Indications, Dosages and Administration of FDA-Approved Drugs

- Clinical Policy Bulletins
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Number: 0156

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Policy

1. In the absence of a published Aetna Clinical Policy Bulletin (CPB) to the contrary, U.S. Food and Drug Administration (FDA)-approved prescription drugs are considered medically necessary for an indication if:

    1. The drug is approved for that indication by the FDA; *or*
    2. At least 1 of the standard pharmacy compendia lists the drug to be accepted as safe and effective for this indication: American Society of Health-System Pharmacists Drug Information [AHFS Drug Information], Micromedex (Merative L.P.), Clinical Pharmacology (Elsevier/Gold Standard, Inc.), Lexidrug (UpToDate Inc.), or the National Comprehensive Cancer Network (NCCN) Drug and Biologics Compendium; *or*
    3. The safety and effectiveness of use for this indication has been demonstrated by at least 1 well-designed controlled clinical trial (i.e., a Phase III or so called Phase IIb [single center controlled] trial) published in a nationally recognized peer-reviewed medical journal; *and*
    4. If the drug is to be used in combination with other drugs for a particular indication, the safety and efficacy of use of those drugs in combination must be supported by reliable evidence in the peer-reviewed published medical literature.

2. In the absence of a published Aetna CPB to the contrary, the medically necessary dosage of an FDA-approved presciption drug for an indication is equal to any of the following:

    1. The dosage for the indication as recommended in the FDA-approved labeling; *or*
    2. The dosage for the indication as recommended by one of the standard pharmacy compendia; *or*
    3. The dosage has been demonstrated to be safe and effective for this indication as demonstrated by 1 or more well-designed controlled clinical trials in the peer-reviewed published medical literature.
3. In the absence of a published Aetna CPB to the contrary, continued use of a drug is considered not medically necessary for members who have developed an absolute contraindication or intolerance to the drug, or who have failed to respond or who have lost response to the drug.

Note: Nothing in this policy should be interpreted as limiting Aetna's ability to require pre-certification of coverage of any given product. Coverage may also be subject to pharmacy benefit management programs and formulary restrictions. Please check benefit plan descriptions for details.

Background

For purposes of this policy, a U.S. Food and Drug Administration (FDA)-approved prescription drug is defined as an FDA-approved drug, biological, or compounded prescription which, by State and Federal Law, may be dispensed only by prescription or administered by a person who is acting within his or her capacity as a paid health professional.

For purposes of this policy, compendia accepted indications and Level of Evidence (LOE) include the following:

- American Society of Health-System Pharmacists Drug Information (AHFS Drug Information) or Lexidrug (UpToDate Inc): Supportive;

- Micromedex (Merative L.P.): Must have both Strength of Recommendation Class I or IIa plus Strength of Evidence Category A or B;
- Clinical Pharmacology (Elsevier/Gold Standard, Inc.): Must have both Quality of Evidence High or Moderate plus Strength of Recommendation Strong;
- National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium: Categories of Consensus I and IIa.

References

The above policy is based on the following references:

1. Abernathy AP, Hammond JM, Hubbard ML, et al; Duke Evidence-Based Practice Center (EPC); Tufts EPC. Compendia for coverage of off-label uses of drugs and biologics in an anticancer chemotherapeutic regimen. Technology Assessment. Rockville, MD: AHRQ; May 7, 2007.
2. AHFS Drug Information. Bethesda, MD: American Society of Health-System Pharmacists; updated periodically.
3. Gold Standard. Clinical Pharmacology powered by ClinicalKey. Tampa, FL: Gold Standard/Elsevier; updated periodically.
4. Merative L.P. In-Depth Answers. Merative Micromedex. Ann Arbor, MI: Merative; updated periodically.
5. McKinney R, Abernethy AP, Matchar DB, Wheeler JL; Duke Evidence-Based Practice Center (EPC). White paper: Potential conflict of interest in the production of drug compendia. Technology Assessment. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); April 27, 2009.
6. National Comprehensive Cancer Network (NCCN). Drug and Biologics Compendium. Plymouth Meeting, PA: NCCN; updated periodically.
7. Physicians' Desk Reference (PDR). Montvale, NJ: Thomson PDR; updated periodically.
8. Rothgeb A, Beckett RD, Daoud N. Off-label use information in electronic drug information resources. J Med Libr Assoc. 2022;110(4):471-477.
9. UpToDate Inc. UpToDate Lexidrug [online]. Waltham, MA: UpToDate; updated periodically.

Policy History

- Last Review 12/20/2024

  Effective: 05/14/1997

  Next Review: 11/13/2025

- Review History
- Definitions

Additional Information

- Clinical Policy Bulletin Notes