Medicare Medical Policy

Genetic and Molecular Testing

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes:

- **The list of genetic tests addressed in this policy is not all-inclusive.**
- **In compliance with Medicare guidelines, some LCDs and LCAs used may be for service areas outside of the Company's primary service area, based on where the performing laboratory is located.**
- Other Company Medical Policies may be available for specific tests or indications:
  - Most of these tests are listed within Criteria VI, IX and X below.
  - See Cross References section for medical policies which may apply to specific hereditary or oncologic conditions.
  - If a test is not found in this policy, see separate genetic testing policies to confirm coverage resources are not provided in another location.
- Due to the rapidly changing field of genetic testing, panel names, genes included, and coding may change subsequent to the last update of this policy.
- CMS guidance is also subject to change at any time. Therefore, while lists of covered or non-covered tests were accurate at the time of publication, they are subject to change at any time by a Medicare contractor.

Medical Policy Quick Links

❖ Excluded Genes

- Non-Covered Tests
- Potentially Medically Necessary Genes
- Miscellaneous Genetic or Molecular Tests
- Genetic and Molecular Panel Tests
  - Table 1 – Tests with specific LCD or LCA guidance which applies
- Policy Guidelines – General information regarding Medicare coverage of diagnostic laboratory testing, including genetic testing.
  - Table 2 – Service areas which have adopted MolDX coverage decisions.
  - Table 3 – Service areas which do not use MolDX policies and how coverage decisions are made for testing performed in these regions
- CPT and HCPCS Codes

Coverage Determination Process for Tests Not Called Out by Name Within a Medical Policy

I. Because it is impossible to address every single commercially-available genetic or molecular test by name within a medical policy, then for tests **not otherwise listed by name or when no specific Medicare reference is provided for a test** within this medical policy (or any other Medicare medical policy), individual review will be required and performed. The review will apply the following considerations and resources to evaluate Medicare benefit eligibility, as well as determine whether or not the test has established analytical validity (AV), clinical validity (CV) and clinical utility (CU), which will determine if the test would be considered reasonable and necessary for the individual Medicare member. Considerations for this decision-making may include any of the following:

A. Medicare statutory coverage requirements: Testing meets Medicare's medically reasonable and necessary requirements for coverage. For examples of non-covered testing situations, see Criterion III below.
B. Member clinical history: Member has signs or symptoms of an illness or disease related to the test. Each individual's unique clinical history may or may not warrant genetic or molecular testing. For non-covered clinical scenarios where genetic/molecular testing would be not medically necessary, see Criterion III below.
C. Medical records: Medical documentation supports how the ordering physician intends to promptly use the test results to make treatment decisions that would not otherwise be made in the absence of the testing.
D. Establish analytical validity (AV), clinical validity (CV) and clinical utility (CU): To be considered medically necessary, all tests must demonstrate analytical validity (AV), clinical validity (CV) and clinical utility (CU) to a level that supports Medicare coverage. This is determined by one of the following;

i. FDA approval or clearance status:

1. For tests **with** FDA approval or clearance as a companion diagnostic test, the NCD 90.2 may or may not apply. See Criterion XXIII and Policy Guidelines below regarding this NCD.
2. For tests **without** FDA approval or clearance, or for tests not otherwise subject to the NCD, then LCDs and LCAs are considered.

ii. MolDX service areas (See Table 2 below): For testing performed in a service area that **does** utilize MolDX coverage outcomes, the DEX® Registry resource will be searched to determine if the test in question has undergone the required technical assessment (TA) review. ***The DEX Diagnostics Exchange Registry (DEX) is a publicly available database of genetic and molecular tests evaluated by the MolDX Program Contractor with respective coverage outcomes.***

1. If a test is found and listed as "Covered," then that test may be **medically necessary IF** all applicable Medicare regulatory coverage requirements and any applicable LCD criteria are met.
2. If a test is found and listed as "Not Covered," then that test will be considered **not medically necessary** because analytical validity (AV), clinical validity (CV) and clinical utility (CU) have not been established.
3. If a test is **not found listed** in the registry at all, then that test will be considered **not medically necessary** because it has not met the MolDX requirement for successful TA review completion.

iii. Non-MolDX service areas (See Table 3 below):

1. The Plan may utilize the DEX® Registry to determine if the MolDX Program has completed a TA review for the test even if the test is performed in a non-MolDX service area to evaluate clinical utility, analytical and clinical validity, in addition to all other Medicare reasonable and necessary requirements.
2. If test is not listed in the DEX® Registry, or if the outcome is "Not Covered," the Plan may consider generally accepted standards based on scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, specialty society recommendations, and clinical practice guidelines to determine medical necessity. Full evidence reviews may or may not be found in published Company medical policies.

E. Clinical judgement of the reviewing physician: For all cases, the clinical judgement of the reviewing physician will also be used to assess whether or not criteria are met, and if not, if a special exception may be made.

F. Research status: Tests identified as part of an active clinical trial for the member's indication **or** tests labeled as for "Research Purposes Only," "For Research Use Only," "For Investigative Purposes Only," or similar language by the laboratory/manufacturer/developer will be considered **not medically necessary**. If the member enrolls in the clinical trial, then standard Medicare coverage rules for clinical trials apply *(see Cross References)*.

Excluded Genes

II. The following **single gene** tests are **not medically necessary** in many service areas *(**NOTE:** This list is NOT all-inclusive and there may be exceptions to non-coverage for some of the genes listed, depending on location of and purpose for testing. See the applicable LCA or LCD for information.):*

NOTE: Tests with available LCD or LCA guidance are identified below for each respective service area. Single gene tests which do **not** have an available LCD or LCA for their service area may use the LCD/LCA of another service area to allow for consistent coverage outcomes across all Medicare plan members.

GENE	LOCATION/MEDICARE CONTRACTOR					
	NORIDIAN J-F OR, WA, AK, ID, UT, AZ, MT, ND, SD, and WY	***NORIDIAN J-E*** CA and NV	***PALMETTO GBA J-J AND J-M*** NC, SC, AL, GA, TN, VA, and WV	***WISCONSIN J-5 AND J-8*** IA, KS, MO, NE, IN, and MI	***CGS ADMINISTRATORS J-15*** KY and OH	***WELLPOINT FEDERAL J-6 and J-K*** IL, MN, WI, CT, NY, ME, MA, NH, RI, VT
ASPA (CPT 81200)	**NOTE:** While LCDs L35351, L38274, L38288, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *ASPA* testing for all service areas listed.					A56199
BCKDHB (CPT 81205)	**NOTE:** While LCDs L35351, L38274, L38288, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *BCKDHB* testing for all service areas listed.					A56199
DMD (CPT 81161)	**NOTE:** While LCDs L35351, L38274, L38288, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are					A56199

	considered “not fully established” as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint FederalWellpoint LCA A56199 for *DMD* testing for all service areas listed.				
F5 (CPT 81241)	**Prior to 10/11/2026:** L36155	**Prior to 10/11/2026:** L36089	**Prior to 10/11/2026:** L36400	**Prior to 10/11/2026:** L35984	L35000 / A56199
F2 (CPT 81240)	**Prior to 10/11/2026:** L36155 / A57423	**Prior to 10/11/2026:** L36089 / A56899	**Prior to 10/11/2026:** L36400 / A57571	**Prior to 10/11/2026:** L35984 / A56980	L35000 / A56199
FANCC (CPT 81242)	**NOTE:** While LCDs L35351, L38274, L38288, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered “not fully established” as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *FANCC* testing for all service areas listed.				A56199
FMR1 (CPT 81243, 81244)	**NOTE:** While LCDs L35351, L38274, L38288, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered “not fully established” as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *FMR1* testing for all service areas listed.				A56199
GBA (CPT 81251)	**NOTE:** While LCDs L35351, L38274, L38288, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered “not fully established” as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *GBA* testing for all service areas listed.				A56199
HAX1	**NOTE:** There is no LCD or LCA for this single gene test for these service areas. In this case, Medicare coverage criteria are considered “not fully established” as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCD L35000 & LCA A56199 for *HAX1* testing for all service areas listed.				A56199

HBB (CPT 81361-81364)	**NOTE:** While LCDs L35351, L38274, L38288, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *HBB* testing for all service areas listed.	A56199
HEXA (CPT 81255)	**NOTE:** While LCDs L35351, L38274, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCD L35000 & LCA A56199 for *HEXA* testing for all service areas listed.	A56199
IKBKAP (CPT 81260)	**NOTE:** For OH and KY, the plan will apply LCA A54270. For all other service areas, while LCDs L35351, L38274, L38288, and L38429 for repeat germline testing and LCDs L35160, L35025, and L36807 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *IKBKAP* testing for all service areas listed.	A56199
MCOLN1 (CPT 81290)	**NOTE:** While LCDs L35351, L38274, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *MCOLN1* testing for all service areas listed.	A56199
MECP2(CPT 81302, 81304)	**NOTE:** While LCDs L35351, L38274, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *MECP2* testing for all service areas listed.	A56199

MTHFR (CPT 81291)	L36155 / L36358 *(In addition to L36155, the LCD L40242 notes MTHFR testing has not conclusively demonstrated association with venous thromboembolism or VTE, so it isn't included as a covered service for this Medicare policy.)*	**Prior to 10/11/2026:** L36089 / L36129 *(In addition to L36155, the LCD L40238 notes MTHFR testing has not conclusively demonstrated association with venous thromboembolism or VTE, so it isn't included as a covered service for this Medicare policy.)*	L36400 / L36523	L35984 / L36139	L35000 / A56199
NSD1	**NOTE:** There is no LCD or LCA for this single gene test for these service areas. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *NSD1* testing for all service areas listed.				A56199
SLC6A4 (aka HTTLPR)	A55264	A53480	A55169	A54269	**NOTE:** There is no LCD or LCA for this single gene test for these service areas. Medicare coverage criteria are considered "not fully established" as defined under CFR

					§ 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available by this service area MAC. Therefore, the Plan will apply the Palmetto LCA A53480 for *SLC6A4* (or *HTTLPR*) testing for this service area.
SMN1 (CPT 81329, 81336, 81337)	**NOTE:** While LCDs L35351, L38274, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCD L35000 & LCA A56199 for *SMN1* testing for all service areas listed.				L35000 / A56199
SMPD1 (CPT 81330)	**NOTE:** While LCDs L35351, L38274, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCA A56199 for *SMPD1* testing for all service areas listed.				A56199
SULT4A1	A55596	A53538	A55210	A54283	**NOTE:** There is no LCD or LCA for this single gene test for these service areas. Medicare coverage criteria

					are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available by this service area MAC. Therefore, the Plan will apply the Palmetto LCA A53538 for *SULT4A1* testing for this service area.
VEGFR2	**NOTE:** There is no LCD or LCA for this single gene test for these service areas. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCD L35000 & LCA A56199 for *VEGFR2* testing for all service areas listed.				L35000 / A56199

Non-Covered Tests

III. Based on the Medicare statutory Benefit requirements, **all** of the following test types and scenarios are excluded and are denied as **not medically necessary** on a national basis (see Policy Guidelines for detailed information):

A. Tests performed in the absence of clinical signs and symptoms of disease (e.g., testing requested due to family history when the member does not personally have signs/symptoms of disease relevant to the requested test) are considered screening and are not medically necessary based on *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*;

B. Tests that do not provide the clinician with actionable data for the member (information that will not improve patient outcomes and/or change physician care and treatment of the patient) (this includes at-risk relative testing);
C. Tests that confirm a diagnosis or known information;
D. Tests to determine risk for developing a disease or condition;
E. Tests performed to measure the quality of a process, or tests performed to confirm the sample belongs to a particular member;
F. Tests without diagnosis specific indications;
G. Carrier testing (tests to determine if they or offspring are potential carriers of a genetic variant);
H. Tests identified as investigational by all available literature and/or the literature supplied by the developer and are not a part of a clinical trial as determined by LCD, LCA, or the MolDX program (when applicable);
I. Repeat testing of the same or similar genetic content (i.e., repeat testing of the genomic regions/variants previously interrogated) is considered duplicative. Thus, in accordance with NCD 90.2, as well as LCDs L38119/L38123, L38067/L38070, L38045/L38047, L38158/L38176, L35000, L35396/L35062, and L34519, genetic and molecular tests which analyze the same genetic content and same genetic information that has already been tested in the same individual are also **not medically necessary**, even if the requested test is a different proprietary (brand) test from a different laboratory. (Exceptions may be made for repeat somatic (acquired) cancer testing ***if*** the results of the subsequent test(s) will be used to inform therapeutic decision-making [e.g., recurrence of disease, change in behavior of disease, evaluating response to therapy, etc.). Clinical documentation must demonstrate that the requested repeat test will provide clinically meaningful genetic information not previously assessed and that repeat testing of overlapping genetic content is expected to impact clinical management.

