POLICY AND PROCEDURE	
Title: Therapeutic Interchange and Biosimilar Substitution Policy	
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 & Social Services (BH/SS) 3) ☐Benefits Administration (BA) 4) ☐Case 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) 20) ☐ Procurement (PRM) 21) ☐ Administration (SAF/BC/EM) 22) ☐ Medical Management (MM)
Product type: ☒Medi-Cal ☐D-SNP	**Supersedes Policy Number:** N/A

I. PURPOSE

To explain the purpose, situations, and rationale for when therapeutic interchanges or biosimilar substitution 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**

1. 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.
2. 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.
3. 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:
    a. Improve clinical outcomes.
    b. Enhance compliance.
    c. Reduce side effects.
    d. Lessen patient risk.

e. Produce equivalent clinical outcomes while reducing cost.

4. Drugs may be considered for Therapeutic Interchange if they are:
    a. High risk.
    b. High volume.
    c. High cost.
    d. Overused in routine conditions.
5. 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:
    a. Published scientific literature, including clinical practice guidelines and algorithms.
    b. Facts and Comparison Formulary Services.
    c. Micromedex.
    d. National Guidelines Clearinghouse, of the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services.
    e. American Hospital Formulary Services.
    f. Food and Drug Administration.
    g. FDA-approved manufacturer labeling information.
    h. Recommendations of medical and health care specialty and standard-setting organizations.
    i. The recommendations of governmental health care, research, and regulatory bodies.
6. In designing Therapeutic Interchange protocols, drug characteristics are considered including:

a. 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.

b. Effectiveness, the expected partial or total response or tolerance by a patient to a complete course of therapy in the usual clinical practice setting.

c. Dosage formulation, including the convenience of preparation and administration, frequency of dosing, range of dosage forms, and stability.

d. Safety, including contraindications, warnings, and adverse effects, as well as look-alike and sound-alike products.

e. Cost, usually focused on acquisition cost, although other costs are sometimes relevant such as ancillary supplies for intravenous formulations.

f. Pharmacoeconomic variables, other than drug cost, such as costs for laboratory tests.

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

    a. 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.

    b. 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.

8. 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.

a. 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.

b. If the prescribing practitioner approves the Therapeutic Interchange, the new prescription is reviewed and validated by the servicing provider before it is filled.

c. The servicing provider or the prescribing practitioner notifies the member of the Therapeutic Interchange.

d. Therapeutic Interchange is voluntary on the part of the member and the prescribing practitioner. Any proposed Therapeutic Interchange may be refused.

e. 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.

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

a. Verifies documentation of the approved Therapeutic Interchange protocol in the P&T meeting minutes.

b. Notifies individuals responsible for implementing the Therapeutic Interchange protocol of the change.

c. Formally documents the Therapeutic Interchange protocol.

d. Ensures that:

1. Affected providers are notified in writing no less than forty-five (45) business days before the changes take effect.
2. 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.

B. **Biosimilar Substitution**

1. A Biosimilar is a biologically engineered medication that is highly similar to existing U.S. Food and Drug Administration (FDA)-approved innovator drugs. The are no clinical differences between the biosimilar and the FDA approved innovator product.
2. An Innovator is the brand biologic medication that was first to market for a unique drug or product.
3. Biosimilar substitution occurs when Health Plan requires the use of a biosimilar medication before the approval of the FDA approved innovator product. The goal is to improve patient access to more affordable health care when there are multiple products in the marketplace to treat a condition.
4. Health Plan may require a biosimilar medication prior to approval of innovator products based on the following criteria. Health Plan incorporates biosimilar substitution requirements into the respective agent's Health Plan Pharmacy and Therapeutics Coverage Policy Criteria.

    a. In designing Biosimilar Substitution protocols, drug characteristics are considered including:

        i. 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.

ii. Effectiveness, the expected partial or total response or tolerance by a patient to a complete course of therapy in the usual clinical practice setting.

iii. Dosage formulation, including the convenience of preparation and administration, frequency of dosing, range of dosage forms, and stability.

