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## Pharmacy Policy Off-Label Indication Policy

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**Line of Business:** All lines of business

**P & T Approval Date:** February 27, 2026

**Effective Date:** March 1, 2026

*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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### **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\*\*, OR, the drug has been recognized by one of the following for the requested treatment condition:
    - 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.
  - d. The drug has a clinically significant therapeutic advantage in safety, effectiveness, or clinical outcome over other conventional drugs or the alternatives.
  
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.




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*Pharmacy Policy*  
**Off-Label Indication Policy**

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**REFERENCES**

1. Social Security Act Section 1927(k)(6).  
[https://www.ssa.gov/OP\\_Home/ssact/title19/1927.htm](https://www.ssa.gov/OP_Home/ssact/title19/1927.htm). Accessed January 16, 2026.
2. CA Health & Safety Code §1342.71.  
[https://california.public.law/codes/ca\\_health\\_and\\_safety\\_code\\_section\\_1342.71](https://california.public.law/codes/ca_health_and_safety_code_section_1342.71). Accessed January 16, 2026.
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](https://california.public.law/codes/ca_health_and_safety_code_section_1367.24). Accessed January 16, 2026.

<b>Change Control</b>		
<b>Date</b>	<b>Change</b>	<b>Authors</b>
01/16/2026	<ul style="list-style-type: none"> <li>• Combined Policy criteria 1c and 1d</li> </ul>	SV
01/06/2025	<ul style="list-style-type: none"> <li>• Deleted reference to IEHP formulary (Policy section 1e)</li> </ul>	SV
01/12/2024	<ul style="list-style-type: none"> <li>• Update line of business to reflect all lines of business</li> </ul>	SV
07/11/2022	<ul style="list-style-type: none"> <li>• References updated</li> <li>• Minor format updates</li> </ul>	SV
07/21/2022	<ul style="list-style-type: none"> <li>• Renewed with no changes</li> </ul>	TL
06/25/2021	<ul style="list-style-type: none"> <li>• Line of Business updated to include Medicare</li> </ul>	SV
05/07/2021	<ul style="list-style-type: none"> <li>• Removed phrase "non-formulary" regarding drug under review.</li> <li>• Added "(including physician-administered drugs)".</li> <li>• Added "Milliman Care Guidelines".</li> <li>• Added "(For Prescription Drug Prior Authorization requests only)."</li> </ul>	TL
05/20/2020	<ul style="list-style-type: none"> <li>• Renew with no change</li> </ul>	SV
05/15/2019	<ul style="list-style-type: none"> <li>• Add meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy.</li> </ul>	JT
05/01/2019	<ul style="list-style-type: none"> <li>• Change title from Off Label Indications of Non-Formulary to "Off-Label Indication Policy".</li> </ul>	JT
08/16/2018	<ul style="list-style-type: none"> <li>• 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.</li> </ul>	JT