IV. **Whole exome and whole genome sequencing/tests** are considered **not medically necessar**y for Medicare under *Social Security Act, §1862(a)(1)(A).* Applicable Medicare references include the following:

A. Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, and WY, as well as CA and NV:

i. For MolDX service areas: There is no LCD or LCA for whole exome or whole genome sequencing/tests for these service areas. In this case, Medicare coverage criteria are considered "not fully established" as defined under *CFR § 422.101(b)(6)(i)(C)* as there are no Medicare coverage criteria available by the plan's service area MAC. However, MolDX requires all tests to successfully complete a technical assessment (TA). The Plan will apply coverage or non-coverage information as found in the DEX® Registry. Tests which are not listed in the registry will be considered not medically necessary as not complying with the required TA review requirement. Examples of non-covered tests includes, but may not be limited to, the following:

1. GPS Cancer® (NantHealth, D/B/A NantOmics; California) - This test is listed as “not covered” in the DEX Registry.
2. Augusta Optical Genome Mapping (Bionano Genomics, Inc.; 0260U) - This test is listed as “not covered” in the DEX Registry.
3. Optical Genome Mapping (Praxis Genomics; 0264U) – Several versions of this test are listed as “not covered” in the DEX Registry.
4. Praxis Whole Genome Sequencing (Praxis Genomics LLC; 0265U) - Several versions of this test are listed as “not covered” in the DEX Registry.
5. Praxis Transcriptome (Praxis Genomics; 0266U) - Several versions of this test are listed as “not covered” in the DEX Registry.
6. Praxis Combined Whole Genome Sequencing and Optical Genome Mapping (Praxis Genomics LLC; 0267U) - Several versions of this test are listed as “not covered” in the DEX Registry.
7. Augusta Hematology Optical Genome Mapping (Georgia Esoteric and Molecular Labs; 0331U) - This test is listed as “not covered” in the DEX Registry.
8. RCIGM Rapid Whole Genome Sequencing, Comparator Genome (0425U) (Rady Children's Institute for Genomic Medicine) - Test is not listed in the DEX Registry, which means it has **not** met the required technical assessment (TA) review, and therefore, is not medically necessary.
9. RCIGM Ultra-Rapid Whole Genome Sequencing (0426U) (Rady Children's Institute for Genomic Medicine) - Test is not listed in the DEX Registry, which means it has **not** met the required technical assessment (TA) review, and therefore, is not medically necessary.
10. Chromosome Genome Mapping (UR Medicine Labs, which is in Rochester NY and Bionano Genomics, Inc., which is in San Diego, CA; 0454U) - Test is not listed in the DEX Registry, which means it has **not** met the required technical assessment (TA) review, and therefore, is not medically necessary.
11. However, tests may be considered for coverage on a case-by-case basis, as more LCDs and LCAs are developed.

ii. **EXCEPTIONS:** Coverage may be considered for tests marked as “Covered” in the DEX® Registry. If a whole exome/whole genome test is not listed by name in this policy, additional research will be necessary to determine Medicare/MolDX coverage, using guidance above.

B. Testing performed in in IL, MN, WI, CT, NY, ME, MA, NH, RI, or VT: LCA for Billing and Coding: Molecular Pathology Procedures (A56199)

i. Since current codes for whole exome and genome sequencing (e.g., 81460, 81465, 81415-81417) are non-covered by this local contractor, all whole exome and genome sequencing tests are considered non-covered, regardless of what CPT code is used, **until** this MAC publishes LCDs or LCAs which indicate otherwise. In addition, consistent with Criterion I above, the DEX® Registry may also be used.
ii. Non-coverage of whole genome and whole exome analysis includes:
iii. EXaCT-1 Whole Exome Test (0036U)
iv. IriSight™ Prenatal Analysis – Proband, IriSight™ Prenatal Analysis – Comparator, and IriSight™ CNV Analysis (a by Variantyx, Inc.; 0335U,0336U and 0469U, respectively)
v. Rapid Whole Genome Sequencing (0582U) and Rapid Genome Sequencing Family Member Comparator (0583U) (both by Mayo Clinic; Minnesota): LCD L35000 requires tests meet analytical validity and clinical utility standards. These tests are not FDA approved or cleared and the base test (Rapid Whole Genome Sequencing) is listed as "not covered" in MolDX® DEX® Registry, and therefore are considered not medically necessary.
vi. **EXCEPTIONS:** Coverage may be considered for tests marked as "Covered" in the DEX® Registry. If a whole exome/whole genome test is not listed by name in this policy, additional research will be necessary to determine Medicare coverage, using guidance found in Criterion I above.

C. Testing performed in in for testing performed in CO, NM, OK, TX, AR, LA, MI, DE, MD, NJ, and PA

i. Complex I Assembly Western Blot Assay (0654U), Complex V Hydrolysis Enzyme Assay (0655U), and Pyruvate Dehydrogenase (PDH) Enzyme Assay (0656U) (all by Children's Hospital Colorado Laboratory), as well as GenomeDx Rapid, Comparator (0657U), GenomeDx Rapid, Proband (0658U), and GenomeDx ultraRapid, Proband (0659U) (all by GeneDx): LCD L35062 requires tests meet analytical validity and clinical utility standards. Consistent with Criterion I above, the DEX® Registry may also be used to evaluate whether or not a given test meets analytical and clinical validity and clinical utility standards. Most of these tests are not FDA approved or cleared and therefore, are considered not medically necessary.
ii. **EXCEPTIONS:** Coverage may be considered for tests marked as "Covered" in the DEX® Registry. If a whole exome/whole genome test is not listed by name in this policy, additional research will be necessary to determine Medicare coverage, using guidance found in Criterion I above.

V. For all service areas/jurisdictions, single gene and panel testing for **hereditary hearing loss** (genes GJB2 [81252, 81253] and GJB6 [81254], and panel tests [81430, 81431]) are considered **not medically necessar**y for Medicare based on criteria and guidance found in the Wellpoint Federal LCD L35000 and companion LCA A56199. Under LCD L35000, some genetic tests are non-covered due to lack of relevance to an

individual of Medicare age, such as testing for conditions or disease that manifest signs or symptoms in newborns or during childhood. Therefore, according to LCA A56199, hereditary hearing loss genetic testing procedures are considered "unlikely to impact therapeutic decision-making in the clinical management of the patient and will be denied automatically as not medically necessary." ***EXCEPTIONS:*** *Coverage may be considered for tests marked as "Covered" in the DEX® Registry.*

VI. The following **reproductive planning and prenatal genetic tests** are considered **not medically necessar**y for Medicare (this list may not be all-inclusive. Additional Medicare guidance pertaining to this testing can be found in the "Policy Guidelines" section below).

A. Carrier screening (e.g., the Genesys Carrier Panel by Genesys Diagnostics, Inc. [0400U], the UNITY Carrier Screen™ test by BillionToOne, Inc. [0449U])
B. Preimplantation genetic testing (examples include, but may not be limited to, PGT-M [0552U], Smart PGT-A [0553U], Smart PGT-SR [0554U], Smart PGT-SR Plus [0555U], all by Igenomix).
C. Noninvasive prenatal screening (NIPS), also known as noninvasive prenatal testing (NIPT) (this is not an all-inclusive list, but examples include, tests reported with CPT 81420 [e.g., Panorama™ Prenatal Panel by Natera] or CPT 81422 [e.g., MaterniT21 Plus Core + ESS], PGIF Preeclampsia Screen [PerkinElmer Genetics, Inc.] [0243U], PreTRM® [Sera Prognostics] [0247U]), Single Cell Prenatal Diagnosis (SCPD) Test by Luna Genetics, Inc. (0341U), PEPredictDx, OncoOmicsDx Laboratory [0390U], Preeclampsia sFlt1/PlGF Ratio (PERA) [Mayo Clinic; 0482U], UNITY Fetal Antigen™ NIPT [BillionToOne Laboratory; 0488U], UNITY Fetal Risk Screen™ [BillionToOne Laboratory; 0489U], PreClara™ Ratio (sFlt-1/PlGF) [by Thermo Fisher Scientific; 0524U]), UNITY Fetal RhD NIPT™ (0632U) (BillionToOne Laboratory; Californnia), Fetal Focus (0633U) (Natera, Inc.; California). These tests screen for the risk of a pregnancy having a specific genetic condition; however, these tests do not make a final diagnosis and it cannot be known for certain if a baby has a specific condition based on these tests alone. Additional testing – either during pregnancy or testing the baby after birth – is required to make a final diagnosis.
D. Short tandem repeat (STR) analysis (81265-81268) for twin zygosity, as well as noninvasive prenatal screening to predict twin zygosity (0060U).
E. Pregnancy loss.
F. Direct-to-consumer testing for reproductive planning or prenatal testing.

VII. The following **red blood cell antigen typing and genotyping tests** (0180U-0201U, 0221U, 0222U, 0246U, 0494U, and 0632U) are **not medically necessary**:

A. Various Navigator Sequencing tests (Grifols Immunohematology Center; California) (See LCA A57124)

B. Precision Blood™, San Diego Blood Bank; California (LCD A57124 and related LCD require successful TA; this test does not meet this requirement)

C. Rh Test (0494U) (Natera, Inc.; California). Apply the LCD L38331. This LCD states, "Laboratory developed tests (LDTs)… may be considered covered for the same indications if the test demonstrates validity and clinical utility equivalent to or better than covered tests as demonstrated in a technical assessment." This test does **not** meet this LCD requirement as it has not completed a technical assessment by the MolDX Program and therefore, is considered **not medically necessary**.

Potentially Medically Necessary Genes

VIII. The following **single gene** tests may be **medically necessary** when criteria from the noted LCA/LCD are met ***(NOTE:** This list is NOT all-inclusive and some tests may be non-covered, depending on location of testing. See the applicable LCA or LCD for specific coverage requirements.):*

NOTE: Tests with available LCD or LCA guidance are identified below for each respective service area. Single gene tests which do **not** have an available LCD or LCA for their service area may use the LCD/LCA of another service area to allow for consistent coverage outcomes across all Medicare plan members.

GENE	LOCATION/MEDICARE CONTRACTOR					
	NORIDIAN J-F OR, WA, AK, ID, UT, AZ, MT, ND, SD, and WY	***NORIDIAN J-E*** CA and NV	***PALMETTO GBA J-J AND J-M*** NC, SC, AL, GA, TN, VA, and WV	***WISCONSIN J-5 AND J-8*** IA, KS, MO, NE, IN, and MI	***CGS ADMINISTRATORS J-15*** KY and OH	***WELLPOINT FEDERAL J-6 and J-K*** IL, MN, WI, CT, NY, ME, MA, NH, RI, VT

APOE	A57384 (companion to LCD L38335) *(see criteria below, based on these LCDs)*	A58318 (companion to LCD L38294) *(see criteria below, based on these LCDs)*	A58395 (companion to LCD L38435) *(see criteria below, based on these LCDs)*	A58324 (companion to LCD L38394) *(see criteria below, based on these LCDs)*	Prior to 2/12/26, APOE was a non-covered test in L35000 / A56199 As of 2/12/26, while *APOE* was removed from the non-covered list, no criteria were provided. Without "fully established" criteria as defined by CFR § 422.101(b)(6)(i)(C) by this service area MAC, the Plan will apply the *APOE* criteria used for MolDX service areas (see left) to J-K service areas.
	I. Medicare Advantage plans must follow Medicare rules for coverage of medically necessary services. Medicare rules and regulations can be found in multiple references, including local coverage determinations (LCDs) noted above, representing all service areas and jurisdictions. According to Medicare coverage policy guidelines, genetic testing for the apolipoprotein E (*APOE*) gene may be **medically necessary** for Medicare Advantage members when **both** of the following are met (A and B): A. The individual is diagnosed with Alzheimer's disease (AD); **and** B. They are being considered for treatment with an U.S. Food and Drug Administration (FDA) -approved Aβ monoclonal antibody drug (eg, lecanemab-irmb [Leqembi], donanemab-azbt [Kisunla]). *(There may be a Medicare Pharmacy policy for these treatments and review may be required.)* II. For *symptomatic* individuals, genetic testing of the *APOE* gene is considered **not medically necessary** for Medicare Advantage members in all other situations, including when used to diagnose AD. Establishing a diagnosis of Alzheimer disease relies on clinical-neuropathologic assessment. Neuropathologic findings of β-amyloid plaques and intraneuronal neurofibrillary tangles remain the gold standard for diagnosis. III. For *asymptomatic* individuals, there are current clinical practice guidelines recommend against the use of *APOE* genetic testing as predictive testing. In addition, testing for disease				

	risk assessment for ***asymptomatic*** individuals is considered screening and therefore, is **not medically necessary** as it would not meet Medicare's medically reasonable and necessary criteria, as defined by the *Social Security Act, §1862(a)(1)(A)*.					
ATP7B	**NOTE:** There is no LCD or LCA for this single gene test for these service areas. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCD L35000 & LCA A56199 for *ATP7B* testing for all service areas listed.					L35000 / A56199
BLM (CPT 81209)	**NOTE:** While LCDs L35351, L38274, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCD L35000 & LCA A56199 for *BLM* testing for all service areas listed.					L35000 / A56199
BRAF	A54420	A54418	A54018	A55161	A54191	L35000 / A56199
EGFR	A54424	A54422	A54021	A55193	A54192 / A54189 / A54199	L35000 / A56199
F2 (CPT **81240)**	**As of 10/12/2026:** L40242		**As of 10/12/2026:** L40238	**As of 10/12/2026:** L40274	**As of 10/12/2026:** L40259	See "Excluded Tests" table above
F5 (CPT 81241)	**As of 10/12/2026:** L40242		**As of 10/12/2026:** L40238	**As of 10/12/2026:** L40274	**As of 10/12/2026:** L40259	See "Excluded Tests" table above
	L38649	L38647	L38576	L38684	L38586	L35000 / A56199

