



Pharmacy Policy Off-Label Indication Policy

Line of Business: All lines of business

P & T Approval Date: February 2, 2024

Effective Date: March 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.

POLICY

1. A drug (including physician-administered drugs) may be considered for off-label coverage through IEHP's prior authorization process, if all the following conditions have been met:
 - a. Meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy.
 - b. The drug is approved by the FDA.
 - c. The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition*; or the drug is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating condition**.
 - d. The drug has been recognized for treatment of that condition by one of the following:
 - i. American Hospital Formulary Service Drug Information
 - ii. DRUGDEX Information System
 - iii. The National Comprehensive Cancer Network Drug and Biologics Compendium
 - iv. Milliman Care Guidelines
 - v. Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.
 - e. The drug has a clinically significant therapeutic advantage in safety, effectiveness, or clinical outcome over other drugs that are included in IEHP's formulary.

2. If a drug does not meet the above requirements, the Pharmacist's recommendation is to be reviewed by IEHP Medical Directors on a case-by-case basis (For Prescription Drug Prior Authorization requests only).

* For purposes of this section, "life-threatening" means at least one of the following:

- (1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.
- (2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

**For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing monitoring.



Pharmacy Policy
Off-Label Indication Policy

REFERENCES

1. Social Security Act Section 1927(k)(6).
https://www.ssa.gov/OP_Home/ssact/title19/1927.htm. Accessed January 12, 2024.
2. CA Health & Safety Code §1342.71.
https://california.public.law/codes/ca_health_and_safety_code_section_1342.71. Accessed January 12, 2024.
3. CA Health & Safety Code §1367.24 (Coverage for Non-formulary Drugs).
https://california.public.law/codes/ca_health_and_safety_code_section_1367.24. Accessed January 12, 2024.

Change Control		
Date	Change	Authors
01/12/2024	<ul style="list-style-type: none"> • Update line of business to reflect all lines of business 	SV
07/11/2022	<ul style="list-style-type: none"> • References updated • Minor format updates 	SV
07/21/2022	<ul style="list-style-type: none"> • Renewed with no changes 	TL
06/25/2021	<ul style="list-style-type: none"> • Line of Business updated to include Medicare 	SV
05/07/2021	<ul style="list-style-type: none"> • Removed phrase "non-formulary" regarding drug under review. • Added "(including physician-administered drugs)". • Added "Milliman Care Guidelines". • Added "(For Prescription Drug Prior Authorization requests only)." 	TL
05/20/2020	<ul style="list-style-type: none"> • Renew with no change 	SV
05/15/2019	<ul style="list-style-type: none"> • Add meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy. 	JT
05/01/2019	<ul style="list-style-type: none"> • Change tile from Off Label Indications of Non-Formulary to "Off-Label Indication Policy". 	JT
08/16/2018	<ul style="list-style-type: none"> • Update references, medical conditions (life-threatening and debilitating) and two articles from major peer reviewed medical journals that present data supporting the proposed off-label use. 	JT