

Policy Key: Laboratory and Pathology

TriWest Clinical Operations – TRICARE West

SCOPE

This Policy Key provides criteria to be used during medical necessity review for Laboratory and/or Pathology services.

FDA-Approved Tests on this PK

- **NAAT Tests for Bacterial Vaginosis**
 - Bacterial Vaginosis (BV) Assay (CPT 81513)
 - BD Max™ Vaginal Panel (Becton Dickinson)
 - Xpert® Xpress MVP (Cepheid)
- **ClonoSeq Assay** - Indicated for detection and monitoring of minimal residual disease (MRD) in patients with acute lymphoblastic leukemia (ALL), multiple myeloma (MM), and chronic lymphocytic leukemia (CLL).
- **therascreen @She PIK3CA RGQ PCR Test** for the detection of PIK3CA mutations in tumor tissue or plasma

NOT COVERED [1,2,3,4]

- Autopsy or Postmortem laboratory or pathology testing.
- Sperm penetration assay (hamster oocyte penetration test or the zona-free hamster egg test) is excluded for In Vitro Fertilization (IVF).
- In-vitro chemoresistance and chemosensitivity assays (stem cell assay, differential staining cytotoxicity assay and thymidine incorporation assay).
- Insemination of oocytes
- Extended culture of oocyte(s) embryo(s) four to seven calendar days
- Assisted oocyte fertilization, microtechnique
- Biopsy oocyte polar body or embryo blastomere Biopsy oocyte polar body or embryo blastomere; greater than four embryos
- Cryopreservation reproductive tissue, testicular oocyte(s) and ovarian tissue.
- Storage (per year) embryo(s), sperm/semens, reproductive tissue, testicular/ovarian, or oocyte
- Thawing of cryopreserved, embryo(s). Thawing of cryopreserved, sperm/semens, each aliquot
- Thawing of cryopreserved, reproductive tissue, testicular/ovarian Thawing of cryopreserved, oocytes, each aliquot
- Oncotype Dx Colon Cancer is on the health.mil LDT Excluded List and is not approved.
- OVA1™ test for ovarian cancer
- The Pathwork® Tissue of Origin Test is unproven to assist in identifying the origin of poorly differentiated, undifferentiated, or metastatic tumors.

- Vitamin D screening in asymptomatic individuals in the general population, as a preventive measure, and/or during examinations without abnormal findings
- Blood typing for paternity testing
- Unused whole blood and blood components
- Testing of autologous blood
- Transfusion service for autologous blood and blood components in the absence of a scheduled covered surgical procedure.
- Genetic testing that is not medically necessary and does not influence medical management, such as the Agenda® Breast Cancer Test Suite (MammaPrint, TargetPrint, and BluePrint), AncestryDNA, 23andMe Personal Genome Service, and other direct-to-consumer genetic testing, even if FDA approved.
- Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family, as this code is limited to genetic counselors that are not recognized as TRICARE-authorized providers
- FDA approved tests that represent preventive services that are not recommended by HHS.
- Drug screening using blood and urine simultaneously
- Drug screening for medico-legal purposes (i.e., court-ordered, forensic, criminal, social service agency investigations, parents involved in legal cases), employment purposes (i.e., as a prerequisite for employment or continuation of employment), or for drug testing or compliance in school settings.
- Routine drug screening, except when permitted by policy (e.g., monitoring for patient compliance during active treatment).
- Other drug screening for purposes unrelated to medical necessity and for situations where drug testing will not impact the medical management of the patient.
- Laboratory or pathology services related to non-covered services.

Note: Services related to Cryopreservation and/or Assisted Reproductive Technology (ART) services may be covered under the Supplemental Health Care Program (SHCP), for eligible beneficiaries. See Policy Key: SHCP Reproductive Services if beneficiary is covered under SHCP.

COVERAGE CRITERIA

ClonoSeq [8]

- **Initial Level of Review** may approve for the following:
 - FDA-Approved indications for Measurable Residual Disease (MRD)
 - Bone marrow specimens:
 - Acute Lymphoblastic Leukemia B-ALL (**not** T-cell or T-ALL)
 - Multiple Myeloma (MM)
 - Blood or bone marrow specimens:
 - Chronic Lymphocytic Leukemia (CLL)

Note: Non-FDA Approved indications should be denied. Examples of non-FDA approved indications, though not limited to, are investigational or off-label, Mixed Phenotype Acute Leukemia (MPAL), Cutaneous T-cell Lymphoma (CTCL), Large B-cell Lymphoma (LBCL), and other lymphoid cancers.