FGFR2 / FGFR3	According to these LCDs, FGFR3 and FGFR2 mutations may be associated with response to erdafitinib, which is Food and Drug Administration (FDA) approved for use in bladder cancer with *FGFR3* and/or *FGFR2* mutations and thus **may be medically necessary** when used for this purpose.					L35000 / A56199 According to this LCD, these tests are **not medically necessary**.
IDH2	A55712	A55711	A55695	A55738	A55716	L35000 / A56199
KIF6	**NOTE:** While LCDs L35351, L38274, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCD L35000 & LCA A56199 for *KIF6* testing for all service areas listed.					L35000 / A56199
KRAS	A54500	A54498	A54472	A55162	A54688 / A54200	L35000 / A56199
NRAS	L36335 / A57486		L35073 / A53585	L35442 / A56962	L36797 / A56998	L35000 / A56199
PIK3CA	A55602	A55597	A53558	A55200	A54295	L35000 / A56199
SERPINA1 (CPT 81332)	**NOTE:** While LCDs L35351, L38274, and L38429 for repeat germline testing and LCDs L35160, L35025, L36807 and L36021 all include this CPT code in their respective companion billing and coding articles, there are no coverage criteria provided for this single gene test. Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available for these service areas by their regional MAC. Therefore, the Plan will apply the Wellpoint Federal LCD L35000 & LCA A56199 for *SERPINA1* testing for all service areas listed.					L35000 / A56199

Miscellaneous Genetic or Molecular Tests

IX. **Chimerism analysis (CPT codes 81265-81268)** may be **medically necessary** for some indications (see Criterion VI for the use of these tests for twin zygosity testing). Applicable Medicare references include the following:

A. Billing and Coding: MolDX: Short Tandem Repeat (STR) Markers and Chimerism (codes 81265-81268)

i. Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, and WY: A57843 (Noridian J-F)
ii. Testing performed in CA or NV: A57842 (Noridian J-E)
iii. Testing performed in OH and KY: A54830 (CGS Administrators, LLC)
iv. Testing performed in VA, WV, NC, SC, GA, TN, and AL: A54832 (Palmetto GBA)

v. Testing performed in IA, KS, MO, and NE: A55621 (Wisconsin Physician Services)

B. Billing and Coding: Molecular Pathology Procedures (A56199) for testing performed in IL, MN, WI, CT, NY, ME, MA, NH, RI, and VT (Wellpoint Federal, Inc.)

X. **Select colorectal cancer screening and pre-screening tests** are **not medically necessary** when they are not called out as eligible preventive benefits under Medicare's NCD 210.3. These non-covered tests include, but may not be limited to the following:

A. BeScreened™-CRC (0163U), Epi proColon (81327), FirstSight^{CRC} (0091U), and Colonsentry® (81479).

i. **NOTE:** While coverage for blood-based biomarker tests reported with HCPCS code G0327 was added to NCD 210.3 effective January 2021, according to the *Medicare Decision Memo for Screening for Colorectal Cancer - Blood-Based Biomarker Tests (CAG-00454N)*, the **Epi proColon®** test does not meet the Medicare criteria for blood-based biomarker CRC screening tests. Specifically, the Epi proColon® test does not meet test performance characteristic requirements regarding sensitivity and specificity. Epi proColon® is reported with CPT 81327 and is noncovered as of the time of this policy update, but as new blood-based biomarker tests for colorectal cancer screening are developed, they will be evaluated for coverage against the NCD requirements.

NOTE: *HCPCS code G0327 should only be used for tests which meet **all** of the NCD 210.3 test requirements. As of the date of this policy review, Shield™ (by Guardant Health) is the only test that meets this. It received FDA approval on July 29, 2024, and satisfies the requirements regarding sensitivity and specificity. From July 29, 2024 through March 31, 2025, this test can be reported with HCPCS G0327 and claims will adjudicate according to member benefits and eligibility. As of April 1, 2025, this test was assigned a specific code (0537U) to be used. In addition, Colosense™ by Geneoscopy, Inc. (0421U) is allowed under NCD 210.3 as of June 8, 2026.*

XI. Genetic testing of tumor tissue for the following genes may be considered **medically necessary** for non-small cell lung cancer (NSCLC) targeted therapy selection**: ALK, HER2 (ERBB2), MET, RET, and ROS1**

A. Other gene tests such as BRAF, KRAS, and EGFR may also be medically appropriate, but these have specific Medicare references that would be used to determine medical necessity.

B. Testing of these genes for conditions ***other than*** NSCLC will require additional research.

C. For panel tests which include genes other than those listed, look for the test by name in this policy – if a panel is not listed, additional research will be required.

XII. The following **Genomic Unity® single gene analysis tests** may be **medically necessary** when documentation supports that the test will provide actionable data to be used promptly by the treating physician to treat or diagnose an illness or condition AND that the gene test in question has established clinical utility (CU) and analytical validity (AV) relevant to the indication/condition. In the absence of guidance within the LCD or LCA to provide this information, Company policy criteria or evidence reviews may be used to determine established CU/AV. (LCD L35000 requires established CU/AV and LCA A56199 lists CACNA1A, CSTB, and PTEN testing as tests which require "individual review" to establish coverage.)

A. Genomic Unity® CACNA1A Analysis (0231U)
B. Genomic Unity® CSTB Analysis (0232U)
C. Genomic Unity® PTEN Analysis (0235U)

XIII. Genetic testing to **guide therapy selection in rheumatoid arthritis treatment** may be **medically necessary** when criteria from the listed relevant LCD are met *(as of this policy update, the **PrismRA** test **meets** the technical assessment requirement to review analytical validity (AV), clinical validity (CV) and clinical utility (CU) - if a different test is not listed by name, additional research will be required).*

A. LCD for MolDX: Molecular Biomarker Testing to Guide Targeted Therapy Selection in Rheumatoid Arthritis:

i. Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA and NV: LCD for L39467 (Noridian J-E) (companion coding/billing LCA A59521)
ii. Testing performed in OH and KY: L39427 (CGS Administrators, LLC) (companion coding/billing LCA A59529)
iii. Testing performed in VA, WV, NC, SC, GA, TN, and AL: L39424 (Palmetto GBA) (companion coding/billing LCA A59484)
iv. Testing performed in IA, KS, MO, and NE: L39481 (Wisconsin Physician Services) (companion coding/billing LCA A59536)

XIV. Genetic testing for **transplant rejection (transplantation medicine tests)** may be **medically necessary** when criteria from the listed relevant LCD are met *(unless indicated otherwise, tests listed below have met the MolDX technical assessment requirement to review analytical validity (AV), clinical validity (CV) and clinical utility (CU) - if a test is not listed by name, additional research will be required).*

A. LCD for MolDX: Molecular Testing for Solid Organ Allograft Rejection:

i. Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY: L38671 (Noridian J-F) (companion coding/billing LCA A58170)

1. Molecular Microscope® MMDx—Heart (0087U) and Molecular Microscope® MMDx—Kidney (0088U) (Kashi Clinical Laboratories; Oregon)

ii. Testing performed in CA and NV: LCD for L38629 (Noridian J-E) (companion coding/billing LCA A58168)
   1. AlloMap (81595), as well as AlloSure-Heart and AlloSure-Kidney (both can use 0540U), by CareDx, Inc.
      a. **NOTE**: When AlloMap and AlloSure-Heart are performed together on the same sample, this combination is known as the HeartCare test and should be reported with CPT 81479 alone.
   2. Prospera™ [0493U] by Natera
   3. HepatoTrack™ (0575U; LuminoDx Laboratory; California): This test is not listed in the DEX Registry, which means it has **not** met the required technical assessment (TA) review, and therefore, is not medically necessary.

iii. Testing performed in OH and KY: L38582 (CGS Administrators, LLC) (companion coding/billing LCA A58061)

iv. Testing performed in VA, WV, NC, SC, GA, TN, and AL: L38568 (Palmetto GBA) (companion coding/billing LCA A58019)
   1. Protega™ (0664U; Verici Dx; Tennessee): This test is not listed in the DEX Registry, which means it has **not** met the required technical assessment (TA) review, and therefore, is not medically necessary.
   2. GraftAssure™ (0690U; Insight Molecular Diagnostics Inc.; Tennessee)
      a. While the laboratory developed test (LDT) version of GraftAssure™ has met the MolDX TA requirement, GraftAssureIQ and GraftAssureDx have not. These versions of this test should not be reported with 0690U, and are considered not medically necessary.

v. Testing performed in IN, IA, KS, MO, and NE: L38680 (Wisconsin Physician Services) (companion coding/billing LCA A58207) (Includes TruGraf® Kidney, as well as Viracor TRAC™ dd-cfDNA, [0118U], both by Eurofins Transplant Genomics Inc.; Missouri)
   1. OmniGraf® Liver (0576U; Eurofins Transplant Genomics; Kansas): This test has **not** met the required TA review, and therefore, is not medically necessary. This test is listed as "not covered" in the DEX Registry.
   2. Exosome Kidney Transplant Report (EkTRA) (0662U; One Lambda™ Laboratories, part of Thermo Fisher Scientific; Indiana): This test has **not** met the required TA review, and therefore, is not medically necessary. This test is listed as "not covered" in the DEX Registry.

XV. Pharmacogenomic (aka, pharmacogenetic or PGx) **single gene** tests may be ***either*** medically necessary or not medically necessary, as indicated by the noted Medicare reference for that gene test (pharmacogenomic **panel tests** are listed separately in this policy).

NOTE #1: Some tests subject to the LCD L35000 and LCA A56199 will require individual review on a case-by-case basis. For these tests, documentation must support that the test will provide actionable data to be used promptly by the treating physician to treat or diagnose an

illness or condition in order to be considered medically reasonable and necessary AND that the gene test in question has established CU and AV relevant to the indication/condition. In the absence of guidance within the LCD or LCA to provide this information, Company policy criteria or evidence reviews may be used to determine established CU/AV.

NOTE #2: Tests in MolDX service areas (Columns Noridian J-F through CGS Administrators) require MolDX approval, which is determined by viewing the DEX Registry. If a specific proprietary test is not listed, additional research will be necessary to apply the correct guidance.

NOTE #3: Not all service areas are represented in this table. If a service area is not represented, or if there is no relevant LCD or LCA listed to address gene testing for a service area, additional research will be necessary to apply the correct Medicare guidance.

