



Reimbursement Policy

Policy Number: RPLAB038

Policy Title: Urinary Tumor Markers for Bladder Cancer

Approval Date: May 15, 2026

Effective Date: Sept. 4, 2026

Policy Disclaimer

If a conflict arises between a Reimbursement Policy and any Plan document under which a member is entitled to covered services, the Plan document will govern. If a conflict arises between a reimbursement policy and any provider contract pursuant to which a provider participates in and/or provides covered services to eligible member(s) and/or plans, the provider's contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, Benefit Booklets, Summary Plan Descriptions, and other coverage documents. Blue Cross and Blue Shield of Texas may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSTX has full and final discretionary authority for their interpretation and application to the extent provided under any applicable Plan documents.

Providers are responsible for submitting accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing Editor, American Medical Association, Current Procedural Terminology (CPT®) Assistant, Healthcare Common Procedure Coding System, ICD-10-CM and ICD-10-PCS, National Drug Codes, Diagnosis Related Group guidelines, Centers for Medicare & Medicaid Services National Correct Coding Initiative Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services and procedures billed. Claim submissions are subject to claim review, including but not limited to, any terms of benefit coverage, provider contract language, medical policies, and reimbursement policies, as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Description

The Plan has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information

1. As an adjunct to cystoscopy, urinary biomarkers (bladder tumor antigen test/BTA, nuclear matrix protein [NMP22] test, or fluorescence in situ hybridization/FISH UroVysion Bladder Cancer test) testing **may be reimbursable** in **any** of the following situations:
 - a. In the diagnostic exclusion of bladder cancer for individuals who have an atypical or equivocal cytology;
 - b. In the monitoring of high-risk, non-muscle invasive bladder cancer.
2. As an adjunct to cystoscopy or urinary cytology in the monitoring of individuals with bladder cancer, the use of fluorescence immunocytology (ImmunoCyt/uCyt) **may be reimbursable**.
3. For the evaluation of hematuria, to screen for bladder cancer in asymptomatic individuals, to diagnose bladder cancer in symptomatic individuals, or for any other indications not discussed above, the following tests **are not reimbursable**:
 - a. Urinary biomarkers (bladder tumor antigen test/BTA, nuclear matrix protein [NMP22] test, or fluorescence in situ hybridization/FISH UroVysion Bladder Cancer test);
 - b. Fluorescence immunocytology (ImmunoCyt/uCyt).
4. Any other urinary tumor markers for bladder cancer not mentioned above **are not reimbursable**.

Procedure Codes

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

Code	Description
86294	IMMUNOASSAY TUMOR QUAL
86316	IMMUNOASSAY TUMOR OTHER
86386	NUCLEAR MATRIX PROTEIN 22
88120	CYTP URNE 3-5 PROBES EA SPEC
88121	CYTP URINE 3-5 PROBES CMPTR

88346	IMFLUOR 1ST 1ANTB STAIN PX
88350	IMFLUOR EA ADDL 1ANTB STN PX
0365U	ONC BLDR 10 UR HRBR URTHL CA
0366U	ONC BLDR 10 PRB RECR BLDR CA
0367U	ONC BLDR 10 FLWG TRURL RESCJ

CPT copyright 2025 American Medical Association (AMA). All rights reserved. CPT is a registered trademark of the AMA.

