HEALTH PLAN OF SAN JOAQUIN						
Subject: **Therapeutic Interchange**						
Department: Medical Management		**Unit:** Pharmacy		**Policy #:** PH11		
Effective Date: 09/18/2012	**Committee/Approval Date:** P&T 02/16/16	**Review/Revision Dates:** 9/12, 11/15, 02/16				
Applies To:	Medi-Cal	Yes	**X**	No		
	MCAP	Yes	**X**	No		
	TPA	Yes		No	**X**	

POLICY

A. HPSJ 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.

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 considered in light of the characteristics of HPSJ'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. The 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 a 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, thought 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 insert 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 dispensing 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 at the point-of-dispensing, the dispensing provider receives relevant clinical information about the proposed Therapeutic Interchange and a message asking him/her 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 dispensing practitioner before it is filled.

3. The dispensing practitioner notifies the member of the Therapeutic Interchange.

4. If the prescribing practitioner does not approve the proposed Therapeutic Interchange, the member's file is marked to prevent future intervention on that drug.

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

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 and of the relevant point-of-service messaging.

3. Formally documents the Therapeutic Interchange protocol.

4. Ensures that:

a. The on-line Formulary is updated prior to the effective date of the change.

b. Affected members and providers are notified in writing no less than 30 days before the changes take effect.

c. Member and Provider quarterly newsletters remind their recipients that formulary and/or formulary management policies are available online and/or in the Provider Manual (for providers).

d. The hard copy Formulary is updated at the next printing.

REFERENCE

A. NCQA Standard UM 13 – Procedures for Pharmaceutical Management

Health Plan of San Joaquin
Approval: Signatures on File

DHCS Contract Deliverables

Contract Reference	*Date of Approval*	*DHCS Unit*		*Contract Reference*	*Date of Approval*	*DHCS Unit*