<table>
<tr><th rowspan="2">GENE</th><th colspan="6">LOCATION/MEDICARE CONTRACTOR</th></tr>
<tr><th>NORIDIAN J-F

OR, WA, AK, ID, UT, AZ, MT, ND, SD, and WY</th><th>NORIDIAN J-E

CA and NV</th><th>PALMETTO GBA J-J AND J-M

NC, SC, AL, GA, TN, VA, and WV</th><th>WISCONSIN J-5 AND J-8

IA, KS, MO, NE, IN, and MI</th><th>CGS ADMINISTRATORS J-15

KY and OH</th><th>WELLPOINT FEDERAL J-6 and J-K

IL, MN, WI, CT, NY, ME, MA, NH, RI, VT</th></tr>
<tr><td>BCHE</td><td colspan="2" rowspan="12">L38335 / A57384</td><td rowspan="12">L38294 / A58318</td><td rowspan="12">L38435 / A58395</td><td rowspan="12">L38394 / A58324</td><td rowspan="12">L35000 / A56199</td></tr>
<tr><td>CACNA1S</td></tr>
<tr><td>CFTR</td></tr>
<tr><td>CYP2B6</td></tr>
<tr><td>CYP2C19</td></tr>
<tr><td>CYP2D6</td></tr>
<tr><td>CYP2C9</td></tr>
<tr><td>CYP3A5</td></tr>
<tr><td>CYP4F2</td></tr>
<tr><td>DPYD</td></tr>
<tr><td>G6PD</td></tr>
<tr><td>HLA Class Typing</td></tr>
<tr><td>IFNL3</td></tr>
<tr><td>NAT2</td></tr>
</table>

NUDT15					
RYR1					
SLCO1B1					
TPMT					
UGT1A1					
CYP2C9	*In addition to the above references, when VKORC1 and CYP2C9 are tested for warfarin response, see NCD 90.1.*				
VKORC1					

XVI. Genetic testing for **heritable thoracic aortic disease (HTAD)** (CPTs 81410, 81411) may be **medically necessary** when criteria from the listed relevant LCD are met *(tests listed below indicate whether or not they have met the MolDX technical assessment requirement to review analytical validity (AV), clinical validity (CV) and clinical utility (CU) - if a test is not listed by name, the DEX® Registry will need to be consulted).*

A. LCD for MolDX: Genetic Testing for Heritable Thoracic Aortic Disease:

i. Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA and NV: LCD for L39944 (Noridian J-E) (companion coding/billing LCA A59868)
   1. Example: Invitae Aortopathy Comprehensive Panel, by LabCorp (California), which has **not** met the required TA review, and therefore, is not medically necessary. This test is listed as "not covered" in the DEX Registry.
   2. Example: Genetic Aortopathy and Arteriopathy Panel, by OHSU Knight Diagnostics (Oregon), which is not listed in the DEX Registry, which means it has **not** met the required technical assessment (TA) review, and therefore, is not medically necessary.

ii. Testing performed in OH and KY: L39938 (CGS Administrators, LLC) (companion coding/billing LCA A59860)

iii. Testing performed in VA, WV, NC, SC, GA, TN, and AL: L39933 (Palmetto GBA) (companion coding/billing LCA A59847)

iv. Testing performed in IA, KS, MO, and NE: L39989 (Wisconsin Physician Services) (companion coding/billing LCA A59908)

XVII. Genetic testing for identification and management of **hereditary transthyretin amyloidosis (hATTR)** may be **medically necessary** when criteria from the listed relevant LCD are met *(example tests listed below indicate whether or not they have met the MolDX technical assessment requirement to review analytical validity (AV), clinical validity (CV) and clinical utility (CU) - if a test is not listed by name, the DEX® registry will need to be consulted).*

A. LCD for Molecular Testing for Identification and Management of Hereditary Transthyretin Amyloidosis:

i. Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA and NV: LCD for L39948 (Noridian J-E) (companion coding/billing LCA A59872)
ii. Testing performed in OH and KY: L39940 (CGS Administrators, LLC) (companion coding/billing LCA A59862)
iii. Testing performed in VA, WV, NC, SC, GA, TN, and AL: L39935 (Palmetto GBA) (companion coding/billing LCA A59849)
iv. Testing performed in IA, KS, MO, and NE: L39987 (Wisconsin Physician Services) (companion coding/billing LCA A59906)

XVIII. Next-generation sequencing (NGS) for **myeloid malignancies or suspected myeloid malignancies** may be **medically necessary** when criteria from the listed relevant LCD are met *(example tests listed below indicate whether or not they have met the MolDX technical assessment requirement to review analytical validity (AV), clinical validity (CV) and clinical utility (CU) - if a test is not listed by name, the DEX® Registry will need to be consulted).*

A. LCD for MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies:

i. Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY. CA and NV: L38123 (Noridian J-E) (companion coding/billing LCA A57891)
   a. GeneTrails Hematologic Malignancies 220 Gene Panel (81450), by Knight Diagnostics/OHSU (Oregon). This test **has** met the TA requirement found in the LCD.
   b. GeneTrails® Hematologic Malignancies 76 Gene Panel (OHSU Knight Diagnostic Laboratories; Oregon), which is not listed in the DEX Registry, which means it has **not** met the required technical assessment (TA) review, and therefore, is not medically necessary.
   c. MyAML® NGS Panel (0050U), by Laboratory for Personalized Molecular Medicine (LabPMM) (California), which has **not** met the required TA review, and therefore, is not medically necessary. This test is listed as “not covered” in the DEX Registry.
   d. MyMRD® NGS Panel (0171U), by Laboratory for Personalized Molecular Medicine (LabPMM) (California), which is not listed in the DEX Registry, which means it has **not** met the required technical assessment (TA) review, and therefore, is not medically necessary.
ii. Testing performed in OH and KY: L38070 (CGS Administrators, LLC) (companion coding/billing LCA A57873)
iii. Testing performed in VA, WV, NC, SC, GA, TN, and AL: L38047 (Palmetto GBA) (companion coding/billing LCA A57837)

a. FoundationOne Heme, by Foundation Medicine, Inc. (Massachusetts or North Carolina). Use LCD L38047 for all service areas. The LCD requires successful completion of TA review of the test; this test **does** meet this LCD requirement.

1). According to the Foundation Medicine test requisition form, medical necessity of this test for Medicare members is based on criteria for myeloid malignancies or myeloproliferative neoplasms. The website also states this test was "designed specifically for blood cancers like leukemia and lymphoma." For patients diagnosed with a solid tumor, ordering physicians may want to consider the use of either the FoundationOne®Liquid CDx or FoundationOne®CDx. Tests instead. This test will be considered "not medically necessary" for solid tumors; however, this non-coverage doesn't restrict patient access because other test options are available.

b. Lumera™ Heme NGS Panel by Fulgent Oncology (specimens are shipped to Georgia), have **met** the required TA review, and therefore, may be medically necessary when LCD criteria are otherwise met.

2). The Lumera™ Comprehensive Hematological Evaluation, also by Fulgent Oncology, involves more than NGS testing, and according to National Comprehensive Cancer Network (NCCN) Guidelines for Myelodysplastic Syndromes, all of the included components may be clinically appropriate for initial diagnosis/evaluation when a hematological disease or malignancy is suspected (e.g., undefined cytopenia for greater than 4 months and other possible causes have been reasonably excluded, as called out in LCD L38047). Therefore, the Lumera Comprehensive Hematological Evaluation may also be considered medically necessary under the MolDX Program and the *Social Security Act, §1862(a)(1)(A)* when all other criteria from LCD L38047 are met.

c. Tempus xR Heme (Tempus Labs, Inc.; Testing may be done in varying locations, including Illinois, Georgia, or North Carolina). To allow for consistent outcomes across all plan members, the North Carolina LCD will be applied. This test is listed in the DEX Registry as "not covered," and therefore, it has **not** met the required technical assessment (TA) review and is not medically necessary.

iv. Testing performed in IA, KS, MO, and NE: L38176 (Wisconsin Physician Services) (companion coding/billing LCA A57878)

XIX. Next-generation sequencing (NGS) for solid tumors *(**excluding** circulating tumor or ctDNA or liquid biopsy, which are addressed in a separate policy)* may be **medically necessary** when criteria from the listed relevant LCD are met *(example tests listed below indicate whether or not they have met the MolDX technical assessment requirement to review analytical validity (AV), clinical validity (CV) and clinical utility (CU) - if a test is not listed by name, the DEX® Registry will need to be consulted).*

A. LCD for MolDX: Next-Generation Sequencing for Solid Tumors:

i. Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY. CA and NV: Testing performed in CA and NV: LCD for L38119 (Noridian J-E) (companion coding/billing LCA A57901)

   a. Example: GeneTrails Comprehensive Solid Tumor Panel (81479), by Knight Diagnostics/OHSU (Oregon). This test **has** met the TA requirement found in the LCD.
   b. GeneTrails® GIST Genotyping Panel (OHSU Knight Diagnostic Laboratories; Oregon). As of the date of the most recent policy review, this test does **NOT** meet the TA requirement found in the LCD.
   c. OptiSeq™ Colorectal Cancer NGS Panel (DiaCarta, Inc.; California; 0498U). As of the date of the most recent policy review, this test does **NOT** meet the TA requirement found in the LCD.
   d. OptiSeq™ Dual Cancer Panel Kit (DiaCarta, Inc.; California; 0499U). As of the date of the most recent policy review, this test does **NOT** meet the TA requirement found in the LCD.
   e. MI TumorSeek and MI Profile (81479), by Caris Life Sciences (Arizona). This test **has** met the TA requirement found in the LCD.
      Note: If the MI TumorSeek is deemed medically necessary, the MI Profile may be approved.
      Background: MI TumorSeek is a next-generation sequencing (NGS) tumor profiling assay that covers DNA mutations, copy number alterations, insertions/deletions, and RNA fusions for select lineages. When microsatellite instability (MSI) and tumor mutational burden (TMB) are included, the full comprehensive genomic profile (CGP) assay is known as the MI Profile test. According to MolDX, the MI Profile in its entirety has been approved for coverage when the medical necessity criteria for the MI TumorSeek component are met. As of January 2019, MolDX determined CPT 81455 is no longer appropriate for this test. As a CGP assay, a single code (CPT 81479) should be used to report the test in its entirety (see A56518 for CGP test coding instructions).
   f. MI Tumor Seek Hybrid (81479), by Caris Life Sciences (Arizona). This test **has** met the TA requirement found in the LCD.
   g. UW-OncoPlex - Cancer Gene Panel (University of Washington; Washington). This test **has** met the TA requirement found in the LCD.
   h. Oncoplex Select Cancer Gene Panel (University of Washington; Washington). This test **has** met the TA requirement found in the LCD.
   i. Oncotype MAP® Pan-Cancer Tissue Test (formerly Paradigm Cancer Diagnostic or PCDx) (0244U), by Paradigm Diagnostics (Arizona) (Test may be billed by Genomic Health, but it is performed by Paradigm Diagnostics). As of the date of the most recent policy review, this test does **NOT** meet the TA requirement found in the LCD.

j. OncoExTra™ (formerly Oncomap™ ExTra and GEM ExTra®) (0329U), by Exact Sciences, Inc. and Genomic Health Inc. (May be performed by Ashion Analytics on behalf of Genomic Health/Exact Sciences, in Phoenix, AZ). This test **has** met the TA requirement found in the LCD.

k. Providence GenOmic Cancer Profiling, Solid Tumor (previously the Providence Personalized Medicine Panel, Solid Tumor, aka, ProvSeq523) (81455), by Providence St. Joseph (Oregon). This test **has** met the TA requirement found in the LCD.

i. The add-on test, ProvSeq Homologous Recombination Deficiency (HRD) or ProvSeq HRD, also **has met** the TA requirement found in the LCD. According to the performing laboratory and the DEX®) Registry entry for this test, it is used in the diagnosis of HRD status **solely in ovarian cancer.** Also according to the performing laboratory, this test **cannot** be ordered as a standalone test, but rather, it must be performed in conjunction with the GenOmic Cancer Profiling, Solid Tumor panel test.

ii. Testing performed in OH and KY: L38067 (CGS Administrators, LLC) (companion coding/billing LCA A57870)

iii. Testing performed in VA, WV, NC, SC, GA, TN, and AL: L38045 (Palmetto GBA) (companion coding/billing LCA A57831)

1. Tempus xR Solid Tumor (Tempus Labs, Inc.; Testing may be done in varying locations, including Illinois, Georgia, or North Carolina). To allow for consistent outcomes across all plan members, the North Carolina LCD will be applied. This test is listed in the DEX Registry as "not covered," and therefore, it has **not** met the required technical assessment (TA) review and is not medically necessary.

iv. Testing performed in IA, KS, MO, and NE: L38158 (Wisconsin Physician Services) (companion coding/billing LCA A57858)

a. Example: Strata Select™ panel test (0391U) and StrataNGS, both by Strata Oncology, Inc. (Michigan). These tests **have** met the TA requirement found in the LCD.

XX. Coverage for multianalyte serum biomarker testing is as follows:

A. Ova1™ (81503) and Overa (0003U) (Aspira Labs, Inc., a Vermillion Company; Texas) (When combined, these are known as OVA1plus®): Apply the LCD L35396. Allow these tests when performed according to the Food and Drug Administration [FDA] label. For coding, see companion article, which can be accessed directly from the LCD.)