References

1. Lerner SP, Raghavan, Derek. Overview of the initial approach and management of urothelial bladder cancer. Updated July 29, 2024. <https://www.uptodate.com/contents/overview-of-the-initial-approach-and-management-of-urothelial-bladder-cancer>
2. Hottinger AF, Hormigo A. Serum Biomarkers. In: Schwab M, ed. *Encyclopedia of Cancer*. Springer Berlin Heidelberg; 2011:3390-3394.
3. ACS. Key Statistics for Bladder Cancer. Updated March 12, 2024. <https://www.cancer.org/cancer/types/bladder-cancer/about/key-statistics.html>
4. NCCN. NCCN Guidelines Version 3.2025 Bladder Cancer. Updated December 19, 2025. https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf
5. DeGeorge KC, Holt HR, Hodges SC. Bladder Cancer: Diagnosis and Treatment. 2017;(1532-0650 (Electronic))
6. Perazalla M. Evaluation of hematuria in adults. Updated October 1, 2025. <https://www.uptodate.com/contents/evaluation-of-hematuria-in-adults>
7. Lotan Y, Choueiri T. Clinical presentation, diagnosis, and staging of bladder cancer. Updated December 18, 2025. <https://www.uptodate.com/contents/clinical-presentation-diagnosis-and-staging-of-bladder-cancer>
8. Sutton AJ, Lamont JV, Evans RM, et al. An early analysis of the cost-effectiveness of a diagnostic classifier for risk stratification of haematuria patients (DCRSHP) compared to flexible cystoscopy in the diagnosis of bladder cancer. *PloS one*. 2018;13(8):e0202796. doi:10.1371/journal.pone.0202796
9. Kaufman DS, Shipley WU, Feldman AS. Bladder cancer. *Lancet (London, England)*. Jul 18 2009;374(9685):239-49. doi:10.1016/s0140-6736(09)60491-8
10. Chou R, Dana T. Screening adults for bladder cancer: A review of the evidence for the u.s. preventive services task force. *Annals of Internal Medicine*. 2010;153(7):461-468. doi:10.7326/0003-4819-153-7-201010050-00009
11. Mitra A, Birkman M, Penson D, Cote R. Urine biomarkers for the detection of urothelial (transitional cell) carcinoma of the bladder Updated January 18, 2024. <https://www.uptodate.com/contents/urine-biomarkers-for-the-detection-of-urothelial-transitional-cell-carcinoma-of-the-bladder>
12. Lopez-Beltran A, Cheng L, Gevaert T, et al. Current and emerging bladder cancer biomarkers with an emphasis on urine biomarkers. *Expert Rev Mol Diagn*. Dec 11 2019;1-13. doi:10.1080/14737159.2020.1699791

-
13. D'Costa JJ, Goldsmith JC, Wilson JS, Bryan RT, Ward DG. A Systematic Review of the Diagnostic and Prognostic Value of Urinary Protein Biomarkers in Urothelial Bladder Cancer. *Bladder cancer (Amsterdam, Netherlands)*. 2016;2(3):301-317. doi:10.3233/blc-160054
 14. Lotan Y, Elias K, Svatek RS, et al. Bladder cancer screening in a high risk asymptomatic population using a point of care urine based protein tumor marker. *The Journal of urology*. Jul 2009;182(1):52-7; discussion 58. doi:10.1016/j.juro.2009.02.142
 15. Li HT, Duymich CE, Weisenberger DJ, Liang G. Genetic and Epigenetic Alterations in Bladder Cancer. *Int Neurourol J*. Nov 2016;20(Suppl 2):S84-94. doi:10.5213/inj.1632752.376
 16. Mahnert B, Tauber S, Kriegmair M, et al. BTA-TRAK--a useful diagnostic tool in urinary bladder cancer? *Anticancer research*. Jul-Aug 1999;19(4a):2615-9.
 17. Grossman H, Messing E, Soloway M, et al. Detection of bladder cancer using a point-of-care proteomic assay. *JAMA*. 2005;293(7):810-816. doi:10.1001/jama.293.7.810
 18. Zuiverloon TCM, de Jong FC, Theodorescu D. Clinical Decision Making in Surveillance of Non-Muscle-Invasive Bladder Cancer: The Evolving Roles of Urinary Cytology and Molecular Markers. *Oncology (Williston Park, NY)*. Dec 15 2017;31(12):855-62.
 19. Abbott. ALERE NMP22® BLADDERCHEK®. <https://www.globalpointofcare.abbott/en/product-details/nmp22-bladderchek.html>
 20. Diagnostics I. Bladder Cancer Detection. <https://arocell.com/products/oncology/ubc-rapid/>
 21. Ecke TH, Weiß S, Stephan C, et al. UBC(®) Rapid Test-A Urinary Point-of-Care (POC) Assay for Diagnosis of Bladder Cancer with a focus on Non-Muscle Invasive High-Grade Tumors: Results of a Multicenter-Study. *Int J Mol Sci*. Dec 2 2018;19(12)doi:10.3390/ijms19123841
 22. NICE. URO17 for detecting bladder cancer. Updated February 4, 2021. <https://www.nice.org.uk/advice/mib250/chapter/The-technology>
 23. KdX Diagnostics. URO17® A Better test For Better Health. <https://kdxdiagnostics.com/uro17/>
 24. Vasdev, Hampson A, Agarwal S, et al. The role of URO17™ biomarker to enhance diagnosis of urothelial cancer in new hematuria patients-First European Data. *BJUI Compass*. Jan 2021;2(1):46-52. doi:10.1002/bco2.50
 25. Nonagen Bioscience. Bladder Cancer. <https://www.nonagen.com/products>
 26. Soubra A, Risk MC. Diagnostics techniques in nonmuscle invasive bladder cancer. *Indian journal of urology : IJU : journal of the Urological Society of India*. Oct-Dec 2015;31(4):283-8. doi:10.4103/0970-1591.166449
 27. Lotan Y, Roehrborn CG. Sensitivity and specificity of commonly available bladder tumor markers versus cytology: results of a comprehensive literature review and meta-analyses. *Urology*. 2003;61(1):109-118. doi:10.1016/S0090-4295(02)02136-2
 28. Hirasawa Y, Pagano I, Chen R, et al. Diagnostic performance of Oncuria™, a urinalysis test for bladder cancer. *Journal of Translational Medicine*. 2021/04/06 2021;19(1):141. doi:10.1186/s12967-021-02796-4
 29. Schmitz-Dräger BJ, Droller M, Lokeshwar VB, et al. Molecular Markers for Bladder Cancer Screening, Early Diagnosis, and Surveillance: The WHO/ICUD Consensus. *Urologia Internationalis*. 2015;94(1):1-24. doi:10.1159/000369357

