

Bladder Cancer Treatment and Recurrence Algorithmic Tests

- I. The use of bladder cancer treatment and recurrence algorithmic tests is considered **medically necessary** when:
 - A. The member has a diagnosis of bladder cancer, **AND**
 - B. The results of algorithmic testing will affect management decisions for the member's bladder cancer, **AND**
 - C. The member has not previously undergone bladder cancer treatment and recurrence algorithmic testing for the current cancer diagnosis.
- II. The use of bladder cancer treatment and recurrence algorithmic test is considered **investigational** for all other indications.

RATIONALE AND REFERENCES

Bladder Cancer Treatment and Recurrence Algorithmic Tests

Centers for Medicare and Medicaid Services (CMS)

The CMS local coverage determination (LCD) entitled "MoIDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer" states the following regarding bladder cancer molecular diagnostic tests, including algorithmic tests:

"This contractor will cover molecular diagnostic tests for use in a beneficiary with bladder cancer when all of the following conditions are met:

1. The beneficiary is being actively managed for bladder cancer.
2. At least 1 of the 2 criteria are met:
 - a. The patient is a candidate for multiple potential treatments, which could be considered to have varied or increasing levels of intensity based on a consensus guideline, and the physician and patient must decide among these treatments. OR
 - b. The patient is a candidate for multiple therapies, and the test has shown that it predicts response to a specific therapy among accepted therapy options based on nationally recognized society consensus guidelines

3. The test successfully completes a Molecular Diagnostic Services Program (MoIDX) technical assessment that ensures the test is reasonable and necessary as described above.
4. Only 1 test may be performed prior to the initiation of therapy UNLESS a second test that interrogates different genomic content AND meets all the criteria established herein, is reasonable and necessary.
5. The genomic content interrogated by the test must be relevant to the therapy under consideration”.

Centers for Medicare & Medicaid Services., Dep't of Health & Human Services (CMS), Medicare Coverage Database: Local Coverage Determination MoIDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (L38576). Available at:

<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38576>