ONCOLOGY ANALYTICS

Chemotherapy Review Criteria

Reference #: DD 2024-H1
Signature/Date/Last Approved: Rick J. Dean, 7/21/2020
Department/Approved By: Organization Wide, CEO

Purpose:
To explicitly state criteria on which chemotherapy prior authorization reviews are based.

Process:
Oncology Analytics, Inc. (OA) reviews chemotherapy prior authorization requests forcancer patients. To properly perform this function, OA evaluates the medical literature and reviews national guidelines, e.g., from the National Comprehensive Cancer Network® (NCCN®) and the American Society of Clinical Oncology (ASCO), and recommendations in the 5 compendia approved by the Centers for Medicare and Medicaid Services (CMS).

OA has developed a database comprised of chemotherapy and supportive agent treatment options that it refers to as "protocols." Treating physicians (typically oncologists) or their staff assign the appropriate chemotherapy ± supportive agent protocol(s) to their cancer patients to initiate prior authorization reviews by OA.

OA's clinical staff maintains the database of chemotherapy and supportive agent treatment options. OA's board-certified hematologists/medical oncologists and other oncology specialists and board-certified oncology pharmacists review the database in an ongoing fashion and update the protocols, as necessary, no less than annually. (Policy DD 1010-A Protocol Generation and Review Procedure) OA recognizes that the fields of hematology and oncology are changing rapidly. Accordingly, new protocols are evaluated and continually added to OA's database.

Review criteria used by OA to determine whether chemotherapy ± supportive agent(s) are medically necessary for anticancer treatment include the following:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA), i.e., that are used on-label.
- Drugs and biologics may be used off-label, i.e., without FDA approval. They are considered medically accepted or necessary if supported by any of the following 5 compendia that Medicare uses to determine a "medically accepted indication" for off-label drugs and biologics in anticancer chemotherapeutic treatment and are not listed as unsupported, not indicated, or not recommended within any one of the compendia 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 if listed in at least one of the 5 Medicare-recognized compendia or supported by peer-reviewed scientific literature eligible for coverage as outlined below. Meeting abstracts and case reports are excluded from consideration
        - Category 3 listings are considered not medically accepted uses
            - OA subscribes to the NCCN Flash Updates™ which immediately inform 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”
- Off-label use of drugs and biologics 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; this is in accordance with the medical literature used by local Medicare contractors to determine medically-accepted indications for drugs and biologics used in anticancer treatment:
    - 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; or
  - Radiation Oncology
  - Pediatric Hematology and Oncology
  - Pediatric Blood and Cancer
  - Journal of Adolescent and Young Adult Oncology

  Meeting abstracts and case reports are excluded from consideration

- Coverage determination may also be directed by CMS National Coverage Determinations (NCDs) or state-specific Local Coverage Determinations (LCDs), state-specific Medicaid drug utilization requirements and/or health plan-specific drug coverage policies, where applicable.
- Unique cases that do not fit NCCN Categories 1-3:
  - Non-standard protocols may be approved based on unique clinical circumstances, especially for rare diseases that may lack guideline-based treatment recommendations
  - Non-standard protocols are entered into the database, as needed

Any practicing oncologist can request that a protocol be added to OA's database.

Based on ongoing reviews of the medical literature and national guidelines, e.g., from the NCCN and ASCO, obsolete treatment protocols are inactivated making them no longer available for view by treating oncologists and their staff.