ONCOLOGY ANALYTICS

Molecular Testing Review Criteria

Reference #: Ref #: DD 2024-H1-A UM 1 A 5 & 6
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Department/Approved By: Organization Wide, CEO

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

Process:

Oncology Analytics, Inc. (OA) reviews molecular testing prior authorization requests for patients with cancer and for any individual at potentially elevated risk for cancer. For these purposes, OA reviews requests for molecular characterization of tumors ("tumor profiling"). It also reviews requests for molecular analysis of non-cancerous ("germline") DNA to assess genetic contributions to cancer susceptibility ("tumor susceptibility") and response to anti-cancer therapy.

To properly perform this function, OA evaluates the medical literature and reviews national guidelines, e.g., from the National Comprehensive Cancer Network® (NCCN®), the American Society of Clinical Oncology (ASCO), the American Society of Human Genetics (ASHG), and the College of American Pathologists (ACP).

OA has developed a database comprised of molecular testing options that it refers to as "protocols." Treating physicians (typically oncologists, but in some cases, practitioners of various surgical sub-specialties, geneticists, pathologists, or other providers) or their staff assign the appropriate test protocol(s) to their patients to initiate prior authorization review.

OA's clinical staff maintains the database of test protocols. 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, pathology, genetics, and other cancer-related specialties are changing rapidly. Accordingly, new protocols are evaluated and continually added to OA's database.

Review criteria used by OA to determine whether test(s) are medically necessary:

- Use of a test in a manner consistent with a payer's commercial or Medicare coverage policies.
- If a test is required for the appropriate prescribing of an anti-cancer drug (i.e., a "companion diagnostic test"), that the test is included in those included in the list maintained by the FDA as a companion diagnostic test at https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools
- Where appropriate, a test that is substantially similar to that recognized by the FDA as a companion diagnostic test, and where the similar test is performed in CLIA-certified laboratory, as defined by https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA
- Where appropriate, where a test is included in the clinical pathways or other medical-decision-making processes outlined in the guidelines of the National Comprehensive Cancer Network (NCCN®), www.nccn.org, as follows:
    - NCCN Guidelines® for treatment of cancer by site OR
    - NCCN Biomarkers Compendium® OR
    - NCCN Guidelines for Detection, Prevention and Risk Reduction
    - In all cases, the following criteria will apply:
        - Category 1-2A recommendations are considered medically accepted uses

    - Category 2B recommendations will be considered if identified as medically accepted supported by peer-reviewed scientific literature eligible for coverage, as outlined below.
    - Category 3 listings are considered not medically accepted uses
- Where appropriate, where a test is included in the guidelines maintained by the American Society of Clinical Oncology (ASCO), www.asco.org, the American Society of Human Genetics (ASHG), www.ashg.org, and the College of American Pathologists (ACP), www.acp.org.
- Non-guideline use of tests may also be considered medically accepted if supported as medically necessary 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

Clinical trials can establish the comparative effectiveness of tests and produce the best data for decision-making. 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 requirements and/or health plan-specific policies, where applicable.
- Unique cases (e.g., those 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 physician 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, obsolete treatment protocols are inactivated, making them no longer available for view by treating oncologists and their staff.

In general, when reviewing a prior authorization request, OA considers value to medical decision-making, followed by cost. OA never recommends denial of a request based on cost alone. OA uses a proprietary method to create a high-quality, value-based subset of test options that are automatically approved (which OA refers to as "auto protocols"). In general, if a value-based treatment option is selected, then OA quickly recommends to the payer that the request be approved. All requests that are may not be value-based (which OA refers to as "non-auto protocols") are reviewed by members of the OA clinical team, which includes board-certified medical oncologists. If a recommendation for adverse determination (RAD) or a denial based on a lack of medical necessity is issued, then a detailed, written explanation with references is provided, which includes the rationale for the decision and possible alternative choices, along with the guidelines used to make the decision.