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*Pharmacy Policy*  
**Quantity Limit Policy**

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**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.*

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**I. POLICY:**

1. 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 (i.e. per administration, 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 of the requested non-formulary medication.
  - d. Documented clinical justification to demonstrate medical necessity of quantities greater than quantity limit and/or drug safety quantity control (DUR edit).



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4. Physician-administered drug(s) that exceed the dosage limit recommended by the U.S. Food and Drug Administration (FDA) may be approved when all of the following requirements are met:
  - a. Requested quantities must be within the dosage limit recommended by 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).
  
5. Emergency Fill Quantity Limit
  - a. Emergency drug dispensing claims will be limited to up to 14-day supply and a limit of 2 fills in a 30-day period for the same drug and dose.



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References

1. Prescription Drug Benefit Manual, Chapter 6: Part D Drugs and Formulary requirements. Accessed on October 3, 2024. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>
2. Title 42, Code of Federal Regulations (CFR), §§ 423.120(b)(vii). Accessed on October 3, 2024. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-C/section-423.120>
3. Title 42, Code of Federal Regulations (CFR), §§438.3(s). Accessed on October 3, 2024. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-438/subpart-A/section-438.3>
4. DHCS Medi-Cal Rx Provider Manual, Version 23.0. October 1, 2024. Accessed on October 3, 2024. [https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/manuals/Medi-Cal\\_Rx\\_Provider\\_Manual.pdf](https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/manuals/Medi-Cal_Rx_Provider_Manual.pdf)
5. DHCS- Revised Emergency Fill Quantity Limit and Frequency Policy. February 6, 2022. Accessed on October 3, 2024. [https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/bulletins/2022.02\\_A\\_Revised\\_Emergency\\_Fill\\_Quantity\\_Frequency\\_Policy.pdf](https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/bulletins/2022.02_A_Revised_Emergency_Fill_Quantity_Frequency_Policy.pdf)

Change Control		
Date	Change	Author
10/03/2024	<ul style="list-style-type: none"><li>• Updated Policy 4 as there is no DUR edit in PAD</li></ul>	SV
10/25/2023	<ul style="list-style-type: none"><li>• Updated LOB from “Both LOB” to “All LOB”</li></ul>	SV
10/05/2022	<ul style="list-style-type: none"><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 style="list-style-type: none"><li>• Updated to include physician-administered drugs</li></ul>	VM
08/06/2021	<ul style="list-style-type: none"><li>• Renew with no change</li></ul>	VM
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 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