B. Risk of Ovarian Malignancy Algorithm (ROMA™) (81500) (Quest Diagnostics [Headquartered in New Jersey] or LabCorp [Headquartered in North Carolina]):

i. For testing performed in laboratories in OR, WA, AK, ID, UT, AZ, MT, ND, SD, WY, CA, NV, HI, NC, SC, AL, GA, TN, VA, WV, KY, OH, IA, KS, MO, NE, IN, and MI: The ROMA™ test is noted as a covered test by MolDX when Medicare medical necessity criteria are met. This means documentation must support that the test is ordered to provide actionable data to be used promptly by the treating physician to treat or diagnose an illness or condition in order to be considered medically

reasonable and necessary. (Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services) (See U.S. Food and Drug Administration [FDA] label here)

ii. For testing performed in laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT: LCD L38371 (Search for "Risk of Ovarian Malignancy Algorithm")

iii. For testing performed in laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA: LCD L35396 (Search for "Risk of Ovarian Malignancy Algorithm")

C. OvaWatch℠ (0375U; Aspira Women's Health℠ and Aspira Labs; Texas) and GlycoKnow™ Ovarian (0577U; InterVenn Biosciences; California): These tests are considered **not medically necessary** for the medical management of patients with a pelvic mass, including but not limited to, for determining malignancy in women with adnexal masses prior to surgery, as detailed in the Company policy for Multimarker Serum Testing for Ovarian Cancer. In the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria are applied for medical necessity decision-making for multianalyte serum biomarker testing which doesn't have a relevant Medicare coverage policy. *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the individual Company medical policy links below [CFR § 422.101(6)(ii)(A) and (B)].*

Genetic and Molecular Panel Tests

XXI. The tests in **Table 1** have specific LCD policies or LCA articles available. Additional notes are provided when necessary.

Table 1

IMPORTANT NOTE: Several CPT codes which represent full gene sequence, full sequence analysis, and duplication/deletion tests are considered to be non-covered as of August 20, 2022 by the local Medicare Administrative Contractor (MAC) and the Medicare Molecular Diagnostics (MolDX) Program. These CPT codes will deny as not medically necessary based on the billing and coding lab-developed test (LDT) LCAs. Claims for medically necessary tests will need to be reported using CPT codes approved for coverage. Tests reported with non-covered CPT codes, even if the test itself is medically necessary, will deny based on Medicare LCAs.

Proprietary Test Name	Laboratory (Location)	Medicare Policy Cross Reference or Medicare Citation/Rationale
BDX-XL2 (0080U) (aka, Nodify XL2®)	Biodesix, Inc. (Kansas)	Cite LCD L37054 (if performed in Seattle) or LCD L37216 (if performed in Kansas) (the criteria are the same in each LCD)

		NOTE: The test known today as Nodify XL2® has evolved over time, and prior generations of this test were previously known as Xpresys Lung, Xpresys Lung 2 or BDX-XL2. Therefore, apply the same coverage criteria to Nodify XL2 since it is the same test.
BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel (0594U)	bioMérieux	This test is intended to be used in an emergency room (ER) setting for rapid results, and thus is a kit, billed by the facility where the testing will take place. LCDs for infectious disease testing indicate coverage is available for FDA approved or cleared tests. This test received FDA clearance in December 2024 (K243463), and therefore, this test will be considered ***medically necessary*** when used to diagnose an illness or condition for individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the target pathogens (chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), Leptospira spp., and Plasmodium spp. (including species differentiation of Plasmodium falciparum and Plasmodium vivax/ovale]).
BluePrint® (0630U as of 4/1/2026 or 81479 prior to 4/1/2026)	Agendia (California)	Apply the LCA A55115.
CancerTypeID (81540)	bioTheranostics, Inc. (California)	Apply the LCA A54386. While it doesn't give specific criteria, it does provide a list of ICD-10 codes that support medically necessity. These are used to determine coverage. Under Medicare, all diagnostic laboratory testing must be ordered by a practitioner treating the member for a condition and the clinical documentation must show the test results are expected to be used to make a diagnosis or treatment decisions.
Caris GPSai™	Caris Life Sciences (Arizona)	I. If this test is requested alone, apply criteria for Whole Exome Whole Genome Testing above.

*A **Genomic Prevalence Score, using whole exome (DNA) sequencing and whole transcriptome (RNA) sequencing coupled with machine learning to aid in identifying the tissue of origin.***		II. If this test is requested in conjunction with another test (e.g., MI Tumor Seek), and **will** be billed separately, apply criteria for Whole Exome Whole Genome Testing above. III. If this test is requested in conjunction with another Caris test (e.g., MI Tumor Seek or MI Tumor Seek Hybrid), and is ***not*** going to be billed separately, coverage is based on the coverage outcome for the other requested test.
PreTransplant Risk Assessment (PTRA) (0319U; formerly known as Clarava™) and Tutivia™ (0320U; formerly known as Tuteva™)	Verici Dx (Tennessee)	Apply the LCA A58019 and LCD L38568. The LCD requires successful completion of TA review of the test; the Clarava test **does not** meet this LCD requirement and therefore is **not medically necessary**. The Tutivia test meets this LCD requirement and may be eligible for coverage as of 2/8/2025.
CKM PGx™ Panel (Hypertension and Cardiovascular-Kidney-Metabolic Pharmacogenetic Panel) (0650U)	Personalized Medicine Care Diagnostics (Maryland)	Apply the LCD L39063 and LCA A58801.
CNT (CEP72, TPMT and NUDT15) genotyping panel (0286U)	RPRD Diagnostics (Wisconsin)	Apply the LCA A59915. *(Full pharmacogenomic testing criteria for are in LCD L39995, but clearer guidance for this specific code is detailed in the LCA)*
Colvera (0229U)	Clinical Genomics Pathology Inc. (New Jersey)	Apply the LCD L39365.
CRCdx® RAS Mutation Detection Kit (0471U)	EntroGen, Inc. (California)	This test is the analysis of variants of the KRAS and NRAS genes. The LCA for KRAS testing (A54498) and the LCD for NRAS testing (L36335) both reflect coverage for FDA-approved tests. Therefore, this CRCdx® test will be considered **medically necessary** when used to aid in the identification of colorectal cancer patients for treatment with Vectibix® (panitumumab). As of the date of this policy review, this is the only approved drug/test combination, but the FDA website can be viewed to

		determine if the test has been approved for use for consideration of additional drugs or indications.
Custom Next-Generation Sequencing (NGS) Panel Tests	Any lab testing performed in a MolDX service area (AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, HI, CA, NV, OH, KY, VA, WV, NC, SC, GA, TN, AL, IA, KS, MO, and NE) *Custom NGS panel tests performed in any other state will require individual review.*	**Criteria:** Custom NGS panel tests performed within a MolDX service area and when performed for solid tumors or myeloid malignancies (known and suspected) are **all** subject to LCDs which require completion of a technical assessment and approval for coverage by the Molecular Diagnostic Services Program (MolDX). Examples of such LCDs include, but are not limited to, L38119 and L38123. According to communication received directly from MolDX, "there is no intended use patient population or diagnosis codes that can be associated with a 'custom' panel. Therefore, the test would not pass a technical assessment and would not meet policy criteria for coverage." Therefore, custom NGS panel tests are **not medically necessary**. *(Special consideration may be given to panels requested for unique clinical situations, such as for rare medical conditions and when panel tests are not already commercially available for that condition. This is not expected to be a common occurrence, and all other clinical criteria found in the applicable LCD must still be met.)* **Billing & Coding:** When reporting for a custom NGS panel test, the practice of stacking multiple Tier I codes is not appropriate coding. The laboratory should submit a single service mapped to the most appropriate code. If no specific panel code exists, then an unlisted code (e.g., 81479) should be used.
RiskReveal™ (previously known as DetermaRX™, aka, RiskReveal14 Gene	Razor Genomics (Tennessee) (previously Oncocyte Corp. in California)	Apply the LCD L38238.

Lung Assay or the Razor 14-Gene Lung Cancer Assay) (0288U)		
DCISionRT® (0295U)	Prelude Corp. (California)	Apply the LCA A59641. **NOTE:** This LCA states, "all proteomics tests in MolDX jurisdictions must register with the DEX® Diagnostics Exchange Registry." While DCISionRT® is listed in the registry, the registry does not indicate this test is "Covered" so this test has **not** successfully completed the required MolDX TA review. This test is considered **not medically necessary** until indicated otherwise by the MolDX MAC.
Decipher Bladder (0016M)	Veracyte Labs SD (California)	Apply the LCD L38647. The LCD requires successful completion of technical assessment review of the test; this test **does** meet this LCD requirement.
DecisionDX®-SCC (0315U)	Castle Biosciences (Arizona)	Apply the LCD L39589
Envisia® Genomic Classifier (81554)	Veracyte™, Inc. (California)	Apply the LCD L37887 (for billing and coding guidance, see also the LCA A57419)
EpiSwitch® Prostate Screening Test (PSE) (0433U)	Oxford BioDynamics, Inc.	Apply the NCD 210.1. **NOTE:** The EpiSwitch® Prostate Screening Test is **not medically necessary** based on the above NCD. Coverage of prostate cancer screening tests is limited to a screening digital rectal exam or a screening prostate specific antigen test. See also the member's EOC for prostate cancer screening benefits and the Medicare Preventive Services interactive chart for Prostate Cancer Screening.
Galleri® Screening test (81479)	GRAIL, LLC (North Carolina, but apply to all test locations)	Apply the LCA A59892. *(**NOTE:** This LCA includes lifetime limits for this test as well. Claims must be submitted with ICD-10 code Z00.6, as well as modifier -Q0. Medicare-approved Category B IDE information includes NCT# NCT05673018 & IDE# G220255.)*

GeneSight® Psychotropic (as of 10/1/2022 0345U or 81479 prior to 10/1/2022)	AssureRx Health, Inc. (Ohio)	Apply the LCD L38394. *(LCA A58324 includes GeneSight® as an approved multi-gene test, but LCD clinical criteria must still be met)*
GENETWORx UTI with ABR (Between 10/1/2023 and **4/1/2024 code** used **was 0416U)**	RCA Laboratory Services LLC d/b/a GENETWORx (Virginia)	Apply LCD L38988. For tests without FDA approval or clearance, the LCD requires successful completion of TA review of the test; this test **does not** meet this LCD requirement and therefore is **not medically necessary**.
Guardant360® Tissue Tests	Guardant Health, Inc. (California)	This Guardant Health test portfolio includes: • Guardant360 Tissue (this is **DNA** testing **only**) (successful TA completion as of 1/27/2022) (billed with 0334U - previously known as TissueNext, but it was not identified in the Registry with this name, so it appeared previously non-covered) • Guardant360 Tissue RNA (this is **RNA** testing **only**). *Intended use: Patients diagnosed with solid tumor cancers who have a tumor sample at either initial diagnosis or upon progression that has **not** been previously tested for RNA using NGS testing. This service is only performed when Guardant360 Tissue is not performed* (successful TA completion as of 11/19/2024) (may be billed with 81456 prior to 10/1/2026, or with 0696U as of 10/1/2026) • Guardant360 Tissue and Guardant360 Tissue RNA (this is **combined** DNA **and** RNA testing, in one test). *Intended use: Patients diagnosed with solid tumor cancers who have a tumor sample at either initial diagnosis or upon progression that has **not** been previously tested using comprehensive genomic profiling (CGP)* (successful TA completion as of 11/19/2024) (should be billed with CPT 81479, per billing instruction found in LCA A55624, which states "If two targeted panels (one for DNA and the other for RNA) are always performed together and meet

		policy criteria, 81479 should be used for such a service to reduce claims processing errors as this would constitute one service.") • Guardant360 Tissue RNA. *Intended use: Patients diagnosed with solid tumor cancers who have a tumor sample at either initial diagnosis or upon progression that has not been previously tested for RNA using NGS testing. This service is only performed when a previous Guardant360 Tissue service was reported and billed* (successful TA completion as of 11/19/2024) For all of these tests, apply LCD L38043. The LCD requires successful completion of TA review of the test; as of the respective dates for each test above, all of these tests meet this LCD requirement.
Her2DX	Reveal Genomics (North Carolina)	Apply LCD L35025. • **NOTE:** This LCD states, "Molecular Diagnostic Services Program (MolDX®) will review all new test/assay clinical information to determine if a test meets Medicare's reasonable and necessary requirement." The Her2DX test is listed in the DEX® Registry as "not covered" for MolDX. Therefore, this test is considered **not medically necessary**.
High Risk HLA Panel *(this test consists of HLA-A*31:01, HLA-B*15:02, HLA-B*57:01, HLA-B*58:01)*	Genelex Corporation (Washington)	• For non-transplant testing: Apply the LCD L38335 and A57384 • For transplant testing: LCA A57972
IDH1, IDH2, and TERT Mutation Analysis, Next-Generation Sequencing, Tumor (IDTRT) **(0481U)**	Mayo Clinic, Laboratory Developed Test (Minnesota)	Apply LCA A56199 **NOTE:** This panel consists of only three (3) genes (IDH1, IDH2 and TERT), which are all medically necessary for certain indications. If diagnosis code "coverage" for TERT

