

## Pharmacy Policy Quantity Limit Policy

### 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.

#### I. POLICY:

- Inland Empire Health Plan enforces quantity limitations on Formulary medications, Non-Formulary medications, and physician-administered drugs. Quantity limits are based on criteria including, but not limited to, FDA label indications, safety, potential overdose hazard, or approximation of usual doses per month. These limits exist to ensure appropriate clinical utilizations and to promote efficient and safe medication dosing administration.
- 2. Formulary medication(s) that exceed IEHP's drug quantity limits (e.g., quantity limit, DUR edit) may be approved when all of the following requirements are met:
  - a. Requested quantities must be within the dosage limit recommended by the U.S. Food and Drug Administration (FDA) or one of the following compendia:
    - i. American Hospital Formulary Service Drug Information
    - ii. DRUGDEX Information System
    - iii. United States Pharmacopeia-Drug Information
  - b. Meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy.
  - c. Documented clinical justification to demonstrate medical necessity of quantities greater than quantity limit and/or drug safety quantity control (DUR edit).
- 3. Non-Formulary Medication(s) that exceed IEHP's drug quantity limits (e.g., quantity limit, DUR edit) may be approved when all of the following requirements are met:
  - a. Requested quantities must be within the dosage limit recommended by the U.S. food and Drug Administration (FDA) or one of the following compendia:
    - i. American Hospital Formulary Service Drug Information
    - ii. DRUGDEX Information System
    - iii. United States Pharmacopeia-Drug Information
  - b. Meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy.
  - c. Prior authorization criteria must be met with documented clinical justification to demonstrate medical necessity.



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- d. Documented clinical justification to demonstrate medical necessity of quantities greater than quantity limit and/or drug safety quantity control (DUR edit).
- 4. Physician-administered drug(s) that exceed IEHP's drug quantity limits (e.g., quantity limit, DUR edit) may be approved when all of the following requirements are met:
  - a. Requested quantities must be within the dosage limit recommended by the U.S. Food and Drug Administration (FDA) or one of the following compendia:
    - i. American Hospital Formulary Service Drug Information
    - ii. DRUGDEX Information System
    - iii. United States Pharmacopeia-Drug Information
  - b. Meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy.
  - c. Documented clinical justification to demonstrate medical necessity of quantities greater than quantity limit and/or drug safety quantity control (DUR edit).

## References

1. Title 42, Code of Federal Regulations (CFR), §§ 438.3(s).

Change Control		
Date	Change	Author
10/05/2023	<ul> <li>Updated LOB</li> <li>Retire a section (emergency fill quantity limit), as not applicable to medical benefit</li> <li>Retire the references related to pharmacy benefits</li> </ul>	SV
10/05/2022	<ul> <li>Added Emergency Fill Quantity Limit policy per DHCS</li> <li>Added references from CMS and DHCS</li> <li>Updated P&amp;T Approval Date and Effective Date</li> </ul>	YA
11/22/2021	<ul> <li>Updated to include physician-administered drugs</li> </ul>	VM
08/06/2021	Renew with no change	VM
05/20/2020	Renew with no change	SV
05/15/2019	<ul> <li>Add FDA label indications to bullet 1</li> <li>Add Meet all requirements in IEHP Prescription Drug Prior Authorization Drug Treatment Criteria and Policy</li> </ul>	JT



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