

MEDICAL POLICY

POLICY TITLE	INVESTIGATIONAL MISCELLANEOUS GENETIC AND MOLECULAR TESTS
POLICY NUMBER	MP 2.277

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	RETIRED 7/1/2026

POLICY

All of the tests listed in this policy are considered **investigational**, and are grouped according to the categories of genetic testing as outlined in **MP 2.326 General Approach to Genetic Testing**:

- Testing of an affected (symptomatic) individual's germline to benefit the individual (excluding reproductive testing)
- Diagnostic testing
- Prognostic testing
- Therapeutic testing
- Testing an asymptomatic individual to determine future risk of disease.

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these tests.

POLICY GUIDELINES

Genetic testing is considered investigational when criteria are not met, including when there is insufficient evidence to determine whether the technology improves health outcomes.

Genetic Counseling

Genetic counseling is primarily aimed at patients who are at risk for inherited disorders, and experts recommend formal genetic counseling in most cases when genetic testing for an inherited condition is considered. The interpretation of the results of genetic tests and the understanding of risk factors can be very difficult and complex. Therefore, genetic counseling will assist individuals in understanding the possible benefits and harms of genetic testing, including the possible impact of the information on the individual's family. Genetic counseling may alter the utilization of genetic testing substantially and may reduce inappropriate testing. Genetic counseling should be performed by an individual with experience and expertise in genetic medicine and genetic testing methods.

Cross-References:

- MP 2.326 General Approach to Genetic Testing**
- MP 4.002 Experimental and Investigational Procedures**

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PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

DESCRIPTION/BACKGROUND

There are numerous commercially available genetic and molecular diagnostic, prognostic, and therapeutic tests for individuals with certain diseases or asymptomatic individuals with future risk. This evidence review evaluates miscellaneous genetic and molecular tests not addressed in a separate review. If a separate evidence review exists, then conclusions reached there supersede conclusions here. The main criterion for inclusion in this review is the limited evidence on the clinical validity for the test. As a result, these tests do not have clinical utility, and the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Tests Addressed in This Medical Policy

Tests assessed in this medical policy are listed in Table 1. All coding information is also found in this Table. Three types of tests are related to testing of an affected (symptomatic) individual's germline to benefit the individual (excluding reproductive testing): diagnostic testing, prognostic testing, and therapeutic testing. The fourth type of test reviewed is testing of an asymptomatic individual to determine future risk of disease.

Table 1. Genetic and Molecular Tests in This Medical Policy

All tests listed in this table are considered **investigational** therefore not covered.

Test Name	Manufacturer	Coding Information
Augusta Hematology Optical Genome Mapping	Georgia Esoteric and Molecular Labs	0331U
AidaBreast™	PreludeDx, Prelude Corporation	0597U
AssureMDx	Vesica Health, Inc.	0613U
Avent Lymphoma	Aventa Genomics, LLC	0592U
Avantect Ovarian Cancer Test	ClearNote Health	0507U
Avantect Pancreatic Cancer Test	ClearNote Health	0410U
Aventa FusionPlus	Aventa Genomics	0444U
BDX-XL2	Biodesix Inc	0080U
BeScreened-CRC	Beacon Biomedical	0163U

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Test Name	Manufacturer	Coding Information
BluePrint	Agendia	81479
BTG Early Detection of Pancreatic Cancer	Breakthrough Genomics	0405U
Catechol-O-Methyltransferase (COMT) Genotype	Mayo Clinic	0032U
CELLSEARCH® Circulating Melanoma Cell (CMC) Test	Menarini Silicon Biosystems Inc	0490U
ColonSentry®	Stage Zero Life Sciences	81479
Cxbladder Detect+	Pacific Edge Diagnostics	0420U
Decipher Bladder TURBT	Veracyte	0016M
DecisionDx® - SCC	Castle Biosciences	0315U
DetermaRx™	Oncocyte Corporation	0288U
DEPArray™	PacificDx	0009U
DH Optical Genome Mapping Assay	Dartmouth Health/Bionano Genomics	0413U
Diabetes Risk Test	Kihleath, Inc.	0602U
DNA Methylation Pathway Profile	Great Plains Laboratory (now Mosaic Dxcs)	81479
DNA Methylation Profiling	NA	81524
EarlyDx MethylScan HCC	Early Diagnostics Laboratory	0565U
Envisia® Genomic Classifier	Veracyte, Inc	81554
EPISEEK MPE	Precision Epigenomics	0566U
EpiSwitch® CiRT	Next Bio-Research Services	0332U
GI Effects® (Stool)	Genova Diagnostics	82274, 82725, 82784, 83520, 83993, 84311, 87045, 87046, 87075, 87102, 87177, 87209, 87328, 87329, 87336, 87505, 87798
Guardant360 Response	Guardant Health	0422U
Guardant Reveal	Guardant Health	0569U
HelioLiver™ Test	Fulgent Genetics LLC	0333U
HelioHCC™ Strat	Helio Genomics	0611U
HelioHCC™ Trace	Helio Genomics	0612U
HepatoTrack	LuminoDx Laboratory	0575U
HeproDX™	GoPath Laboratories LLC	0006M