		testing is met (see the Group 32 medically necessary diagnosis codes for TERT), then this test can be approved as medically necessary and clinically indicated.
InVisionFirst®-Lung	Inivata; Research Triangle Park (North Carolina)	Apply the LCD L37897
IVD CAPSULE PSP –Rapid Sepsis Test (0595U)	Abionic SA	This test is intended to be used in an emergency room (ER) setting for rapid results, and thus is a kit, billed by the facility where the testing will take place. LCDs for infectious disease testing indicate coverage is available for FDA approved or cleared tests. This test received FDA clearance in September 2024 (K240041), and therefore, this test will be considered **medically necessary** when used to diagnose an illness or condition for a member showing signs or symptoms of sepsis.
KidneyIntelX™ and kidneyintelX.dkd™ (0105U and 0407U, respectively)	RenalytixAI (New York)	• As of August 1, 2024: Apply the LCD L39726 and LCA A59595 • Prior to August 1, 2024: These tests were considered not medically necessary.
Memorial Sloan Kettering-Integrated Mutation Profiling of Actionable Cancer Targets™ (MSK-IMPACT™) (0048U)	Memorial Sloan Kettering (New York)	Apply the LCD L37810 and LCA A56867
Mental Health DNA Insight™	Pathway Genomics® (California)	Apply the LCD L38335 and LCA A57384. The LCD requires successful completion of TA review of the test; as of the date of the most recent policy review, this test **does not** meet this LCD requirement and therefore is **not medically necessary**.
MyGenVar Pharmacogenomics Test (0516U)	Geisinger Medical Laboratories (Pennsylvania)	Apply the LCD L39063. **NOTE:** This LCD states, “Some panel/combinatorial tests may include content that has demonstrated actionability and some that has not. In these circumstances, the components of the tests that have demonstrated actionability as noted in #2 will be considered medically

		reasonable and necessary." Therefore, since this panel is reported under a single CPT code, if the member meets "criteria" for a single gene analyzed in the test using LCD/LCA information, then the test may be medically necessary.
MyPhenomeRx™ (0697U)	Phenomix Sciences Clinical Laboratory (California)	Apply the general coverage guidance found in LCD L35160. The LCD calls out the requirement of a successful TA review of each test; this test does **not** meet this LCD requirement. In addition, this test is a weight management and screening tool rather than a diagnostic tool for a core medical illness. Therefore, it does not meet Medicare's coverage requirements and is **not medically necessary**.
NeuroIDGenetix (0411U; May also be known as IDgenetix®**)**	AltheaDx, Inc. (California)	Apply the LCD L38335 and A57384. The LCD requires successful completion of TA review of the test; this test meets this LCD requirement.
Nodify CDT® (0360U)	Biodesix, Inc. (Kansas)	Cite LCD L37054 (if performed in Seattle) or LCD L37216 (if performed in Kansas) (criteria in these LCDs are the same) **NOTES:** • **Nodify XL2** ***(previously known as Xpresys Lung, Xpresys Lung 2 or BDX-XL2 – addressed in separate row)*** measures the abundance of 2 plasma proteins (LG3BP and C163A) and combines the results with 5 clinical risk factors (age, smoking status, nodule diameter, edge characteristics, and location) to provide a post-test probability of a lung nodule being benign. According to both of the above LCDs, "The intended use of the test is to assist physicians in the management of lung nodules by identifying those lung nodules with a high probability of being benign. These lung nodules would then be

		candidates for non-invasive computed tomography (CT) surveillance instead of invasive procedures." • **Nodify CDT** measures 7 autoantibodies associated with tumor antigens to provide a post-test probability of a lung nodule being malignant. • These 2 tests are offered alone, or in conjunction with each other as the "Nodify Lung."
NPM1 MRD by NGS (0049U)	Laboratory for Personalized Molecular Medicine (LabPMM) (California)	Apply the LCD L38814. The LCD requires either FDA approval or successful completion of TA review of the test; this test **does not** meet this LCD requirement and therefore is **not medically necessary**.
Oncotype DX® AR-V7 Nucleus Detect Test (CPT 81479)	Epic Sciences (California)	Apply the LCD L38643. The LCD requires successful completion of TA review of the test; this test meets this LCD requirement.
PancraGEN (aka Pathfinder® Pancreas) (81479)	Interspace Diagnostics (Pennsylvania)	Apply the LCD L39365. *(Search by test name)*
PancreaSeq® Genomic Classifier (0313U)	Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center	Apply the LCD L39365. *(Search by test name)*
Percepta Bronchial Genomic Classifier (BGC) and Percepta Genomic Sequencing Classifier (GSC) (81479)	Veracyte, Inc. (San Francisco, CA)	Apply the LCD L39678 **NOTE:** The Percepta Bronchial Genomic Classifier (BGC) is considered the "first generation" version of this test, and the Percepta Genomic Sequencing Classifier (GSC) is the "second generation" offering of this same test.
PersonalizedRX	Lab Genomics LLC (California)	Apply the LCD L38335 and LCA A57384. The LCD requires successful completion of TA review of the test; this test meets this LCD requirement as of 5/11/2023 (this test would be considered not medically necessary prior to this date).
PGDx elio™ tissue complete (0250U)	Personal Genome Diagnostics, Inc. (Maryland)	The LCD L35396 for genetic testing for the state of Maryland directs readers to NCD 90.2 for coverage details related to Next Generation Sequencing (NGS) for

		Patients with Advanced Cancer. Therefore, this test may be considered **medically necessary** when Medicare coverage criteria found in NCD 90.2 are met.
ProMark Risk Score (CPT 81479)	MetaMark Genetics (Massachusetts or Georgia)	Apply the LCD L36665. (Use this LCD for either location)
Prometheus® IBD sgi Diagnostic® test (81479)	Prometheus Laboratories (California)	Apply the LCD L37299.
Prostate Health Index (PHI or phi) **ExoDx prostate (also known as ExosomeDx®, EPI, or IntelliScore) (CPT 0005U)**	Beckman Coulter Exosome Diagnostics (Massachusetts)	These tests are considered **medically necessary** when ordered by a physician or other qualified health care professional for the treatment of prostate cancer. It is expected that the ordering provider is familiar with the proper parameters of use of the test they are ordering. *(Source: LCA: Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis, A56609)*
RenaPGx™ (Renal Pharmacogenetic Test) (0652U)	Personalized Medicine Care Diagnostics (Maryland)	Apply the LCD L39063 and LCA A58801.
Solid Tumor Expanded Panel (0379U)	Quest Diagnostics (Headquartered in New Jersey, but testing may be done in varying locations)	To allow for consistent outcomes for all members who have this test performed, regardless of testing location, apply the following reference: Apply LCD L38043. The LCD requires successful completion of TA review of the test; this test **does** meet this LCD requirement.
Tempus nP (0419U)	Tempus Labs, Inc. (Testing may be done in varying locations, including Illinois, Georgia, or North Carolina)	To allow for consistent outcomes for all members who have this test performed, regardless of testing location, apply the following reference: Apply LCD L38294. The LCD requires successful completion of TA review of the test; this test **does** meet this LCD requirement.
TriVerity™ (0588U)	Inflammatix™, Inc.	This test is intended to be used in an emergency room (ER) setting for rapid results, and thus is a kit, billed by the facility where the testing will take place. LCDs for infectious disease testing indicate coverage is available for FDA approved or cleared tests. This test received FDA clearance in January 2025 (K241676), and therefore, this test will be considered **medically necessary** when used

		to diagnose an illness or condition for a member showing signs or symptoms of sepsis.
VeriStrat® (CPT 81538)		Apply the LCD L35396. Search the LCD for the test by name and apply noted criteria.

XXII. The following tests are **not medically necessary**.

D. The following tests are **not medically necessary** based on the Medicare guidance found in Table 2 in the Policy Guidelines section.
   i. The following tests are **not medically necessary** due to **not** being listed within the DEX® Registry at all, and thus no required technical assessment (TA) has been performed by the MolDX Program Contractor:
      1. NextStep DX Plus (Lineagen, Inc.; Utah)
      2. Bridge Women's Health Infectious Disease Detection (Bridge Diagnostics [California]; 0330U)
      3. DEPArray™ HER2 (0009U) (PacificDX; California)
      4. Pharmacogenomic/Pharmacogenetic Tests
         a. GeneSight® ADHD (AssureRX Health, Inc. [Ohio])
         b. GeneSight® Analgesic Panel (AssureRX Health, Inc. [Ohio])
         c. SureGene Test for Antipsychotic and Antidepressant Response (STA2R) (SureGene LLC. and PGXL Laboratories [Kentucky])
         d. Pain Panel (aka, "Pain/Psychiatry Panel") (Alpha Genomix [Georgia])
         e. Pain Medication DNA Insight™ (Pathway Genomics® [California])
         f. Polypharmacy Panel (Genelex Corporation [Washington])
         g. Polypharmacy Comprehensive Panel (Genelex Corporation [Washington])
         h. Psychiatry/ADHD Panel (Alpha Genomix [Georgia])
         i. UCSF Pharmacogenomics Panel (Univ. of California San Francisco Genomic Medicine Laboratory; California; 0533U)
      5. TargetPrint® (Agendia®; California)
      6. BreastOncPx™ (LabCorp; headquartered in North Carolina)
      7. BreastPRS™ (Signal Genetics; California)
      8. Mammostrat® (Clarient Diagnostic Services; California)
      9. AidaBreast™ (0597U) (PreludeDx™; California)
      10. NeoLAB Prostate Liquid Biopsy (CPT 0011M) (NeoGenomics Laboratories, Inc.; (California)
      11. Apifiny® Score (0021U) (Armune BioScience, Inc.; Michigan)
      12. Mi-Prostate score (also known as Michigan Prostate Score or MIPS) (CPT 0113U) (MLabs; Michigan)

13. Stockholm3 (CPT 0495U) (BioAgilytix Diagnostics; North Carolina)
14. Rapid Genome Sequencing Test (Univ. of California San Francisco Genomic Medicine Laboratory; California; 0532U)
15. Prenatal Detect RhD (Devyser Genomic Laboratories; Georgia; 0536U)
16. PredicineATLAS™ Assay (Predicine Inc.; California; 0538U)
17. Bladder CARE™ (Pangea Laboratory LLC; California; 0549U)
18. EarlyDx MethylScan™ HCC (EarlyDiagnostics Laboratory; California; 0565U)
19. AdvanceAD-Tx™ (Castle Biosciences, Inc.; Arizona; 0635U)
20. AssureMDx™ (Vesica Health® Inc.; California; 0613U). This test is intended to be used for patients with hematuria to assess risk of bladder cancer. In addition to not having successfully completed the required MolDX technical assessment (TA) reviews (as required under LCD L35160), according to LCD L36678, "Bladder cancer tumor markers performed by any technology, immunoassay, molecular or FISH testing are not covered for screening of all patients with hematuria. Bladder tumor markers are not expected to be performed until other diagnostic studies fail to identify the etiology of the hematuria. Urine cytology is not considered a bladder tumor marker." The companion LCA A55028 also adds, "Noridian will only cover bladder tumor marker fluorescence in situ hybridization (FISH) testing services when performed using validated assays" and states only the UroVysion® Bladder Cancer Kit is approved for coverage. Therefore, this AssureMDx™ test is considered **not medically necessary** at this time.
21. Macula Risk PGx (ArcticDX Inc. / Arctic Medical Laboratories; Michigan)
22. VitaRisk® (0205U) (ArcticDX Inc. / Arctic Medical Laboratories; Michigan)
23. Epigenetic tests by TruDiagnostic™, Inc. (Kentucky). Tests include, but may not be limited to, the following:
    a. TruD MDS Alzheimer's & MCI (0616U)
    b. TruD MDS ASCVD (0617U)
    c. TruD MDS Bipolar (0618U)
    d. TruD MDS COPD (0619U)
    e. TruD MDS Hepatocellular Carcinoma (0620U)
    f. TruD MDS Lyme Disease (0621U)
    g. TruD MDS Major Depressive Disorder (0622U)
    h. TruD MDS Multiple Sclerosis (0623U)
    i. TruD MDS NASH (0624U)
    j. TruD MDS Osteoporosis (0625U)
    k. TruD MDS Parkinson's (0626U)
    l. TruD MDS Schizophrenia (0627U)

ii. The following tests are **not medically necessary** due to being listed within the DEX® Registry as "Not Covered" following review by the MolDX Program contractor and are considered to be of unproven clinical utility and analytical validity:
    1. Copper Metabolism Disorders Panel (Invitae; California)

