

Medical Drug Clinical Criteria

Subject: Drug Dosage, Frequency, and Route of Administration

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Overview

This document addresses the clinical criteria for review of dosage, frequency, and route of administration of a drug, biologic, or biosimilar product (collectively referred to as drugs within this document).

Note: These criteria apply to those injectables, biologics or specialty pharmacy drugs which fall under the medical benefit. It does not apply to those medications falling under the pharmacy benefit, which include, but are not limited to oral agents.

- Please check appropriate state mandates for laws that will supersede this document when applicable, such as those governing dosage, frequency, or route of administration for prescription drugs.
- Any entity's clinical criteria document on a specific drug takes precedence over this guideline.
- Verify benefits and benefit exclusions. Excluded products or treatments are not covered under this document (e.g., agents for impotency or weight loss).
- This document shall not be construed to require coverage for any drug when the FDA has determined its use to be contraindicated.
- The document shall not be construed to require coverage for any drug when the benefit plan excludes drug coverage.
- The document shall not be construed to require coverage for any drug when the benefit plan includes drug benefit limitations based on a formulary and the drug is not part of the formulary.

Clinical Criteria

Drug Dosage, Frequency, and Route of Administration

The drug dosage, frequency, and route of administration may be approved if the following criteria are met:

- I. The drug dosage, frequency, and route of administration for the treatment indication is supported by one or more of the following:
 - A. U.S. Food and Drug Administration (FDA) prescribing information; **OR**
 - B. American Hospital Formulary Service Drug Information (AHFS) Drug Information; **OR**
 - C. DRUGDEX System; Truven Health Analytics; **OR**
 - D. National Comprehensive Cancer Network (NCCN) Drug & Biologics Compendium;
- OR**
- II. In the absence of information listed in criteria above: the drug dosage, frequency, and route of administration for the treatment indication is supported by published study methodology from a major scientific or medical peer-reviewed journal article which supports the proposed drug dosage, frequency, and route of administration as safe and effective for the treatment indication (Examples of accepted journals include, but are not limited to, *Journal of American Medical Association*, *New England Journal of Medicine*, and *Lancet*)

The drug dosage, frequency, and route of administration of a drug may not be approved when the above conditions are not met.

Document History

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- 06/09/2025 – Annual Review: No changes.
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- 06/14/2021 – Annual Review: No changes.
- 06/08/2020 – Annual Review: No changes.
- 05/17/2019 – Select Review: First review of drug dosage, frequency, and route of administration clinical criteria. No changes.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website.
<http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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