POLICY AND PROCEDURE	
Policy # and TITLE: PH11 Therapeutic Interchange	
Primary Policy owner: Pharmacy	**POLICY #:** PH11
Impacted/Secondary policy owner: Select the department(s) that are responsible for compliance with all, or a portion of the policy or procedure as outlined	
1) ☐All Departments 2) ☐Behavioral Health (BH) 3) ☐Benefits Administration (BA) 4) ☐Care Management (CM) 5) ☐Claims (CLMS) 6) ☐Community Marketplace & Member Engagement (MAR) 7) ☐Compliance (CMP/HPA) 8) ☐Configuration (CFG) 9) ☐Provider Contracting (CONT) 10) ☐Cultural & Linguistics (CL) 11) ☐Customer Service (CS)	12) ☐Facilities (FAC) 13) ☐Finance (FIN) 14) ☐Human Resources (HR) 15) ☐Information Technology / Core Systems (IT) 16) ☒Pharmacy (PH) 17) ☐Provider Networks (PRO) 18) ☐QI Health Equity (GRV/HE/HEQ/PHM/QM) 19) ☐ Utilization Management (UM)
PRODUCT TYPE: ☒Medi-Cal	**Supersedes Policy Number:** N/A

I. PURPOSE

To explain the purpose, situations, and rationale for when therapeutic interchanges may be considered.

II. POLICY

San Joaquin County Health Commission ("Commission"), operating and doing business as Health Plan of San Joaquin and Mountain Valley Health Plan ("Health Plan") uses Therapeutic Interchange to promote rational

pharmaceutical therapy when evidence suggests that outcomes can be improved by substituting a drug that is therapeutically equivalent but chemically different from the prescribed drug. Improved outcomes include, but are not limited to, enhanced compliance, superior side-effect or risk profile, clinically superior results, and equivalent clinical results at reduced cost.

III. PROCEDURE

A. Therapeutic Interchange promotes rational pharmaceutical therapy in a setting of rapid expansion in the number of drugs within the same or comparable therapeutic classes coupled with the need to control drug and related health care costs while improving outcomes. The goal of Therapeutic Interchange is to improve patient access to more affordable health care.

B. Although usually of the same pharmacologic class, drugs appropriate for Therapeutic Interchange may differ in chemistry or pharmacokinetic properties and may possess different mechanism of action, adverse reaction, toxicity, and drug interaction profiles. In most cases, the drugs to be interchanged have very similar efficacy and safety profiles.

C. Therapeutic Interchange promotes rational pharmaceutical therapy by suggesting that a prescribing practitioner consider prescribing an alternate, therapeutically equivalent, drug for one initially prescribed if the alternate has the potential to either:

   1. Improve clinical outcomes.
   2. Enhance compliance.
   3. Reduce side effects.
   4. Lessen patient risk.
   5. Produce equivalent clinical outcomes while reducing cost.

D. Drugs may be considered for Therapeutic Interchange if they are:

   1. High risk

2. High volume
3. High cost
4. Overused in routine conditions

E. Therapeutic Interchange protocols are based upon information from authoritative sources considering the characteristics of the Health Plan's member population and local practice conditions. Information sources considered in the development, revision and approval of Therapeutic Interchange Protocols include:

1. Published scientific literature, including clinical practice guidelines and algorithms.
2. Facts and Comparison Formulary Services.
3. Micromedex.
4. National Guidelines Clearinghouse, of the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services.
5. American Hospital Formulary Services.
6. Food and Drug Administration.
7. FDA-approved manufacturer labeling information.
8. Recommendations of medical and health care specialty and standard-setting organizations.
9. The recommendations of governmental health care, research, and regulatory bodies.

F. In designing Therapeutic Interchange protocols, drug characteristics are considered including:

1. Efficacy, the expected partial or total response or tolerance by a patient to a complete course of therapy under ideal conditions including consideration of the ranges of indications with documented efficacy for each drug in the group.

