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## Pharmacy Policy Drug Trial and Failure

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**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 Therapeutics Subcommittee.*

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- I. IEHP defines trial of a drug as:
  1. Paid Pharmacy claim history (i.e., PBM)
  2. Paid claims noted from the external drug data sources (i.e., CURES, CCI history, etc.)
  3. Provider provides drug history that includes duration of therapy and/or specific date(s)
  
- II. IEHP defines failure of a drug as:
  1. Discontinuation due to:
    - a. Allergy
    - b. Intolerance or adverse drug reaction
    - c. Contraindication
    - d. Sub-therapeutic outcome despite use of an optimal therapeutic dosage over a clinically appropriate duration based on clinical guidelines or practice
      - i. Lack of improvement
      - ii. Worsening of clinical condition
      - iii. Not meeting treatment goals
  
- VI. A Prescriber's statement will be accepted for both trial and failure of a medication
  
- VII. If failure is not provided on the request for a Coverage Determination, outreach to the physician office is to be made to obtain the information.
  
- VIII. If failure cannot be established, clinical review by IEHP pharmacist(s) is required.

**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> Accessed October 5, 2023.
2. Drug Plan Coverage Rules. <https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover/drug-plan-coverage-rules> Accessed October 5, 2023.

Change Control		
Date	Change	RPH
10/5/2023	<ul style="list-style-type: none"> <li>Updated LOB</li> <li>Specified "paid claims" under policy section I</li> </ul>	SV
9/28/2022	<ul style="list-style-type: none"> <li>Updated dates to reflect ad hoc meeting date and correct effective date</li> <li>Added references</li> </ul>	NQ
12/13/2021	<ul style="list-style-type: none"> <li>Updated dates to reflect ad hoc meeting date and correct effective date</li> </ul>	JM
10/30/2021	<ul style="list-style-type: none"> <li>Updated to Medicare-specific policy only</li> <li>Removed policy specific to Medicaid for Medi-Cal Rx Transition</li> </ul>	TL
04/16/2021	<ul style="list-style-type: none"> <li>Renew with no changes</li> </ul>	JM
02/20/2019	<ul style="list-style-type: none"> <li>Added requirement for supporting documentation, chart notes and lab results as appropriate for prescriber's statement of trial and failure (Medicaid only)</li> </ul>	ND