

| HEALTH PLAN OF SAN JOAQUIN | | | | | |
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| Subject: Generic Substitution | | | | | |
| Department: Medical Management | | Unit: Pharmacy | | Policy #: PH12 | |
| Effective Date: 9/18/12 | Committee/Approval Date: P&T 02/13/2018 | | Review/Revision Dates: 09/12, 11/15, 02/16, 02/17, 02/18 | | |
| Applies To: | Medi-Cal | Yes | X | No | |

DEFINITIONS

MedWatch: The FDA MedWatch program collects reports of adverse reactions and quality problems, primary with drugs and medical devices, but also for other FDA-regulated products (e.g. dietary supplements, cosmetics, medical foods, and infant formulas). This includes problems with different manufacturers of the same medication. MedWatch forms can be found at the FDA website (<http://www.fda.gov/Safety/MedWatch/default.htm>) and reporting can be conducted online, by phone 1-800-FDA-1088, or by submitting the MedWatch Form 3500 to the FDA by mail or fax to 1-800-FDA-0178.

POLICY

Whenever an FDA-approved bioequivalent generic drug is available and there are no medical contraindications to patient use of the generic drug HPSJ substitutes the generic drug.

PROCEDURE

- A. HPSJ has a mandatory Generic Substitution process.
 - 1. For those drugs where a generic equivalent exists for the brand name product and no contraindication exists to the use of generics, the generic drug will be dispensed to the member.
 - 2. When available, FDA-approved generic drugs are to be used in all situations, regardless of the brand name indicated.
 - 3. Only drugs with a therapeutic Equivalence Code of A, as rated in the Electronic Orange Book, are eligible for generic substitution.
 - a. The Electronic Orange Book, www.fda.gov/vder/ob/, is a website that is maintained by the FDA which provides updates of all drug patent expiration and bioequivalence classifications for FDA-approved products on a monthly basis.
 - 4. The P&T Committee may identify drugs that have a narrow therapeutic index (NTI) or other safety consideration that makes them unsuitable for generic substitution.
- B. All P&T Committee Formulary decisions apply to subsequent generic versions, unless specified otherwise by the committee.

- C. Generic versions of drugs that become available with an Equivalence Code of A are automatically eligible for coverage.
- D. When a generic drug with an Equivalence Code of A becomes available, the Pharmacy Director ensures that:
 - 1. The pharmaceutical claims adjudication system is updated with the generic information.
 - 2. The on-line Formulary is updated expeditiously.
 - 3. The hard copy Formulary is updated at the next printing.
- E. A prescriber may, for medical reasons, request that a prescription be dispensed as written (DAW), subject to review and approval by HPSJ.
- F. HPSJ 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.
 - 1. The information required is objective documentation of any previous reaction to generic products of the same medication tried before.
 - 2. In general, if a patient is “intolerant” to a product from one manufacturer, products from other manufacturers should be tried.
 - 3. Requests for Brand Name medications will be approved when BOTH of the following conditions have been met:
 - a. Use of at least 1 generic product with the same active and inactive ingredients as contained in the brand name product (such as the FDA authorized generic, the first generic product approved after the patent has expired).
 - b. Documented use of 3 (three) different generic manufacturers of the drug and strength; or use of all different generic manufacturers of the drug if there are less than 3.
 - 4. If the requesting provider states that it is medically necessary to take the brand medication due to an adverse events or side effect experienced with all generic forms of the medication by all generic manufacturers, the requesting provider must provide evidence that a MEDWATCH form has been completed and submitted to the FDA documenting the adverse event experienced with the generic medication but not with the brand name medication.
- G. The processes outlined in policy UM 01, Authorization and Referral Review, and policy UM 07, Notice of Action for Delayed, Denied, Modified, or Terminated Services, are followed in making determinations.
- H. The Appeals process described in policy QM65, Provider Grievances/Appeals, is available for any non-authorization determination.

REFERENCE

A. NCQA Standard UM 13 – Procedures for Pharmaceutical Management

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| Health Plan of San Joaquin |
| Approval: Signatures on File |

DHCS Contract Deliverables

| <i>Contract Reference</i> | <i>Date of Approval</i> | <i>DHCS Unit</i> | | <i>Contract Reference</i> | <i>Date of Approval</i> | <i>DHCS Unit</i> |
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