2. Effectiveness, the expected partial or total response or tolerance by a patient to a complete course of therapy in the usual clinical practice setting.
3. Dosage formulation, including the convenience of preparation and administration, frequency of dosing, range of dosage forms, and stability.
4. Safety, including contraindications, warnings, and adverse effects, as well as look-alike and sound-alike products.
5. Cost, usually focused on acquisition cost, although other costs are sometimes relevant such as ancillary supplies for intravenous formulations.
6. Pharmacoeconomic variables, other than drug cost, such as costs for laboratory tests.

G. Off-label use of drugs is considered when identifying drugs for Therapeutic Interchange protocols.

1. The likelihood of identical package inserts indications for any two or more drugs involved in a Therapeutic Interchange is extremely unlikely.
2. Labeling is an FDA assignment of drug use, not necessarily an up-to-date reflection of clinical drug application from the literature and may not account for more individualized application for each practice setting.
3. The FDA and package labeling are not restrictive of use of the drug and use for off-label medical reasons is a risk-benefit analysis for each patient.

H. Therapeutic Interchange protocols are never automatic. That is, a servicing provider may not substitute an alternate, therapeutically equivalent, drug for a prescribed drug without the knowledge and authorization of the prescribing practitioner.

1. When a Therapeutic Interchange opportunity is identified, the servicing provider and the prescribing provider receives relevant clinical information about the proposed Therapeutic Interchange

and a message asking the servicing provider to discuss the potential Therapeutic Interchange with the prescribing practitioner.

2. If the prescribing practitioner approves the Therapeutic Interchange, the new prescription is reviewed and validated by the servicing provider before it is filled.
3. The servicing provider or the prescribing practitioner notifies the member of the Therapeutic Interchange.
4. Therapeutic Interchange is voluntary on the part of the member and the prescribing practitioner. Any proposed Therapeutic Interchange may be refused.
5. The prescribing practitioner or the member can request an appeal following the processes found within QM65, Member Appeals, for the original request without the use of the Therapeutic Interchange recommended to them.

I. Upon P&T Committee approval of a Therapeutic Interchange protocol, the Pharmacy Director:

1. Verifies documentation of the approved Therapeutic Interchange protocol in the P&T meeting minutes.
2. Notifies individuals responsible for implementing the Therapeutic Interchange protocol of the change.
3. Formally documents the Therapeutic Interchange protocol.
4. Ensures that:
    a. Affected providers are notified in writing no less than forty-five (45) business days before the changes take effect.
    b. Member and Provider quarterly newsletters remind their recipients that the medical benefit has been updated and updates can be viewed on the organization's website.

IV. ATTACHMENT(S)

A. DHCS Medi – Cal Managed Care Plans Definitions (Exhibit A, Attachment I, 1.0 Definitions)
B. Glossary of Terms Link
C. Medi-Cal Managed Care Contract Acronyms List (Exhibit A, Attachment I, 2.0 Acronyms)

V. REFERENCES

A. DHCS APL 22-012 – Governor's Executive Order N-01-19, Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx
B. NCQA Standard UM 13 – Procedures for Pharmaceutical Management

VI. REVISION HISTORY

*Version 001 as of 01/01/2023

Version*	Revision Summary	Date
000	9/12, 11/15, 02/16, 02/17, 02/18, 12/18, 07/19, 12/19, 06/21, 12/21, 12/22	N/A
001	Moved PH11 onto new 2023 template	3/31/2023
002	Reviewed and no changes made.	9/6/2023
Initial Effective Date: 9/18/2012		

VII. Committee Review and Approval

Committee Name	Version	Date
Compliance Committee	002	2/15/2024
• Privacy & Security Oversight Committee (PSOC)		
• Program Integrity Committee		
• Audits & Oversight Committee		
• Policy Review	002	12/20/2023
Quality and Utilization Management	001	1/18/2023

• Quality Of Care		
• Grievance		

VIII. REGULATORY AGENCY APPROVALS

Department	Reviewer	Version	Date
Department of Healthcare services (DHCS)	N/A	N/A	N/A
Department of Managed Care (DMHC)	N/A	N/A	N/A

IX. Approval *signature**

Signature	Name Title	Date
	PRC Chairperson	
	Policy Owner	
	Department Executive	
	Chief Executive Officer	

*Signatures are on file, will not be on the published copy