OncoHealth

Medical Necessity Review Criteria

Effective Date: 1/10/2023
Revision Date(s): 6/26/2022, 1/10/2023, 2/23/2024
Review Date: 2/23/2024
Policy type: Medical Necessity
Line of Business: Commercial

Unless specifically noted elsewhere authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Scope:

Any oncology treatment that is not addressed in a specific medical necessity policy. This includes, but is not limited to chemotherapy, immunotherapy, supportive agents, CAR-T, and any newly approved therapeutic treatments used in oncology. Further, the approval criteria defined below applies to any requested use for drugs with a specific medical necessity policy if the policy doesn't address the patient specific scenario of the requested treatment.

Universal Criteria:

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.; **AND**
- Unless otherwise noted in labeling, NCCN, or available peer-reviewed literature a patient may not have experienced failure with the requested agent when used for the same cancer in the same setting.; **AND**
- If a request is made in which NCCN Guidelines or NCCN Compendia make a statement that a specified use of a medication is not recommended that guidance is used to determine medical necessity. The absence of a supportive statement in the FDA indication does not imply universal support.

Accelerated Approvals:

- Ongoing | Cancer Accelerated Approvals: https://www.fda.gov/drugs/resources-information-approved-drugs/ongoing-cancer-accelerated-approvals
- Verified Clinical Benefit | Cancer Accelerated Approvals: https://www.fda.gov/drugs/resources-information-approved-drugs/verified-clinical-benefit-cancer-accelerated-approvals
- Withdrawn | Cancer Accelerated Approvals: https://www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals
    - Individuals currently receiving treatment for a withdrawn indication should consult with their healthcare provider to determine if they should remain on therapy.

- Continued determination of medical necessity for treatment of a withdrawn indication will be considered if the patient is established on therapy prior to the withdrawal date on the FDA Website.

Universal Approval Criteria:

Unless otherwise noted in a specific medical necessity policy the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include the following:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA)
- Drugs and biologics may be considered medically accepted or necessary if supported by any of the following 5 compendia below:
  - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
  - Clinical Pharmacology (Strong For)
  - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
  - Thompson Micromedex DrugDex® (Class I and IIa)
  - Wolters Kluwer Lexi-Drugs® (Level A)
- Other uses of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals:
  - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; JAMA Oncology, The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; New England Journal of Medicine: Evidence, Radiation Oncology
  - **Meeting abstracts and case reports are excluded from consideration**
- Other resources may be considered on a case-by-case basis per clinical judgement of the OH clinician
- Non-standard protocols may be approved based on unique clinical circumstances

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

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Date	Updates
6/26/22	Policy Creation
1/10/2023	Annual Review
2/23/2024	Annual Review; Updated Universal Criteria; Addition of Accelerated Approvals