NAAT Tests for Bacterial Vaginosis

Bacterial Vaginosis (BV) Assay (CPT 81513) [9-13]

- **Initial Level of Review** may approve test for the diagnosis of bacterial vaginosis in women if all of the following criteria are met:
 - With symptoms of vaginitis or vaginosis
 - 14 years and older
 - Using either clinician- or self-collected vaginal swab specimens

Other FDA-Approved Tests for bacterial vaginosis

- BD Max™ Vaginal Panel (Becton Dickinson)
- Xpert® Xpress MVP (Cepheid)

NOTE: The test is NOT intended for screening asymptomatic patients, prognostic use, or test-of-cure

therascreen® PIK3CA RGQ PCR Test (CPT 81540) [6, 7]

- **Initial Level of Review** may approve test as indicated for the detection of PIK3CA mutations in tumor tissue or plasma if all of the following criteria are met:
 - Hormone receptor-positive (ER+, PR+)
 - HER2-negative (HER-) advanced or metastatic breast cancer
 - Disease progression on or after endocrine therapy

NOTE: The test is used to identify candidates for **treatment with alpelisib in combination with fulvestrant after progression on or after endocrine therapy**. This (treatment) recommendation applies regardless of age, provided the beneficiary is postmenopausal or male. [5, 7]

General Lab and Pathology

Initial Level of Review Follow the steps below in sequential order:

1. Is the service a [Laboratory Developed Test](#)?
 - a. If yes, the request will be reviewed by EviCore.
 - b. If no, go to step #2.
2. Is the requested service listed in the 'Not Covered' section above?
 - a. If yes, refer to the Medical Director for denial.
 - b. If no, go to step #3.
3. If none of the situations in the Not Covered section apply, the service may be approved.
 - a. Examples include, but are not limited to the following:
 - i. Pathology and laboratory services
 - ii. Surgical pathology procedures billed by a pathologist (not by the surgeon)

- iii. Dermatological pathology procedures, including pathological analysis
 - iv. Human papillomavirus testing for Atypical Squamous Cells of Undetermined Origin (ASCUS)
 - v. Nuclear Magnetic Resonance (NMR) Lipo Profile-2 test, used with the NMR Profiler for the management of lipoprotein disorders associated with cardiovascular disease
 - vi. AlloMap for molecular testing for cardiac transplant rejection surveillance
 - vii. Infusion of whole blood and blood components (red cells, platelets, plasma, or leukocytes) or blood derivatives (albumin, gamma globulin, Factors VIII and IX, or Rho[D] Immune Globulins [RhoGAM], and prothrombin) directly into the blood stream, when administered to the patient
 - viii. Transfusion services (as supplies or laboratory services) for allogeneic and autologous blood, when they are used by the patient
 - ix. Blood derivatives (classified as prescription drugs)
 - x. Genetic counseling provided by an authorized provider
 - xi. Genetic tests that have received United States (U.S.) Food and Drug Administration (FDA) medical device 510(k) clearance or premarket approval that are medically necessary for the diagnosis and treatment of an illness or injury and have demonstrated clinical utility are a TRICARE benefit
 - xii. Note: Non-FDA approved genetic tests that are covered under the Defense Health Agency (DHA) Evaluation of Non-FDA Approved Laboratory Developed Tests (LDTs) Demonstration Project may be found in the TRICARE Operations Manual (TOM), Chapter 18, Section 3.
 - xiii. For preconception and prenatal carrier screening tests, see Chapter 6, Section 3.2.
 - xiv. Coverage of FDA-approved genetic tests that represent a preventive service (e.g., Cologuard™) must be based on recommendations from the U.S. Department of Health and Human Services (HHS). This includes recommendations from the United States Preventive Services Task Force (USPSTF) and the Health Resources and Services Administration (HRSA). (See Chapter 7, Sections 2.1 and 2.2.)
- b. The following preconception and prenatal carrier screening tests may be cost-shared (one test per lifetime):
- i. Cystic fibrosis
 - ii. Spinal muscular atrophy
 - iii. Fragile X syndrome
 - iv. Tay-Sachs disease
 - v. Hemoglobinopathies
 - vi. Ashkenazi-Jew-linked conditions
- c. TRICARE covers medically necessary and appropriate qualitative and quantitative drug testing
- i. Unreliable history
 - ii. Multiple drug ingestion



