Updates to Carelon Medical Benefits Management, Inc. Clinical Appropriateness Guidelines

Effective for dates of service on and after November 17, 2024, the following updates will apply to the Carelon Medical Benefits Management, Inc. Clinical Appropriateness Guidelines. As part of the Carelon guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services.

Genetic Testing

Cell-free DNA Testing (Liquid Biopsy) for the Management of Cancer

- Expanded criteria to include a wider scope of testing for metastatic disease: AKT1 and PTEN (related to capivasertib/fulvestrant therapy)
- Added clarification that liquid screening tests are not medically necessary.
- Added clarification that liquid biopsy used to assess MRD during and after treatment is not medically necessary.

Prenatal Testing [changed to Screening] using cell free DNA

- Expanded criteria to include follow-up screening for abnormal maternal serum screen results in viable singleton/twin pregnancies when diagnostic testing is declined.
- Expanded criteria to include screening for pregnancies with multiple anomalies when diagnostic testing is not possible.
- Clarifications added to clinical scenarios in which cfDNA screening is considered not medically necessary.

Somatic Testing of Solid Tumors

- Tissue-agnostic testing for patients with advanced solid tumors
    - Clarification about TMB testing by FDA-approved test with reporting threshold ≥ 10 mutations/megabase (mut/Mb)
- Bladder cancer
    - Expansive changes for microsatellite instability/mismatch repair deficiency (MSI/dMMR)
- Brain cancer
    - New clinical criteria considered clarifications for what may have otherwise been reviewed using general (umbrella) criteria
- Breast cancer, metastatic
    - Expanded criteria to include a wider scope of testing for metastatic disease: AKT1 and PTEN (related to capivasertib/fulvestrant therapy)
- Cholangiocarcinoma (Biliary Tract Cancers)
    - Clarification around specific pathogenic variants in which testing is indicated
- Colorectal cancer, localized and metastatic
    - Newly diagnosed localized or metastatic CRC – Expanded criteria for MSI/dMMR testing to allow in individuals with de novo metastatic disease
    - Metastatic CRC – Expanded POLE/POLD1 testing
- Endometrial carcinoma
    - Expanded routine testing for MSI/dMMR; also expanded POLE and p53 testing
    - Panel size limited to ≤ 50 genes
- Non-small cell lung cancer, metastatic
    - New criteria for metastatic squamous cell carcinoma

    - Allowance for repeat NGS testing in the setting of progressive disease, if a progressing lesion is being used for the repeat testing
- Ovarian (epithelial)
    - Added statement that HRD testing must include evaluation of genomic instability through an FDA approved test
- Pancreatic adenocarcinoma
    - Added criteria for targeted (50 or fewer genes) somatic testing beyond MSI/dMMR in locally advanced, metastatic, or recurrent pancreatic adenocarcinoma
- Prostate cancer, metastatic
    - Specified appropriateness of MSI/dMMR testing is in metastatic prostate cancer
    - Moved ATM from required to "may be included" genes in approvable NGS panels
    - Clarified the HRD genes which may be in panels in addition to BRCA testing
- Thyroid cancer
    - Testing of indeterminate thyroid nodules (ITN) – Afirma GSC added as a gene expression classifier that may be used
    - Somatic testing of thyroid malignancy – Modified language so that BRAF V600E, ALK, NTRK, and RET testing can be done in anaplastic thyroid cancer at any stage, or in unresectable, locally advanced, recurrent, or metastatic thyroid cancer

Somatic Testing of Hematologic Malignancies

- Acute Lymphocytic Leukemia
    - Added statement about NGS testing on bone marrow specimen which specifies time points where testing is appropriate (end of initial induction, end of initial consolidation, etc.)
- Acute Myelogenous Leukemia
    - Added an indication for focused testing using RT-qPCR to measure minimal residual disease (MRD)
- Chronic Myeloid Leukemia
    - Modified the timing for BCR-ABL1 quantification for monitoring in the first year after completion of tyrosine kinase inhibitor (TKI) therapy
    - Added allowance for BCR-ABL1 quantification for monitoring patients at 3-month intervals beyond one year after completion of TKI therapy
- Myeloproliferative Neoplasms
    - Added allowance for additional focused testing for initial risk stratification if a specific myeloproliferative neoplasm is diagnosed on initial diagnostic workup
- Myelodysplastic Syndrome
    - Clarified that testing can be pursued for diagnosis or risk stratification and clarified the list of genes that may be associated with MDS

For questions related to guidelines, please contact Carelon via email at MedicalBenefitsManagement.guidelines@Carelon.com. Additionally, you may access and download a copy of the current and upcoming guidelines here.