

TITLE:	UM Criteria Review	POLICY #: UM 68
DEPARTMENT: Utilization Management	APPROVED BY: Policy Taskforce	
REVIEWED AND APPROVED DATE: 5/31/2024		

### Purpose:

To explicitly state the criteria and the process by which reviews are based.

### Process:

OncoHealth (OH) evaluates the management of cancer patients receiving cancer chemotherapy and associated treatments, including radiation, biologic and gene therapy. To properly perform this function, OncoHealth evaluates the medical literature and reviews national guideline and compendia recommendations.

Based on this information, OncoHealth has developed a database comprised of treatment protocols. Treating physicians and supportive staff assign the appropriate chemotherapy ± supportive agent protocol(s) to patients to initiate prior authorization requests.

OncoHealth's clinical staff maintains the database. The Oncohealth clinical staff, comprised of board-certified hematologists/medical oncologists, radiation oncologists and board-certified oncology pharmacists, review the database on an ongoing basis and no less than annually and update the protocols as necessary. OncoHealth recognizes that the field of oncology is changing rapidly. Accordingly, new protocols are evaluated and added to the database on an ongoing basis.

Oncohealth reviews requests for service and treatment based on the clinical information provided by the treating provider. OH renders determinations that are valid for as long as medically necessary to avoid disruptions in care in accordance with applicable coverage criteria, the individual patient's medical history, and the treating provider's recommendation.

The following highlights the criteria on which protocol reviews are based:

- New drugs or regimens (combinations of drugs) approved by the FDA (on-label use)
- Drugs or regimens may be used off-label (without FDA approval) and considered medically accepted if supported by any of the following compendia below and not listed as unsupported, not indicated, or not recommended within any compendium below.
  - NCCN Drugs & Biologics Compendium ®
    - Category 1-2A recommendations are considered medically accepted uses
    - Category 2B recommendations will be considered if identified as medically accepted in an alternative compendium or supported by peer-reviewed scientific literature eligible for coverage (meeting abstracts and case reports are excluded from consideration)
    - Category 3 listings are considered not medically accepted uses

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- OA subscribes to the NCCN Flash Updates™, which informs OA when the NCCN Guidelines® and the NCCN Drugs & Biologics Compendium are updated
  - Clinical Pharmacology
    - Medically accepted uses are identified by narrative text that is supportive
    - Not medically accepted uses are identified by narrative text that is “not supportive”
  - American Hospital Formulary Service-Drug Information (AHFS-DI)
    - Medically accepted uses are identified by narrative text that is supportive
    - Not medically accepted uses are identified by narrative text that is “not supportive”
  - Thompson Micromedex DrugDex®
    - Class I, IIA, or IIb recommendations are considered medically accepted uses
    - Class III listings are considered not medically accepted uses
  - Wolters Kluwer Lexi-Drugs®
    - Medically accepted uses are identified by an indication listed as “Use: Off-Label” and rated as “Evidence Level A”
    - Not medically accepted uses are those indications listed as “Use: Unsupported”
  - American Society for Radiation Oncology (ASTRO)
  - Clinical Practice Guidelines and Model Policies; American Radium Society Appropriate Use Criteria; American Brachytherapy Consensus Statement
  - American Brachytherapy Consensus Statements
  - Pediatric Hematology and Oncology
  - Pediatric Blood and Cancer
  - Journal of Adolescent and Young Adult Oncology
- Off-label use of drugs or regimens may also be considered medically accepted if supported as safe and effective according to peer-reviewed articles eligible for coverage 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;

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- 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
- Coverage determination may also be directed by the Centers of Medicare & Medicaid Services (CMS) National Coverage Determinations (NCD) or Local Coverage Determinations (LCD), state-specific Medicaid drug utilization requirements, and/or health plan specific drug coverage policies, where applicable.
- Unique cases that do not fit standard criteria
  - Non-standard protocols may be approved based on unique clinical circumstances, especially for rare diseases which may lack guideline-based treatment recommendations
  - Non-standard protocols are entered into the database as needed

In addition, any practicing oncologist can request that a protocol be added to the database.

Also, based on ongoing reviews of the medical literature and the ASCO and NCCN guidelines, obsolete treatment protocols are inactivated making them no longer available for view by the treating practitioner.

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Reference #: DD 2024-H1

DATE/LAST APPROVE: 5/31/2023, 5/19/2022, 5/21/2021

Department/Approved By: Organization Wide, Compliance Policy Committee

Revision Date	Description of Changes
10/21/2010	Creation Date
07/02/2020	New format
08/10/2024	Format & policy number change

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