-
30. Halpern JA, Chughtai B, Ghomrawi H. Cost-effectiveness of Common Diagnostic Approaches for Evaluation of Asymptomatic Microscopic Hematuria. *JAMA internal medicine*. Jun 2017;177(6):800-807. doi:10.1001/jamainternmed.2017.0739
 31. Meleth S, Reeder-Hayes K, Ashok M, et al. AHRQ Technology Assessments. *Technology Assessment of Molecular Pathology Testing for the Estimation of Prognosis for Common Cancers*. Agency for Healthcare Research and Quality (US); 2014.
 32. Tan WS, Tan WP, Tan MY, et al. Novel urinary biomarkers for the detection of bladder cancer: A systematic review. *Cancer Treat Rev*. Sep 2018;69:39-52. doi:10.1016/j.ctrv.2018.05.012
 33. Mossanen M, Wang Y, Szymaniak J, et al. Evaluating the cost of surveillance for non-muscle-invasive bladder cancer: an analysis based on risk categories. *World J Urol*. Oct 2019;37(10):2059-2065. doi:10.1007/s00345-018-2550-x
 34. Vasdev N, Hampson A, Agarwal S, et al. The role of URO17™ biomarker to enhance diagnosis of urothelial cancer in new hematuria patients—First European Data. *BJUI Compass*. 2021;2(1):46-52. doi:10.1002/bco2.50
 35. Davis R, Jones JS, Barocas DA, et al. Diagnosis, evaluation and follow-up of asymptomatic microhematuria (AMH) in adults: AUA guideline. *The Journal of urology*. Dec 2012;188(6 Suppl):2473-81. doi:10.1016/j.juro.2012.09.078
 36. Barocas DA, Boorjian SA, Alvarez RD, et al. Microhematuria: AUA/SUFU Guideline. *The Journal of urology*. Oct 2021;204(4):778-786. doi:10.1097/ju.0000000000001297
 37. Barocas DA, Lotan Y, Matulewicz RS, et al. Updates to Microhematuria: AUA/SUFU Guideline (2025). *The Journal of urology*. May 2025;213(5):547-557. doi:10.1097/JU.0000000000004490
 38. Chang SS, Boorjian SA, Chou R, et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline. *The Journal of urology*. Oct 2016;196(4):1021-9. doi:10.1016/j.juro.2016.06.049
 39. Holzbeierlein J BB, Buckley DI, et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment. *Journal of Urology [Internet]*. 2024 Apr 1 2024;
 40. Chang SS, Bochner BH, Chou R, et al. Treatment of Non-Metastatic Muscle-Invasive Bladder Cancer: AUA/ASCO/ASTRO/SUO Guideline. *The Journal of urology*. Sep 2017;198(3):552-559. doi:10.1016/j.juro.2017.04.086
 41. Moyer VA. Screening for bladder cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. Aug 16 2011;155(4):246-51. doi:10.7326/0003-4819-155-4-201108160-00008
 42. USPSTF. Bladder Cancer in Adults: Screening. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/bladder-cancer-in-adults-screening>
 43. Monteiro LL, Witjes JA, Agarwal PK, et al. ICUD-SIU International Consultation on Bladder Cancer 2017: management of non-muscle invasive bladder cancer. 2018:1-10.
 44. NCI. Bladder and Other Urothelial Cancers Screening (PDQ®)—Health Professional Version. U.S. Department of Health and Human Services. Accessed 12/12/2024, <https://www.cancer.gov/types/bladder/hp/bladder-screening-pdq>

