Pharmacy Policy

Non-Formulary Drug

Line of Business: All lines of business
P&T Approval Date: November 3, 2023 **Effective Date:** December 1, 2023

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 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 the followings:
        i. All IEHP formulary alternatives that are FDA approved or supported by standard pharmacopeias (e.g., DrugDex, AHFS, etc.) for the patient's specific diagnosis.
        ii. FDA approved or Compendia supported (at least IIB level of evidence) non-formulary alternatives
        iii. No other alternative that has the medically accepted use for the patient's specific diagnosis (e.g., orphan drug):
            1. Including alternative treatments (e.g., physical therapy, oral medication(s), etc.) have been tried or considered, have failed and/or are contraindicated.
            2. The least expensive medically necessary option must be used unless supplemental documentation strongly supports the use of the higher cost product.
    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 the following requirements:
        i. Recent pharmacy or medical 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. 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 other benefits [e.g., California Children Services benefits (CCS, Vaccines for Children (VFC)]

References:

1. Medicare Prescription Drug Benefit Manual Chapter 6 -Part D Drugs and Formulary Requirements. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf

Change Control		
Date	**Change**	**Author**
10/05/2023	• Updated LOB	SV
10/07/2022	• Updated with CMS references • Updated P&T Approval Date and Effective Date • Changed line of business to Medicare only	CK
12/13/2021	• Updated P&T Approval Date and Effective Date	JM
11/22/2021	• Included medical claims as part of the re-authorization request requirements • Removed Brand Name Drug Policy for brand name non-formulary drug requests	TL
06/25/2021	• Line of Business updated to include Medicare	SV
05/07/2021	• Added criteria point for least expensive medically necessary options to be tried. • Added criteria point for alternative therapies to be tried. • Added other benefits such as VFC to the non-coverage list	ND
05/20/2020	• Renew with no change	SV
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 • Added requirement for lab results as needed (along with chart note)	ND/HC
02/21/2018	• Added additional criteria for drug criteria that doesn't exist: ○ Failure or clinically significant adverse effects to non-formulary drugs that are FDA approved OR	CT

	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.	
08/16/2017	• Renewed with no updates/changes	CT