z" rating is generally used for entities that have been evaluated by the FDA for similar products, not a particular manufacturer's product, or that the reference product is no longer on the market and therefore equivalent designation could not be made. The publication ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (commonly known as the Orange Book) is the leading authority for basing substitution decisions at the pharmacy level. The FDA has stated that the Orange Book is advisory only; many states use its data to regulate product selection. When a bioequivalent rating for a drug is not provided in the Orange Book, a "Z" rating designation (see below) may be given to the drug if the drug has the same active ingredient at the same concentration and there are no existing therapeutic issues. MedImpact applies only "A" rated products on the MAC list.
      a. **ZA =** FDB assigns a ZA code to pharmaceutical entities evaluated by the FDA for whom the particular labeler's product was not evaluated, and therefore, is not in the Orange Book. The Orange Book lists drugs by the approved application-holder. This is usually, but not necessarily, the manufacturer. It is not possible to track the ultimate labeler of the products because they are not required to immediately notify the FDA when they change source. Therefore, generic distributors who do not hold approved applications will not receive A or B ratings, but will be assigned a ZA by FDB.
      b. **ZB =** FDB assigns a ZB code to all non-prescription pharmaceutical entities and those prescription pharmaceutical entities that are not evaluated in the Orange Book.
      c. **ZC =** FDB assigns a ZC code to products in the Orange Book that do not have a therapeutic equivalency rating. There are prescription products in the Orange Book that are not assigned equivalency ratings. These are single source items. Occasionally, a single source product will have an equivalency code if a company has several applications for the same drug. If a product goes from multi-source to

single source, expect the equivalency rating to change. This could mean going from a B rating to a Z rating.

F. Therapeutic Equivalence
   1. Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. FDA considers drug products to be pharmaceutical equivalent if they contain the same active ingredient(s), are of the same dosage form and route of administration, and identical in strength and concentration.

G. TARs for use of a brand name product when a generic equivalent is available will be considered for review when the following information is provided:
   1. Documentation from the member's prescription profile or from the prescriber's progress notes that the member has had a previous adequate trial of at least two (2) of the requested generic equivalents within 180 days of the request.
   2. Documentation from the member's prescription profile or from the prescriber's progress notes that the member has had a previous adequate trial of therapeutic alternatives within 180 days of the request.
   3. Medical justification why the member is unable to use the generic equivalent.
   4. Medical justification why the member cannot use an alternative therapeutic equivalent.
   5. If member is unable to use a generic equivalent due to an adverse event, a MedWatch form (Attachment A), completed by the prescriber documenting the adverse event with the generic equivalent drug, may be required.

H. Single-source and multisource brand name products are limited to a 30-day supply, unless otherwise allowed by PHC's formulary. Exceptions to this may be requested when monthly dispensing requirements are demonstrated to be an unnecessary burden to a member and filling less frequently is medically necessary to ensure optimum treatment response. Requests for exception to the 30-day limit should include patient-specific reasons why member is at risk with the 30 day requirement and:
   1. Member must be on a stable dose
   2. Member must be tolerating the treatment and not at risk of discontinuation due to adverse drug reactions (ADRs).
   3. The product must be considered to be a maintenance medication for a chronic illness
   4. The product cannot be one that is intended for short-term or "as-needed" (PRN) use
   5. The member must have the ability and education to store the product in compliance with the manufacturer's storage recommendations
   6. Reports of lost or stolen supplies larger than 30 day amounts may cause the approval of larger quantities to be forfeited going forward.
   7. Member must have expected continuation of eligibility beyond 30 days in the plan's eligibility information.
   8. Exceptions to the 30-day limit will not be made for specialty drugs nor for Schedule II-V substances (See policy MPRP4059 *Formulary Utilization Management for Managing Pain Safely program*)

VII. REFERENCES:

N/A

VIII. DISTRIBUTION:

A. PHC Department Directors
B. PHC Provider Manual
C. Pharmacy Procedure Manual

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IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE:
Pharmacy Services Director

X. REVISION DATES:
Medi-Cal
07/07/05; 07/24/08; 10/28/10; 04/04/13; 10/1/15; 10/6/16; *06/13/18; 05/08/19; 05/13/20; 05/12/21; Archived vs. DHCS Carve-Out Effective 01/01/2022

*Through 2017, Approval Date reflective of the Pharmacy & Therapeutics Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO:
Healthy Families:
MPRP4033 - 10/28/2010 to 03/01/2013

Healthy Kids (Healthy Kids program ended 12/01/2016)
07/24/08; 10/28/10; 04/04/13; 10/1/15; 10/6/16 to 12/01/16

XI. POLICY DISCLAIMER:
A. In accordance with the California Health and Safety Code Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:
   1. Consistent with sound clinical principles and processes
   2. Evaluated and updated at least annually
   3. If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request
B. The materials provided are guidelines used by PHC to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under PHC.
C. PHC's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.