3.5.31 Therapeutic Interchange and Automatic Substitution

(a) Procedure Overview

(1) This procedure outlines the process for reviewing and approving medications for use in Therapeutic Interchange and Automatic Substitution. The California Correctional Health Care Services (CCHCS) Drug Formulary creates potential for significant cost savings through Therapeutic Interchange and Automatic Substitution due to the increasing number of medications within therapeutic categories and the wide variation in price among those medications. Authorization to change medications of therapeutic equivalence during national supply shortages may alleviate distribution delays and improve continuity of patient care. Therapeutic Interchange and Automatic Substitution programs also have the potential to ensure quality of care and improve outcomes for patients.

(2) The Systemwide Pharmacy & Therapeutics (P&T) Committee shall continually and objectively evaluate and select medications for the Therapeutic Interchange or Automatic Substitution that are most appropriate for the needs of the patient population based on safety, effectiveness, availability, and cost. The Systemwide 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 CCHCS tools including Care Guides to promote quality medical care.

(b) Procedure

(1) Therapeutic Interchange or Automatic Substitution Approval Process

(A) Proposals for particular Therapeutic Interchange or Automatic Substitution programs shall be submitted to the Statewide Chief of Pharmacy Services or designee for research and development. Based on the findings, the Statewide Chief of Pharmacy Services, or designee, shall make a recommendation to the Systemwide P&T Committee.

(B) Medications 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 medical literature. A statement of financial impact shall also be prepared.

(C) The Systemwide P&T Committee shall review the evidence and provide final approval or denial for each Therapeutic Interchange or Automatic Substitution proposal.

(D) The Systemwide P&T Committee Chairperson shall communicate Therapeutic Interchange or Automatic Substitution approvals to CCHCS clinical leadership, including Chief Executive Officers and the Pharmacists-in-Charge (PIC).

(E) Following implementation, the Systemwide P&T Committee shall monitor, measure, and review economic, clinical, or humanistic outcomes for patients treated under the Therapeutic Interchange or Automatic Substitution programs.

(2) Therapeutic Interchange Procedure

(A) Therapeutic interchanges shall only be implemented at the patient level after their provider has signed an approved Therapeutic Interchange Physician Authorization Form, which is on file in the pharmacy.

(B) The Therapeutic Interchange Physician Authorization Forms shall be used by each institution's PIC to obtain provider authorization to generate a new prescription and convert selected patients from the original medication to the designated therapeutic equivalent.

(C) The Therapeutic Interchange Physician Authorization Forms shall be used by CCHCS pharmacists to dispense the currently preferred product upon presentation of an order for a patient for one of the interchangeable products.

(D) 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.

(E) If the ordering provider chooses not to have a particular patient participate in a specific therapeutic interchange, the prescriber shall include "Do not substitute" on the order.

1. The pharmacist shall incorporate the words "Do not substitute" into the medication directions (sig) for inclusion on the medication label and electronic Medication Administration Record (eMAR).

(F) If the pharmacist determines that the interchange should not be implemented for a patient because of potential adverse clinical consequences, the pharmacist may dispense the originally prescribed product and document in the health record.

1. If the pharmacist decides not to implement the therapeutic interchange, they shall communicate this decision to the ordering provider.
2. "Do not substitute" designations shall be included in the medication directions (sig) for inclusion on the medication label and eMAR.

(G) The pharmacist shall modify the order or enter a new order in the health record. The new order does not require a co-signature by a provider. The order shall include the following:
1. A note referencing the therapeutic interchange that includes the original medication, dose, and route ordered.
2. Name of the provider authorizing the therapeutic interchange as the ordering provider.
3. Required order details including dose, route, and duration.

(H) The patient shall be informed when a therapeutic interchange has occurred.

(I) Signed Therapeutic Interchange Physician Authorization Forms shall be retained by the pharmacy as long as the program is active.

(3) Automatic Substitution Procedure

(A) For medications which are available in different formulations or salts, where the Systemwide P&T Committee deems these to be clinically equivalent, therapeutic substitution at the pharmacy level may be performed by the pharmacist and shall not require the Therapeutic Interchange Physician Authorization Form.

(B) The pharmacist shall modify the order or enter a new order in the health record. The new order does not require a co-signature by a provider. The order shall include the following:
1. A note referencing the automatic substitution per policy that includes the original medication, dose, and route ordered.
2. Name of ordering provider.
3. Required order details including dose, route, and duration.

References

- American College of Clinical Pharmacy 2004 Guidelines for Therapeutic Interchange

Revision History

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