2. Oncuria® Detect [0365U), Oncuria® Monitor (0366U), Oncuria® Predict (0367U)
3. UriFind® Urothelial Carcinoma Assay (0465U) (DiaCarta Clinical Lab, DiaCarta, Inc; California)
4. Avantect™ Pancreatic Cancer Test (0410U) (ClearNote™ Health; California)
5. QClamp® Plex VEXAS UBA1 Mutation Test (DiaCarta, Inc.; California; 0500U)
6. DCMNext (Ambry Genetics; California)
7. HCMNext (Ambry Genetics; California)
8. Lymph3Cx Lymphoma Molecular Subtyping Assay (Mayo Clinic; Test developed and performed in Arizona)
9. Retinal Dystrophy Panel (Univ. of Washington; Washington)
10. Macula Risk PGx (ArcticDX Inc. / Arctic Medical Laboratories; Michigan)
11. VitaRisk® (0205U) (ArcticDX Inc. / Arctic Medical Laboratories; Michigan)
12. Avantect Ovarian Cancer Test (ClearNote® Health; California; 0507U)
13. OtoSCOPE® Panel (University of Iowa, D/B/A Molecular Otolaryngology and Renal Research Laboratories; Iowa)
14. DecisionDx®-SCC (0315U) (Castle Biosciences, Inc.; Arizona)
15. EpiSign Complete (0318U) (Greenwood Genetic Center)
16. Bridge Urinary Tract Infection Detection and Resistance (0321U) (Bridge Diagnostics; California) *(listed as UTI ID with ABR and AST Detection Assay in the Registry)*
17. EpiSwitch® CiRT [Checkpoint-inhibitor Response Test] (0332U; Next Bio-Research Services, LLC. and Oxford BioDynamics, PLC)
18. PROphet® NSCLC (0436U) (OncoHost, Inc.; North Carolina/Israel)
19. Taq Array Card Urinary Tract Infection PCR Panel (0593U) (SoftCell Laboratories LLC; Utah)
20. Insight TNBCtype (0153U) (Insight Molecular Labs; Tennessee)
21. OncoAssure™ Prostate (CPT 0497U) (DiaCarta, Inc.; California)
22. PROSTOX™ ultra (CPT 0534U) (MiraDx, Inc.; California)Pharmacogenomic/Pharmacogenetic Tests
    a. Mind.Px (0258U) (Mindera Corporation; California)
    b. Medication Management Neuropsychiatric Panel (0392U) (RCA Laboratory Services LLC d/b/a GENETWORx; Virginia)
    c. EffectiveRX™ Comprehensive Panel (0438U) (RCA Laboratory Services LLC d/b/a GENETWORx; Virginia)
    d. Personalized Medicine Panel (Center for Spine & Pain Medicine; Georgia)

E. The following tests are **not medically necessary** based on the Medicare guidance found in Table 3 in the Policy Guidelines section (in addition to any specific notes included below).
    i. Ataxia Comprehensive Evaluation Panel (Athena Diagnostics; Massachusetts)
    ii. CNGnome™ PerkinElmer Genomics (Pennsylvania)
    iii. CxBladder Detect (0012M), CxBladder Monitor (0013M), CxBladder Triage (0363U), and Cxbladder Detect+ (0420U), all by Pacific Edge, Ltd. (Pennsylvania)**:** Novitas LCD for Genetic Testing in Oncology: Specific Tests (L39365) *(Search for*

"CxBladder" within the LCD, specifically the "Limitations" section) and the Novitas companion LCA for Billing and Coding: Genetic Testing for Oncology (A59125) *(Codes are in the "Non-Covered CPT Codes" Group 2 list)*

iv. Genomic Unity® Ataxia Repeat Expansion Analysis (0216U) (Variantyx Inc.; Massachusetts)
v. Genomic Unity® Comprehensive Ataxia Repeat Expansion and Sequence Analysis (0217U) (Variantyx Inc.; Massachusetts)
vi. Genomic Unity® DMD Analysis (0218U) (Variantyx Inc.; Massachusetts)
vii. Hemiplegic Migraine Panels (GeneDx, Maryland)
viii. Infantile Epilepsy Panel (GeneDx, Maryland)
ix. myTAIHEART (TAI Diagnostics, Inc.; Wisconsin)
x. OmniSeq Advance℠ (OmniSeq®Corporation; New York)
xi. OmniSeq Comprehensive® (OmniSeq®Corporation; New York)
xii. OtoGenome™ (Laboratory for Molecular Medicine / Partners HealthCare; Massachusetts)
xiii. Tissue of Origin® (TOO®) – Endometrial (Cancer Genetics Inc.; New Jersey, with labs also in California and North Carolina)
xiv. Tissue of Origin® (TOO®) – Head & Neck (Cancer Genetics Inc.; New Jersey, with labs also in California and North Carolina)
xv. ERA® (Endometrial Receptivity Analysis) (Igenomix®; Florida) - In vitro fertilization (IVF) services are not a covered Medicare benefit. See member benefits. In addition, testing to ensure successful IVF does not meet Medicare's definition of medical necessity. Therefore, this test is **not medically necessary** under *Social Security Act, §1862(a)(1)(A)* for Medicare.
xvi. Versiti™ Thrombosis Panel (0278U) (Versiti™ Diagnostic Laboratories; Wisconsin)
xvii. Molecular Grade Index (aka, Aviara MGI℠) (AviaraDx, Inc.) *(This non-coverage position is for the stand-alone Aviara MGI. This non-coverage does not apply to the Breast Cancer Index [81518] by bioThernostics. While the bioThernostics BCI includes an MGI component, it is considered medically necessary for Medicare members)*
xviii. Theralink® Reverse Phase Protein Array (RPPA) (0249U) (Theralink® Technologies, Inc.; Colorado)
xix. PanGIA Prostate (CPT 0228U) (Genetics Institute of America; Florida)
xx. ProsTAV® (CPT 0572U) (Life Length S.L.; Florida)
xxi. MiCheck® Prostate (CPT 0591U) (Minomic® Inc.; Maryland)
xxii. ClarityDx Prostate (CPT 0609U) (Protean BioDiagnostics, Florida)
xxiii. Oncomine™ Lung cfDNA Assay (Thermo Fisher Scientific, Massachusetts)
xxiv. Versiti™ Coagulation Disorder Panel (0270U) (Versiti™ Diagnostic Laboratories; Wisconsin)
xxv. Versiti™ Comprehensive Bleeding Disorder Panel (0272U) (Versiti™ Diagnostic Laboratories; Wisconsin)
xxvi. Genecept™ Assay (Genomind; Pennsylvania)
xxvii. GenoMind Professional PGx Express™, Full Mental Health Report (24 Genes) (Genomind; Pennsylvania)
xxviii. GenoMind Professional PGx Express™, CORE Anxiety & Depression Report (15 Genes) (0175U) (Genomind; Pennsylvania) (According to LCA A58801, this test/code is not covered)
xxix. Genomind® Pharmacogenetics Report – Full, Genomind®, Inc. (0423U) (Genomind; Pennsylvania)
xxx. PGxOne™ Plus Pharmacogenomics Test Admera Health (New Jersey)

xxxi. RightMed Comprehensive Test OneOme (Minnesota)
xxxii. RightMed® Mental Health Gene Report (0476U) and RightMed® Mental Health Medication Report (0477U) (OneOme LLC.; Minnesota)
xxxiii. Focused Pharmacogenomics Panel (0029U) (Mayo Clinic, Mayo Medical Laboratories, headquartered in Minnesota)
xxxiv. Warfarin Response Genotype (0030U) (Mayo Clinic, Mayo Medical Laboratories, headquartered in Minnesota)
xxxv. Catechol-O-Methyltransferase (COMT) Genotype (0032U) (Mayo Clinic, Mayo Medical Laboratories, headquartered in Minnesota)
xxxvi. MindX One™ Blood Test – Anxiety (0437U) (MindX Sciences; Indiana)
xxxvii. Versiti™ Congenital Neutropenia Panel (0271U) (Versiti™ Diagnostic Laboratories; Wisconsin)
xxxviii. Versiti™ Fibrinolytic Disorder Panel (0273U) (Versiti™ Diagnostic Laboratories; Wisconsin)
xxxix. Versiti™ Comprehensive Platelet Panel (0274U) (Versiti™ Diagnostic Laboratories; Wisconsin)
xl. Versiti™ aHUS Genetic Evaluation (0268U) (Versiti™ Diagnostic Laboratories; Wisconsin)
xli. Versiti™ Inherited Thrombocytopenia Panel (0276U) (Versiti™ Diagnostic Laboratories; Wisconsin)
xlii. Versiti™ Platelet Function Disorder Panel (0277U) (Versiti™ Diagnostic Laboratories; Wisconsin)
xliii. Genomic Unity® AR Analysis (0230U) (Variantyx Inc.; Massachusetts)
xliv. Genomic Unity® FXN Analysis (0233U) (Variantyx Inc.; Massachusetts)
xlv. Genomic Unity® MECP2 Analysis (0234U) (Variantyx Inc.; Massachusetts)
xlvi. Genomic Unity® SMN1/2 Analysis (0236U) (Variantyx Inc.; Massachusetts)
xlvii. Genomic Unity® Cardiac Ion Channelopathies Analysis (0237U) (Variantyx Inc.; Massachusetts)
xlviii. Genomic Unity® Lynch Syndrome Analysis (0238U) (Variantyx Inc.; Massachusetts)
xlix. Genomic Unity® Whole Genome Analysis – Proband (0212U) (Variantyx Inc.; Massachusetts)
l. Genomic Unity® Whole Genome Analysis – Comparator (0213U) (Variantyx Inc.; Massachusetts)
li. Genomic Unity® Exome Plus Analysis – Proband (0214U) (Variantyx Inc.; Massachusetts)
lii. Genomic Unity® Exome Plus Analysis – Comparator (0215U) (Variantyx Inc.; Massachusetts)
liii. Genomic Unity® Comprehensive Mitochondrial Disorders Analysis (0417U) (Variantyx Inc.; Massachusetts)
liv. Genomic Unity® 2.0 (0567U) (Variantyx Inc.; Massachusetts)
lv. RightMed® PGx16, RightMed® Comprehensive Test Exclude F2 and F5, RightMed® Comprehensive tests, RightMed® Gene Report, RightMed® Gene Test Exclude F2 and F5 (0434U), RightMed® Oncology Gene Report (0460U) and RightMed® Oncology Medication Report (0461U) (all by OneOme® LLC, Minnesota) (According to Wellpoint Federal, Inc., the LCD L35000 requires all tests to be reviewed using peer reviewed literature and approved manufacturer claims about the test in question. According to this LCD and the companion LCA A56199, several genes included in these panel tests are non-covered (e.g., DPYD, CYP3A4 and CYP3A5). Therefore, a single code to represent the entire panel would be considered **not medically necessary**.)

