



Pharmacy Policy Drug Trial and Failure

Line of Business: All lines of business

P & T Approval Date: November 1, 2024

Effective Date: December 1, 2024

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.

- 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 with or without 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
 2. Contraindication
 3. Sub-therapeutic outcome despite use of an optimal therapeutic dosage over a clinically appropriate duration based on clinical guidelines or practice
 - a. Lack of improvement
 - b. Worsening of clinical condition
 - c. 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 Prior Authorization and/or Coverage Determination review, outreach to the physician office is to be made to obtain the information.

- VIII. If failure cannot be established, clinical review by IEHP or the delegated entity (i.e. Pharmacy Benefit Manager) 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 September 26, 2024.
 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 September 26, 2024.
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Change Control		
Date	Change	RPH
09/26/2024	<ul style="list-style-type: none"> • Minor verbiage updates: <ul style="list-style-type: none"> - Verbiage update to “with or without” under section I3 - Verbiage update to include “Prior Authorization” under section VII - Verbiage update to include “PBM” under section VIII • Minor numbering level change under section II 	SV
10/05/2023	<ul style="list-style-type: none"> • Updated LOB • Specified “paid claims” under policy section I 	SV
09/28/2022	<ul style="list-style-type: none"> • Updated dates to reflect ad hoc meeting date and correct effective date • Added references 	NQ
12/13/2021	<ul style="list-style-type: none"> • Updated dates to reflect ad hoc meeting date and correct effective date 	JM
10/30/2021	<ul style="list-style-type: none"> • Updated to Medicare-specific policy only • Removed policy specific to Medicaid for Medi-Cal Rx Transition 	TL
04/16/2021	<ul style="list-style-type: none"> • Renew with no changes 	JM
02/20/2019	<ul style="list-style-type: none"> • Added requirement for supporting documentation, chart notes and lab results as appropriate for prescriber’s statement of trial and failure (Medicaid only) 	ND