45. Alfred Witjes J, Max Bruins H, Carrion A, et al. European Association of Urology Guidelines on Muscle-invasive and Metastatic Bladder Cancer: Summary of the 2023 Guidelines. *Eur Urol*. Jan 2024;85(1):17-31. doi:10.1016/j.eururo.2023.08.016
46. Babjuk M, Burger M, Capoun O, et al. European Association of Urology Guidelines on Non-muscle-invasive Bladder Cancer (Ta, T1, and Carcinoma in Situ). *European Urology*. 2022;81(1):75-94. doi:10.1016/j.eururo.2021.08.010
47. EAU. EAU Guidelines on Non-muscle Invasive Bladder Cancer. <https://uroweb.org/guidelines/non-muscle-invasive-bladder-cancer>
48. Bhindi B, Kool R, Kulkarni GS, et al. Canadian Urological Association guideline on the management of non-muscle-invasive bladder cancer – Full-text. *Can Urol Assoc J* 2021;
49. Stecca C, Chowdhury D, Blais N, et al. 2024 CUA-GUMOC Expert Report: Management of unresectable locally advanced and metastatic urothelial carcinoma. *Can Urol Assoc J*. 2024;18(12):379-90
50. FDA. 510(k) Summary Information. https://www.accessdata.fda.gov/cdrh_docs/pdf/K964151.pdf
51. FDA. 510(k) Summary Information. https://www.accessdata.fda.gov/cdrh_docs/pdf/K971402.pdf
52. FDA. Premarket Approval. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P940035>
53. FDA. 510(k) Summary. https://www.accessdata.fda.gov/cdrh_docs/pdf2/K021231.pdf
54. FDA. Premarket Approval. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030052>
55. FDA. 510(k) number: K994356. https://www.accessdata.fda.gov/cdrh_docs/pdf/K994356.pdf
56. Darwiche F, Parekh DJ, Gonzalgo ML. Biomarkers for non-muscle invasive bladder cancer: Current tests and future promise. *Indian journal of urology : IJU : journal of the Urological Society of India*. Oct-Dec 2015;31(4):273-82. doi:10.4103/0970-1591.166448

Policy History

Approval Date	Description
05/15/2026	09/04/2026; Document updated with literature review. The following change was made to Reimbursement Information: #1 and #2 were edited for clarity. References revised.
01/12/2026	5/1/2026; Removed codes 0012M, 0013M, 0363U, 0420U, 0452U, 0465U, 0549U. References revised.
02/05/2025	05/15/2025; Added code 0549U. No other changes.
09/13/2024	01/01/2025: New policy.