- iii. Delirium, coma, or unexplained altered mental status
- iv. Severe or unexplained cardiovascular instability
- v. Unexplained metabolic or respiratory acidosis
- vi. Seizures with an undetermined history
- vii. Diagnosis of a medical condition in which drug toxicity may be a contributing factor
- viii. Monitoring patient compliance during active treatment for substance abuse
- ix. Rare instances when a patient requires multiple, medically necessary screening tests for drugs of abuse to be performed in a single day (require medical necessity review)
- x. Drug screening to identify specific drugs, when antagonists may be used, or to provide quantitative information regarding specific drugs (cost shared)
- xi. Verify and further analyze initial drug testing
- xii. When medically necessary and appropriate
- xiii. When results will impact medical management
- xiv. Therapeutic drug assays to monitor clinical response to a known, prescribed medication, when medically necessary and appropriate

DEFINITIONS

NA

CODES

CPT 80048 - 87622, 87640, 87641, 87650 - 87999, 88104 - 89264, 89330 – 89399, 81479, 0364U, 81540

REFERENCES

[1] TRICARE Policy Manual 6010.63-M, April 2021, Change 17 (September 20, 2024), Chapter 6, Section 1.1, General, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C6S1_1.html

[2] TRICARE Policy Manual 6010.63-M, April 2021, Change 17 (September 20, 2024), Chapter 6, Section 4.1, Drug Testing, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C6S4_1.html

[3] TRICARE Policy Manual 6010.63-M, April 2021, Change 17 (September 20, 2024), Chapter 6, Section 2.1, Transfusion Services for Whole Blood Components, and Blood Derivatives, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C6S2_1.html

[4] TRICARE Policy Manual 6010.63-M, April 2021, Change 17 (September 20, 2024), Chapter 6, Section 3.1, Genetic Testing and Counseling, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C6S3_1.html

[5] U.S. Food and Drug Administration (FDA), Premarket Approval (PMA) P190001, theascreen® PIK3CA RGQ PCR Kit, Retrieved August 13, 2025, https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190001B.pdf

[6] U.S. Food and Drug Administration (FDA), Premarket Approval (PMA) P190004, theascreen® PIK3CA RQG PCR Kit, Retrieved August 13, 2025,

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190004>

[7] Burstein HJ, Somerfield MR, Barton DL, et al., Endocrine Treatment and Targeted Therapy for Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Metastatic Breast Cancer: ASCO Guideline Update, *Journal of Clinical Oncology*, Retrieved August 13, 2025,

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8659999/>

[8] U.S. Food and Drug Administration (FDA), Nucleic Acid Based Tests, Retrieved July 20, 2025,

<https://www.fda.gov/medical-devices/in-vitro-diagnostics/nucleic-acid-based-tests>

[9] Miller, J. M., Binnicker, M. J., Campbell, S., et al. (2024). Guide to utilization of the microbiology laboratory for diagnosis of infectious diseases: 2024 update. *Clinical Infectious Diseases, ciae104*.

<https://doi.org/10.1093/cid/ciae104>

[10] Schwebke, J. R., Taylor, S. N., Ackerman, R., et al. (2020). Clinical validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas vaginitis assays: Results from a prospective multicenter clinical study. *Journal of Clinical Microbiology*, 58(2), e01643-19. <https://doi.org/10.1128/JCM.01643-19>

[11] Ruffier d'Epenoux, L., Tessier, E., Guillouzouic, A., et al. (2022). Assessment of the performance of the Aptima Bacterial Vaginosis assay over a 3-month period in a French hospital. *Microbiology Spectrum*, 10(5), e0130122. <https://doi.org/10.1128/spectrum.01301-22>

[12] Caza, M., Charles, M., Locher, K., et al. (2023). Evaluation of the Aptima BV and CV/TV assays compared to conventional laboratory-based testing methods for the diagnosis of vaginitis. *Diagnostic Microbiology and Infectious Disease*, 106(4), 115953. <https://doi.org/10.1016/j.diagmicrobio.2023.115953>

[13] Workowski, K. A., Bachmann, L. H., Chan, P. A., et al. (2021). Sexually transmitted infections treatment guidelines, 2021. *MMWR Recommendations and Reports*, 70(4), 1–187.

<https://doi.org/10.15585/mmwr.rr7004a1>