Pharmacy Policy
Non-Formulary Drug

Line of Business: Medicaid
P&T Approval Date: June 5, 2020
Effective Date: July 1, 2020

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. The IEHP drug formulary is reviewed continuously by the P&T subcommittee based on safety data, clinical efficacy and cost analysis. IEHP mandates the use of formulary medications in order to assure the quality and cost-effectiveness of drug use.
2. If a drug specific IEHP prior authorization criteria does not currently exist (e.g. newly FDA approved drug or formulation), requests of a non-formulary medication will be reviewed based on the following guidelines:
   a. Meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy.
   b. The indication is FDA approved or supported by standard pharmacopeias [e.g. DrugDex Information system, American Hospital Formulary Service Drug Information (AHFS)]
   c. Failure or clinically significant adverse effects to:
      i. All formulary alternatives that are FDA approved or supported by standard pharmacopeias (e.g. DrugDex, AHFS, etc.) for the patient’s specific diagnosis.
      OR
      ii. No other alternative that has the medically accepted use for the patient’s specific diagnosis (e.g. orphan drug)
      OR
      iii. FDA approved or Compendia supported (at least IIB level of evidence) non-formulary alternatives
   d. The dosage requested is appropriate based on age and indication (e.g. FDA labeling, DrugDex).
   e. Chart note documentation or lab results may be required
   f. For re-authorization requests, must meet all of the following requirements:
      i. Recent pharmacy claims within 180 days of request
      ii. Confirmed stability or no disease progression
      iii. Duration of re-authorization: Based on clinical practice guidelines for each specific medication
   g. Pharmacist to conduct final clinical review and determination for both denial and approval.
3. Please refer to Brand Name Drug Policy for brand-name non-formulary drug request
4. The Non-Formulary Drug Policy will not apply to the following:
   a. Drug excluded from the plan benefit
   b. DHCS carve out medications
   c. Drug that is already covered by California Children Services benefits (CCS)
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<th>Date</th>
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<tr>
<td>05/20/2020</td>
<td>• Renew with no change</td>
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| 05/15/2019 | • Add “Meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy”  
• All formulary alternatives that are FDA approved or supported by standard pharmacopeias | JT     |
| 02/20/2019 | • Reformatted document                                                                          | ND/HC  |
|            | • Added requirement for lab results as needed (along with chart note)                           |        |
| 02/21/2018 | • Added additional criteria for drug criteria that doesn’t exist:  
  o Failure or clinically significant adverse effects to non-formulary drugs that are FDA approved OR compendia supported (at least IIB level of evidence) for the approved indications.  
  • Pharmacist to conduct final clinical review and determination for both denial and approval. | CT     |
| 08/16/2017 | • Renewed with no updates/changes                                                                | CT     |