Updates to Carelon Medical Benefits Management Clinical Appropriateness Guidelines

Massachusetts | Commercial

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 annual guideline review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable healthcare 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)

Prenatal 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

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)
- 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
- 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, and the like)
- 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 three-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

Musculoskeletal

Joint surgery:

- Reverse shoulder arthroplasty:
  - Added a requirement for impaired function for six months for consistency with total shoulder arthroplasty
  - Removed requirement for conservative management when there is severe osteoarthritis for consistency with other joint replacements
- Shoulder arthroscopy and open procedures:
  - Removal of loose body — removed requirement for specific findings on exam
  - Rotator cuff repair and revision — added an exclusion for subacromial balloon spacer due to lack of supporting evidence
  - Labrum repair — removed bankart lesion broadening MRI findings to allow for any labral tear
  - Chronic shoulder instability or laxity — broadened exam findings to include any evidence of instability rather than just the apprehension/relocation test
  - Tendinopathy of the long head of the biceps — removed specific exam findings related to long head of biceps pathology
- Primary total hip arthroplasty:
  - Removed the requirements for conservative management and three-month duration of symptoms when radiographs show severe osteoarthritis
- Primary partial hip arthroplasty:
  - Combined criteria for partial hip arthroplasty and partial hip resurfacing
- Hip arthroscopy:
  - Removal of loose body — removed requirement for specific findings on exam
- Knee arthroplasty:
  Added exclusion for the use of an implantable shock absorber due to lack of supporting evidence
- Knee arthroscopy:
  - ACL reconstruction — removed standalone scenario of physically demanding occupation/pattern of activities
  - Excision of popliteal cyst — added imaging requirement
  - Repair of subchondral bone defects (subchondroplasty) — added exclusion for use of engineered calcium phosphate mineral or similar compounds due to lack of supporting evidence
- Osteochondral grafts:
  - Juvenile osteochondritis dissecans — expanded allowances to include either failed conservative management or unstable lesion
  - Added exclusion for use of particulated juvenile articular cartilage due to lack of evidence supporting its use

Small joint surgery:

- Hallux rigidus surgery:
  - First metatarsophalangeal joint arthrodesis — removed three-month requirement for conservative management (not needed with severe osteoarthritis)
  - First metatarsophalangeal joint arthroplasty — removed three-month requirement for conservative management; added allowance for failed prior hallux rigidus surgery
- Ankle arthritis:

  - Ankle arthrodesis and total ankle arthroplasty — removed requirement for conservative management when there is severe osteoarthritis for consistency with other joint replacements
  - Revision total ankle arthroplasty — added requirement for reconstruction after the management of periprosthetic infection to be consistent for staged reconstructions of infected total ankle

As a reminder, ordering and servicing providers may submit prior authorization requests to Carelon Medical Benefits Management using the following:

- Find out more at Carelon.com:
  - Online access is available 24/7 to process orders in real-time and is the fastest and most convenient way to request authorization.

If you have questions related to guidelines, please email Carelon Medical Benefits Management at MedicalBenefitsManagement.guidelines@Carelon.com. Additionally, you may access and download a copy of the current and upcoming guidelines at tinyurl.com/4a8zdzbm.

We look forward to working together to achieve improved outcomes.