OncoHealth

Medical Necessity Review Criteria

Original Effective Date: 1/10/2023
Revision Date(s): 6/26/2022; 1/10/2023; 2/23/2024; 7/12/2024; 5/27/2025
Review Date: 5/27/2025
Policy type: Medical Necessity

Authorizations are issued for 6 (six) months, unless the ordering physician requests a different timespan or the patients' unique circumstance or condition supports the medical necessity for a different authorization timeframe. Reauthorization requests are reviewed for efficacy, safety and tolerability.

Scope:

Any authorization request, which includes, but is not limited to, chemotherapy, immunotherapy, supportive agents, CAR-T, and any newly approved therapeutic treatments used in oncology.

Universal Approval Criteria:

- OncoHealth follows a hierarchical process for reviewing utilization requests. The hierarchy varies depending upon the line of business. Commercial lines of business follow medical policy, however, when no medical policy exists, OH will follow the hierarchy to determine medical necessity. Unless otherwise noted, the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:
    - Coverage determination may be directed, where applicable, by the Centers of Medicare & Medicaid Services (CMS) Medicare Benefit Policy Manual, Chapter 15 or the Medicare Prescription Drug Benefit Manual, Chapter 6. National Coverage Determinations (NCD) or Local Coverage Determinations (LCD) may exist for which compliance is required. Coverage determinations may also be directed by state-specific Medicaid drug utilization requirements and/or health plan specific drug coverage policies; **OR**
    - United States Food and Drug Administration (FDA) labeling - new drugs or regimens (combinations of drugs) consistent with the product labeling (on-label use); **OR**
    - Drugs or regimens may be used off-label (without FDA support) and considered medically necessary if supported by any of the following compendia below and not listed as unsupported, not indicated, or not recommended within any compendia below.
        - National Comprehensive Cancer Network® (NCCN) - use consistent with NCCN recommendations carrying a Category 1 or 2a level of evidence;
            - Category 2B recommendations will be considered medically necessary in the setting of Medicare. In the Commercial and Medicaid setting, 2B recommendations will be considered medically necessary if identified as such in an alternative compendium or supported by peer-reviewed scientific literature eligible for coverage (meeting abstracts and case reports are excluded from consideration); **OR**

- Indications not included in the official FDA labeling or recommended by NCCN (Category 1 or 2A level of evidence) may be considered if determined to be medically necessary per one or more of the following compendia:
  - Clinical Pharmacology (Strong For); **OR**
  - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1); **OR**
  - Thompson Micromedex DrugDex® (Class I, IIa, or IIb); **OR**
  - Wolters Kluwer Lexi-Drugs® (Level A); **OR**
- Other uses of drugs and biologics may be considered medically necessary 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; 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; Radiation Oncology;
- Meeting abstracts and case reports are excluded from consideration**;**

- Non-standard protocols may be approved based on unique clinical circumstances;
- Dose and frequency should be consistent with United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature;
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy, the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Disclaimer

Drug Coverage Policies are developed as needed, reviewed and 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 utilizing this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice nor 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
7/12/2024	Addition of Medicare criteria, Removed Accelerated Approval Language
7/29/2024	Reviewed and approved by OH Compliance
5/27/2025	Annual review, approved by OH P&T 5/27/2025 with minor edit; approved by QUMC 5/30/2025
6/10/2025	Approved by P32H P&T