



Inland Empire Health Plan

---

*Pharmacy Policy*  
**Brand Name Drug Request**

---

**Line of Business:** Medicaid

**P&T Approval Date:** May 15, 2019

**Effective Date:** July 1, 2019

*This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutic Subcommittee.*

---

**I. Policy:**

1. This policy applies to IEHP Medi-Cal only.
2. IEHP is a generic-mandatory plan and requires dispensing of FDA-approved, equivalent generics of brand-name products when available.
3. Requests for brand-name products that have generic equivalents will require a Universal PA request form.
4. Meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy.
5. The dosage requested is appropriate based on age and indication (e.g. FDA labeling, DrugDex).
6. Clinical justification must be provided as to why the brand-name product is necessary and other generic products cannot be considered, including:
  - a. All available equivalent generics OR authorized generics/follow-on biologics (when approved to be used as preferred by P&T subcommittee); AND
  - b. Other formulary agents that may be used for the management of the same condition.

**II. Clinical Justification:**

1. Pharmaceutically equivalent products consist of the same active ingredient(s), strength or concentration, dosage form, and route of administration. According to the FDA, therapeutically equivalent products are pharmaceutically equivalent and expected to produce the same clinical effect and safety profile. Drug products that are considered therapeutically equivalent to other pharmaceutical equivalents are listed as A-rated in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). AB-rated drug products in the Orange Book meet necessary bioequivalence requirements that are supported by adequate in vivo and/or in vitro studies.
2. Any drug product in the Orange Book repackaged and/or distributed by other than the applicant (e.g., an authorized generic) is considered to be therapeutically equivalent to the applicant's drug product even if the applicant's drug product is single source or coded as non-equivalent (e.g., BN). Also, although not identified in the Orange Book, distributors or repackagers of an applicant's drug product are considered to have the same code as the applicant. The details of these codes and the policies underlying them are discussed in Section 1.7, *Therapeutic Equivalence Evaluations Codes*.



Inland Empire Health Plan

---

*Pharmacy Policy*  
**Brand Name Drug Request**

---

**References:**

1. U.S. Food and Drug Administration. Approved Drug Products with Therapeutic Equivalence Evaluations, 38<sup>th</sup> Edition, 2018. Accessed October 1, 2018.
2. U.S. Food and Drug Administration. Orange Book Preface, 38<sup>th</sup> Edition. Available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>. Accessed October 1, 2018.

Change Control		
Date	Change	Author
05/15/2019	<ul style="list-style-type: none"><li>• Meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy.</li></ul>	JT