



CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES

VOLUME 9: PHARMACY SERVICES	Effective Date: 7/07
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9.35 THERAPEUTIC INTERCHANGE AND AUTOMATIC SUBSTITUTION	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. PROCEDURE OVERVIEW

The increasing number of medications within therapeutic categories and the wide variation in price among those medications creates potential for significant cost savings through therapeutic interchange and automatic substitution. Therapeutic Interchange and Automatic Substitution programs also have the potential to ensure quality of care and improve outcomes for patient-inmates. The Systemwide Pharmacy & Therapeutics (P&T) Committee shall continually and objectively evaluate and select medications for Therapeutic Interchange or Automatic Substitution that are most appropriate for the needs of the patient-inmate population based on safety, effectiveness, and cost. The P&T Committee is responsible for Therapeutic Interchange or Automatic Substitution product selection, program monitoring and maintenance, and policy and procedure development. Therapeutic Interchange programs shall be guided by evidence-based prescribing guidelines. The programs shall work in conjunction with other approved California Correctional Health Care Services (CCHCS) tools including Care Guides to promote quality medical care.

II. PURPOSE

To outline the process for reviewing and approving medications for use in Therapeutic Interchange and Automatic Substitution.

III. DEFINITIONS

Automatic Substitution: Drug substitution by the pharmacist without prior approval from the ordering physician based upon the Systemwide P&T’s determination.

Therapeutic Equivalents: Drug products with different chemical structures that are of the same therapeutic or pharmacological class which can usually be expected to have similar outcomes and adverse reaction profiles when administered in therapeutically equivalent doses.

Therapeutic Interchange: The dispensing of a drug that is therapeutically equivalent to but chemically different from the drug originally prescribed by a physician or other authorized prescriber. Although usually of the same pharmacologic class, drugs appropriate for therapeutic interchange may differ in the chemistry or pharmacokinetic properties, and may possess different mechanism of action, adverse-reaction, toxicity, and drug interaction profiles. In most cases, the interchanged drugs have close similarity in efficacy and safety profiles.

IV. PROCEDURE

A. Therapeutic Interchange or Automatic Substitution Approval Process

1. Proposals for particular Therapeutic Interchange or Automatic Substitution programs shall be submitted to the Chief of Pharmacy Services or designee for research and development. Based on this evidence, the Chief of Pharmacy Services will make a recommendation to the P&T Committee.

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2. Drugs chosen for Therapeutic Interchange or Automatic Substitution shall first be evaluated with regard to clinical efficacy and safety using scientific and clinical evidence found in the medical literature. A statement of financial impact shall also be prepared.
3. The P&T Committee shall review the evidence and provide final approval or denial of each Therapeutic Interchange or Automatic Substitution proposal.
4. The P&T Chairperson shall communicate Therapeutic Interchange or Automatic Substitution approvals to CCHCS clinical leadership, including Chief Executive Officers and the Pharmacists-in-Charge (PIC).

B. Therapeutic Interchange Procedure

1. Therapeutic Interchanges shall only be implemented at the patient-inmate level after the patient-inmate's provider has signed an approved Therapeutic Interchange Physician Authorization Form which is on file in the pharmacy.
2. The Therapeutic Interchange Physician Authorization Forms shall be used by each facility's pharmacy manager to obtain provider authorization to generate a new prescription and convert selected patient-inmates from the original medication to the designated Therapeutic Equivalent.
3. The Therapeutic Interchange Physician Authorization Forms shall be used by California Department of Corrections and Rehabilitation (CDCR) pharmacists to dispense the currently preferred product upon presentation of an order for a CDCR patient-inmate for one of the interchangeable products.
4. Each prescribing practitioner who has signed a Therapeutic Interchange Physician Authorization Form may revoke such authorization in writing at any time. Such revocation shall be promptly communicated to the PIC.
5. If the prescribing practitioner chooses not to have a particular patient-inmate participate in a specific Therapeutic Interchange, the prescriber shall write "Do not substitute" on the prescription.
 - a. Pharmacy shall incorporate the words "Do not substitute" into the medication directions (Sig) for inclusion on the medication label, Medication Administration Record (MAR), and medication reconciliation forms.
6. If the pharmacist determines that the interchange should not be implemented for a patient-inmate because of potential clinical adverse consequences, the pharmacist may dispense the originally prescribed product and make an appropriate record of the reason.
 - a. If the pharmacist decides not to implement the therapeutic interchange, he/she will communicate this decision to the prescriber.
 - b. "Do not substitute" designations shall be included in the medication directions (Sig) for inclusion on the medication label, MAR, and medication reconciliation forms.
7. If the originally prescribed product is non-Formulary, the non-Formulary process will be followed.
8. The pharmacist shall write a new order using CDC 7221, Physician's Orders, or medication reconciliation form. The new order does not require a co-signature by a physician. The order shall include the following:
 - a. Therapeutic Interchange per physician's authorization, indicating the name of the physician authorizing the interchange.
 - b. Medication originally ordered including dose, route, and duration.
 - c. Therapeutic Interchange medication including dose, route and duration.
 - d. Signature of the pharmacist and date.

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9. A copy of the order shall be retained by the pharmacy and used to fill the prescription. A copy shall be sent with the medication to the nursing unit. The original and remaining copy shall be sent to medical records to be filed in the electronic Unit Health Record (eUHR).
10. The patient-inmate shall be informed when a Therapeutic Interchange has occurred.
11. Signed Therapeutic Interchange Physician Authorizations shall be retained by the pharmacy as long as the program is active.

C. Automatic Substitution Procedure

1. For medications which are available in different formulations or salts, where P&T deems these to be clinically equivalent, therapeutic substitution at pharmacy level may be performed by the pharmacist and shall not require the use of the Therapeutic Interchange Physician Authorization Form.
2. The pharmacist shall write a new order using CDC 7221, Physician's Orders, or Medication Reconciliation Form. The new order does not require a co-signature by a physician. The order shall include the following:
 - a. "Automatic substitution per policy."
 - b. Name of ordering physician.
 - c. Medication originally ordered including dose, route, and duration.
 - d. Automatic substitution medication including dose, route and duration.
 - e. Signature of the pharmacist and date.
3. A copy of the order shall be retained by the pharmacy and used to fill the prescription. A copy shall be sent with the medication to the nursing unit. The original and remaining copy shall be sent to medical records to be filed in the eUHR.