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Test Name	Manufacturer	Coding Information
HPV-SEQ Test	Sysmex Inostics Inc	0470U
IBSchek®	Commonwealth Diagnostics International	0176U
ibs-smart®	Gemelli Biotech	0164U
Immunoscore®	HalioDx	0261U
inFoods® IBS	Ethos Laboratories, Biomerica	0598U
Kelch-Like Protein 11 Antibody	Mayo Clinic	0432U
Know Error™	Strand Diagnostics	84999
LC-MS/MS Targeted Proteomic Assay	OncoOmicDx Laboratory	0174U
Lifetime Genomics Risk Assessment, VTE	GenomicMD	0529U
LungLB®, LungLife®	LungLife AI	0317U
LungOI	Image AI	0414U
Lymph 2 Cx and Lymph3Cx Lymphoma Molecular Subtyping Assay	Mayo Clinic	0017M, 0120U
Medication Management Neuropsychiatric Panel	GENETWORx	0392U
Merkel smT Oncoprotein Antibody Titer and Merkel Virus VP1 Capsid Antibody	University of Washington, Department of Laboratory Medicine	0058U, 0059U
Merlin™ Test	SkylineDx USA, Inc	0578U
MindX Blood Test™- Longevity	MindX Sciences™ Laboratory	0294U
Molecular Microscope® MMDx-Heart	Kashi Clinical Laboratories	0087U
Navigator RHD/CE Sequencing, Navigator Rh Blood Group NGS	Grifols Immunohematology Center	0198U, 0222U
NavDx®	Naveris, Inc	0356U
NETest	Wren Laboratories LLC	0007M
Nodify CDT®	Biodesix, Inc	0360U
Northstar Response™	BillionToOne Laboratory	0486U
OmniGraf Liver	Eurofins Transplant Genomics, LLC	0576U
OncoSignal 7 Pathway Signal	Protean Bio-diagnostics	0262U
Oncotype DX® Breast DCIS Score™	Genomic Health, Inc	0045U

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Test Name	Manufacturer	Coding Information
Optical Genome Mapping	NA	81195, 81354
OptiSeq Dual Cancer Panel Kit	DiaCarta	0499U
Overa (OVA1 Next Generation), OvaWatch	Aspira Labs	0003U, 0375U
OptiSeq Colorectal Cancer NGS Panel	DiaCarta	0498U
PolypDX™	Atlantic Diagnostic Laboratories	0002U
Praxis Somatic Whole Genome Sequencing/Transcriptome/Optical Genome Mapping/Combined Whole Genome Sequencing and Optical Genome Mapping	Praxis Genomics LLC	0297U, 0298U, 0299U, 0300U
PredictSURE IBD™ Test	KSL Diagnostics	0203U
Prometheus® Celiac	Prometheus Laboratories	81382, 82784, 83520, 86231, 86258, 86364, 88346
ProsTAV	Life Length	0572U
PurIST	Tempus AI	0510U
ResponseDX®: Colon	Cancer Genetics	81479
REVEAL Lung Nodules Characterization	MagArray, Inc	0092U
RightMed® Gene Report	OneOme® LLC	0350U, 0460U
RNA Salah Targeted Expression Panel	Moffitt Cancer Center Advanced Diagnostics Laboratory	0586U
SEPT9 methylated DNA (example ColoVantage and Epi proColon)	Several*	81327
SLCO1B1	NA	81328
SyncView®Rx	Phenomics Health™ Inc.	0520U
Theralink® Reverse Phase Protein Array (RPPA)	Theralink® Technologies, Inc	0249U
UNITY Fetal Risk Screen™	BillionToOne Laboratory	0489U
UroAmp MRD	Convergent Genomics	0467U

* ARUP, Quest, Clinical Genomics and Epigenomics.