iv. Safety, including contraindications, warnings, and adverse effects, as well as look-alike and sound-alike products.

v. Cost, usually focused on acquisition cost, although other costs are sometimes relevant such as ancillary supplies for intravenous formulations.

vi. Pharmacoeconomic variables, other than drug cost, such as costs for laboratory tests.

b. For those drugs where a biosimilar equivalent exists for the brand innovator drug and no contraindication exists to the use of the biosimilar, the biosimilar medication will be required before the brand innovator product.

c. When a new FDA approved biosimilar becomes available in the market, the Pharmacy Director ensures that the medical claims adjudication system is updated with the biosimilar information.

d. Health Plan makes all reasonable attempts to obtain information needed to make a timely determination by contacting the prescribing practitioner or designated staff to obtain needed information.

i. The information required is documentation of any previous reaction to biosimilar products of the same medication tried before.

ii. Requests for the brand innovator drug are approved when the use of at least 1 biosimilar medication with

the same indication and FDA approval as the brand innovator drug has been tried and either:

A. No improvement was noted after an adequate trial of the biosimilar product; OR

B. The patient has documented intolerance to the biosimilar product.

e. Examples of Biosimilars in the marketplace:

i. Biosimilar for Epogen®/Procrit® = Retacrit®

ii. Biosimilar for Neulasta® = Fulphila™, Fylnetra®, Nyvepria™, Stimufend®, Udenyca™, Ziextenzo™

iii. Biosimilar for Neupogen® = Nivestym™, Releuko®, Zarxio®

iv. Biosimilar for Neupogen® = Nivestym™, Releuko®, Zarxio®

v. Biosimilar for Avastin® = Alymsys®, Mvasi™, Vegzelma®, Zirabev™

vi. Biosimilar for Herceptin® = Herzuma®, Kanjinti®, OgivriTM, Ontruzant®, Trazimera™

vii. Biosimilar for Rituxan® = Riabni™, Ruxience™, Truxima®

viii. Biosimilar for Lantus® = Rezvoglar™,Semglee®

ix. Biosimilar for Lucentis® = Byooviz®, Cimerli™

x. Biosimilar for Humira® = Abrilada™, Amjevita™, Cyltezo®, Hadlima™, Hyrimoz®, Hulio®, Idacio®, Yuflyma®, Yusimry™

C. The processes outlined in policy UM01, Authorization/Referral Process, PH05, Prior Authorization Review, and policy UM07, Notification to Members of Denial, Deferral, Modification Actions, are followed in making determinations.

D. The Appeals process described in policy QM65, Member Appeals, is available for any non-authorization determination.

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. Health Plan Policy PH05 – Prior Authorization Review
C. Health Plan Policy UM01 – Authorization/Referral Process
D. Health Plan Policy UM06 – Medical Review Criteria
E. Health Plan Policy UM07 – Notification to Members of Denial, Deferral, Modification Actions
F. NCQA Standard UM 11 – Procedures for Pharmaceutical Management

VI. REVISION HISTORY

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	03/31/2023
002	Reviewed and no changes made.	09/06/2023
003	Updated policy name to Therapeutic Interchange and Biosimilar Substitution Policy. Added procedures related to Biosimilar Substitution processes.	06/12/2024
004	Updated the off-label use procedure for therapeutic interchange. Reviewed and updated references sections.	03/06/2025

005	Formatting edits were made. Reviewed with no further changes.	03/04/2026
Initial Effective Date: 9/18/2012		
Published Date:08/20/2026		

VII. Committee Review and Approval to be Approved by Compliance

Committee Name	Version	Date
Compliance Committee (CC)	005	08/14/2026
• Privacy & Security Oversight Committee (PSOC)		
• Program Integrity Committee (PIC)		
• Audits & Oversight Committee (AOC)		
• Policy Review Committee (PRC)	002	12/20/2023
Quality Improvement Health Equity Committee (QIHEC)	005	05/20/2026
• Quality Operations Committee (QOC)		
• Grievance Committee (GC)		

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