Note: Some genetic tests identified above do not have specific codes (i.e., GI Effects, Prometheus® Celiac, etc.); therefore, identification of a code in this section does not denote coverage. When several or all of the codes listed are used to identify these tests, they are

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considered investigational. The list of codes may not be all-inclusive and are subject to change at any time. Eligibility is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

RATIONALE

SUMMARY OF EVIDENCE

The literature review was not comprehensive, but sufficient to establish lack of clinical utility. If it is determined that enough evidence has accumulated to reevaluate its potential clinical utility, the test will be removed from this evidence review and addressed separately. The lack of demonstrated clinical utility of these tests is based on the following factors: (1) there is no or extremely limited published data addressing the test; and/or (2) there is insufficient evidence demonstrating the clinical validity of the test.

DEFINITIONS

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

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POLICY HISTORY

MP 2.277	12/30/2021 Major Review. Policy title updated (added "Investigational") Removed: DecisionDx-Thymoma and TransPredict FC gamma 3A (no longer marketed). Removed G6PD testing from coding section (see MP 2.326) Added: BeScreened, ibs-smart (moved from MP 4.002 policy) and insight TNBC. Added tests listed in coding section to table 1: Decipher Bladder, IBSChek, Oncosignal 7 and PreductSURE IBC. Added coding for Crohns Prognostic to align with company website. Removed 5 columns from table 1 (date added, diagnostic, therapeutic, prognostic, and future risk) and added one column (coding information). Coding information from the bottom of the policy was moved to coding information column in Table 1. Description/background updated. Updated references. Added NCCN statement.
	03/13/2022 Administrative Update. New code added 0317U; effective 04/01/2022
	12/29/2022 Consensus Review. No change to policy statement, all tests on policy remain. Reformatted and updated background to include OncoSignal 7 and LungLB®. Updated references.
	03/16/2023 Administrative Update. New codes added 0365U, 0366U & 0367U; effective 04/01/2023

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<p>09/07/2023 Administrative Update. New codes added 0405U, 0410U, 0413U, 0414U. Effective 10/01/2023.</p>
<p>10/16/2023 Consensus Review. No changes to policy statement. Added codes: 0006M, 0007M, 0017M, 0002U, 0032U, 0045U, 0058U, 0059U, 0087U, 0120U, 0174U, 0288U, 0294U, 0297U, 0298U, 0299U, 0300U, 0315U, 0331U, 0332U, 0333U, 0350U, 0356U, 81554, 82274, 82542, 82653, 82715, 82725, 83993, 84311, 86231, 86258, 86364, 87505. Removed codes 0001U, 0153U, 0365U-0367U, 81401, 86021, 86036, 86255, 88350. Updated references.</p>
<p>12/12/2023 Administrative Update. Added 0420U, 0422U, and 0432U. Effective 01/01/2024</p>
<p>03/15/2024 Administrative Update. Added 0444U. Effective 04/01/2024.</p>
<p>06/07/2024 Administrative Update. Added New Codes 0467U and 0470U. Effective date 07/01/2024.</p>
<p>09/18/2024 Administrative Update. Added codes 0486U, 0489U, 0498U, 0499U, 0510U, 0520U. Effective 10/01/2024.</p>
<p>09/25/2024 Consensus Review. No changes to policy statement. References updated.</p>
<p>12/11/2024 Administrative Update. Added 0529U, 81195. Effective 01/01/2025.</p>
<p>12/16/2024 Administrative Update. Removed NCCN Statement.</p>
<p>01/02/2025 Administrative Update. No changes to policy statement. Added code 81328 to policy due to retirement of MP 2.361. Added references. Removed codes 82653, 82542, 82715.</p>
<p>06/02/2025 Administrative Update. Added code 0507U. Effective date 07/01/2025</p>
<p>06/09/2025 Administrative Update. Removing the Benefit Variations and updating the Disclaimer.</p>
<p>06/10/2025 Administrative Update. Adding codes 0565U, 0566U, 0569U, 0572U. Effective 07/01/2025.</p>
<p>08/05/2025 Consensus Review. Coding updates. Added 0009U, 0249U, 0198U, 0222U, 0003U, 0375U, 0261U, 0392U, 0460U, 0490U, 0080U, 0092U, 0360U.</p>
<p>09/09/2025 Administrative Update. Added codes 0575U, 0576U, 0578U, 0598U, 0586U, 0592U, 0597U. Effective 10/01/2025</p>
<p>12/11/2025 Administrative Update. New codes 0602U, 0611U, 0612U, 0613U, 81354, 81524 added, effective date 1/1/2026.</p>
<p>03/03/2026 Retirement Review. Evicore delegation.</p>

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