1. The “gene report,” "oncology report,” and “oncology medication report” are all optional reports that may be provided when a provider orders a RightMed® test.)

lvi. Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping (0355U) (Quest Diagnostics®; New Jersey)

lvii. TissueCypher® Barrett’s Esophagus Assay (0108U) (Cernostics; Pennsylvania)

lviii. ESOPREDICT® Barrett's Esophagus Risk Classifier Assay (0398U) (Capsulomics, Inc. d/b/a Previse; Maryland)

lix. Tempus AI augmentative algorithmic analysis of digitized whole-slide imaging is considered not medically necessary. Tests include: PurIST℠ (0510U), PARIS (0511U), Tempus p-MSI (0512U), and Tempus p-Prostate (0513U)

lx. DH Optical Genome Mapping/Digital Karyotyping Assay (0413U) (The Clinical Genomics and Advanced Technology (CGAT) Laboratory at Dartmouth Health, Bionano Genomics; New Hampshire)

lxi. RNA Salah Targeted Expression Panel (0586U) (Moffitt Cancer Center Advanced Diagnostics Laboratory; Florida)

lxii. Aventa Lymphoma (0592U) (Aventa Genomics, LLC; Florida)

lxiii. Tryptase Gene Copy Number Analysis by dPCR (Virant Diagnostics, Inc.; Maryland; 0605U)

lxiv. CNSide CSF Tumor Cell Enumeration (TCE) (CNSide® Diagnostics LLC; Texas; 0640U)

lxv. RenaDx™: Comprehensive Renal Disease Panel Test (0628U) and RenaXome™ (Renal Disease Whole Exome Sequencing) (0653U) (Personalized Medicine Care Diagnostics; Maryland). According to LCDs L35396 and L35062, genetic and molecular tests much have “proven clinical validity/utility (CVU).” When LCDs L35396/L35062 and/or LCA A52986 do not address a specific genetic test, and if the test does not have FDA approval or clearance as an in vitro companion diagnostic test, then Criterion I.D.iii above applies.

lxvi. Metagenomic next-generation sequencing (NGS) infectious disease panel tests are considered **not medically necessary**. These tests are not medically reasonable or necessary. This non-coverage does not limit access to care for patients as alternative clinically acceptable test options are available.

1. Examples include: Bacteria, Viruses, Fungus, and Parasite Metagenomic Sequencing, Spinal Fluid (MSCSF) by the Mayo Clinic (0480U); Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease Diagnostics test by Johns Hopkins Medical Microbiology Laboratory (0323U)

XXIII. The following *tissue-based* tests may be **medically necessary** as FDA approved or cleared companion diagnostic (CDx) next generation sequencing (NGS) DNA in vitro tests when all applicable criteria from the national coverage determination (NCD) for *Next Generation Sequencing (NGS)* (90.2) are met *(**Note**: Not all tests are covered for all cancer types. Use the FDA web page link to determine if a specific test is FDA approved for the individual patient’s cancer type)*:

A. As of 3/16/2018: FoundationOne CDx™ (F1CDx) (0037U) (Foundation Medicine, Inc., Massachusetts)

B. As of 7/1/2020: MyChoice® CDx (0172U) (Myriad Genetics, Utah)

F. Oncomine™ Dx Target Test (0022U) (Thermo Fisher Scientific, Massachusetts)

G. As of 10/1/2019: Praxis™ Extended RAS Panel (0111U) (Illumina, Inc., California)

H. As of 4/28/2023: xT CDx (As of 7/1/2024, code is 0473U. Prior to 7/1/2024, code was 81455) (Tempus Labs, Inc., Illinois)
I. As of 11/5/2024: MI Cancer Seek™ NGS Analysis (0211U) (Caris Life Sciences; Arizona)
J. As of 9/30/2021: oncoReveal™ CDx (As of 1/1/2025, code is 0523U. Between 4/1-12/31/24, code was 0448U) (test formerly known as oncoReveal™ DX Lung and Colon Cancer Assay or O/RDx-LCCA; Pillar Biosciences, Inc.; Massachusetts)
K. As of 8/21/2024: TruSight™ Oncology Comprehensive test (As of 4/1/2025, code is 0543U. Between 8/21/2024-3/31/2025, code was 81455) (Illumina, Inc.)
L. As of 7/2/2025: Oncomine™ Dx Express Test (As of 7/1/2026 code is 0648U. Prior to 7/1/2026, code was 81479) (Thermo Fisher Scientific, Massachusetts) (This was communicated as covered by CMS when the July 2026 CMS CR14356 was released)
M. **NOTE:** *Liquid biopsy/plasma-based* tests subject to this NCD (e.g., FoundationOne® Liquid CDx, Guardant360® CDx, Agilent Resolution ctDx FIRST, etc.) are addressed in the separate Medicare medical policy, Circulating Tumor Cell and DNA Assays for Cancer Management.

NOTES: FDA-approval or clearance alone is not sufficient to warrant coverage under NCD 90.2. The test in question must also:
* Use next-generation sequencing (NGS) methodology.
* Be developed for the purpose of an FDA-approved or cleared for use in cancer.

Tests which do **not** use NGS methodology (e.g., LeukoStrat CDx FLT3 Mutation Assay) and tests which are cleared or approved for use in **non-cancer** indications (e.g., AAV5 DetectCDx) would not meet coverage requirements under NCD 90.2, even if they are listed on the FDA List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) website.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

Medicare Medical Policies

- Circulating Tumor Cell and DNA Assays For Cancer Management, MP306
- Clinical Trials, Studies and Registries, MP233
- Gene Expression Profile Testing for Melanoma, MP253
- Genetic Testing for Myeloproliferative Diseases, MP71
- Genetic Testing for Thyroid Nodules, MP40
- PHA Medicare Medical Policy Development and Application, MP50

Company Medical Policies

- Company policy: Genetic Testing for CADASIL Disease, MP238
- Company policy: Non-Covered Genetic Panel Tests, MP213

Coding Policies

- Laboratory Panel Billing, CP30

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to review for medical necessity, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected:

- Test name;
  - If the test is a panel test, the name of the panel test;
  - For single gene/variant testing, the name of the gene(s) and/or components of the test;
- Name and location of laboratory that performed or will be performing the test;
- Clinical notes should include the following:
  - Documentation supporting the member was advised what tests were being ordered;
  - Condition or suspected condition;
  - What test results are expected to provide (e.g., make diagnosis, determine medication therapy(ies), etc.);
  - Signs/symptoms/prior test results related to reason for genetic testing;
  - Family history, if applicable;
  - How test results will impact clinical decision making
- CPT and/or HCPCS code(s) billed
- For pharmacogenetic testing, the following information is required:

- Clinical documentation supporting the diagnosis for which pharmacologic therapy is requested, as well as which drug(s) is/are being considered and their relevant indication(s).
    - Clinical documentation that an initial personalized decision has been made for the patient based on the patient's diagnosis, other medical conditions, other medications the patient is taking, professional judgement, clinical science and basic science pertinent to the drug (e.g., mechanism of action, side effects), the patient's past medical history and if applicable, relevant family history, patient preferences and values.

GENETIC AND MOLECULAR TESTING

Genetic testing is performed to detect variants in DNA, RNA, and/or chromosomes. Within the Medicare program, genetic testing may also be referred to as molecular or biomarker testing.

According to Human Genome Variation Society (HGVS) nomenclature, the term "variant" is used to describe a change in a DNA or protein sequence, replacing previously-used terms, such as "mutation." Pathogenic variants are variants associated with disease, while benign variants are not. However, the majority of genetic changes have unknown effects on human health. These are referred to as "variants of uncertain significance."

Such testing may be requested for a variety of purposes, such as diagnosing a condition, predicting susceptibility for inherited conditions, determining carrier status, diagnostic and prognostic testing, screening for common disorders, or selecting appropriate treatments (also known as pharmacogenetic testing). However, this is not a complete list of reasons genetic testing may be requested or performed.

Some genetic tests may be eligible for Medicare coverage, while others are potentially covered in select individuals or for certain conditions. Still other tests may not be eligible for Medicare coverage at all due to Medicare's reasonable and necessary requirements for diagnostic testing.

Some tests may be single gene testing, while other tests are offered as multi-gene panels. Panel testing technology, such as next generation sequencing (NGS) and chromosomal microarray, is a testing method that examines multiple genes or mutations simultaneously. There is currently no standardization of the design and composition of panel tests. Therefore, panels can vary by laboratory. Thus, different commercially available test options that appear to be for the same condition may test different sets of genes. In addition, the composition of any individual panel is likely to change over time, as genes are added to or removed from existing panels.

Some tests are performed at one single laboratory, while other tests may be developed as "test kits," which can be sent out by a manufacturer to any laboratory for processing.

While genetic testing has potential benefits for certain conditions, especially cancer, there are also risks associated with genetic testing. These include emotional, social, or financial consequences. Reasons include what test results may reveal, and the feelings that can arise with such test results (e.g., results revealing information about other family members who were not the intended individual the testing was performed for, etc.). In addition, there are limitations to what genetic and molecular tests can provide regarding an inherited condition. Even if a positive result is received, the test may be unable to determine if a person will ever show symptoms of a disorder, how severe the symptoms will be, or

whether the disorder will progress over time. Another limitation of molecular testing is that there may not be treatments or cures available for conditions related to an identified genetic variant or genetic disorder. Therefore, it is very important that any individual who is considering genetic testing understand all aspects of the test results before making a decision. While not a requirement for Medicare coverage in most cases, individuals considering genetic testing may wish to consult with a genetics professional to explain in detail both benefits and risks of testing, as well as any potential and significant limitations of a particular test. (Genetics Home Reference U.S. National Library of Medicine, https://ghr.nlm.nih.gov/primer/testing/genetictesting)

MEDICARE COVERAGE AND MEDICAL NECESSITY BACKGROUND

In order for a laboratory service (including genetic and molecular testing) to be considered for coverage, Medicare requires that the test in question meet all of the following:

- **Not be excluded from coverage** by statute, regulation, National Coverage Determination, (NCD), or Local Coverage Determination (LCD);[2]
- **Be ordered by a physician or practitioner** who is treating the beneficiary;[7,8]
- Provide data that will be **directly used in the management** of a beneficiary's specific medical problem;[7,8]
- **Be considered medically reasonable and necessary**, as required per the *Social Security Act, §1862(a)(1)(A)*. This means the service must be considered reasonable and necessary in the diagnosis or treatment of an illness or injury, or to rule out or confirm a suspected diagnosis because the patient has signs and/or symptoms.[4,5]
    - This also means services deemed ***not*** medically necessary for any reason (including lack of safety and efficacy for investigational services) are also non-covered.[6]

In addition to the above general Medicare requirements, under Chapter 13 of the Medicare Program Integrity Manual, Medicare allows contractors to consider a service "reasonable and necessary" when the service is appropriate for the member's condition. This includes appropriateness in duration, frequency, and that the service is furnished in accordance with accepted standards of medical practice for the condition, furnished in a setting appropriate to the medical needs and condition, ordered and furnished by qualified personnel, that the service meets, but does not exceed, the medical need; and is at least as beneficial as an existing and available medically appropriate alternative.[11]

To effectively manage a patient's specific medical problem using genetic or molecular diagnostic testing, the genetic tests performed must be relevant to the medical condition **and** have established clinical utility and analytical validity for that condition. Therefore, ordering physicians must be familiar with the genetic tests they order to ensure all test result components are clinically actionable.

MEDICARE GUIDANCE ON GENETIC SCREENING TESTS

According to the Medicare Claims Processing Manual, Chapter 16[1]:

> "Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are **not covered** except when there is a statutory provision that explicitly covers tests for screening as described.

If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test. A/B MACs (A) and (B) have discretionary authority to make reasonable and necessary scope of benefit determinations."

REPRODUCTIVE PLANNING AND PRENATAL GENETIC TESTING

Tests performed in the absence of clinical signs/symptoms are considered "screening" tests. For Medicare members of child-bearing age, there are many routine tests, including screening tests, performed during a pregnancy which are covered tests; however, other tests are not eligible for Medicare coverage. These include, but are not limited to, tests performed to determine gender of fetus and carrier screening.

While reproductive planning and prenatal tests may provide useful information, test results are not used to diagnose or make direct treatment decisions for an illness or injury, as defined by Medicare. Some tests are not used in the management of a beneficiary's specific medical problem because they are performed in the absence of signs or symptoms. Since these tests do not meet Medicare's medical and reasonable threshold requirements under *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*, they are considered not medically necessary for Medicare.

Direct-to-Consumer (DTC) and over-the-counter (OTC) tests are also not medically necessary under the Medicare Program. In order to be considered medically reasonable and necessary, Medicare requires that all diagnostic tests be ordered by a treating provider to provide actionable data to be used promptly by that treating physician to treat or diagnose an illness or condition.[8] DTC and OTC testing do not meet this Medicare laboratory testing coverage requirement and therefore, are not medically reasonable or necessary under *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*. DTC and OTC tests are also frequently direct member benefit exclusions as well.

NATIONAL COVERAGE DETERMINATION (NCD) FOR NEXT GENERATION SEQUENCING (NGS)

Medicare does have a national coverage determination (NCD) applicable to some next-generation sequencing (NGS) somatic and germline testing (90.2). However, this NCD has limitations. Specifically, this NCD is only applicable to tests which meet **all** of the following:

- The test is a next-generation sequencing (NGS) test;
- The test performs ***DNA*** sequencing to detect genomic mutations;
- The test **has** FDA approval or clearance as a companion in vitro diagnostic (CDx) test;
- The test is used for **cancer**-related indications.

According to this NCD, coverage for NGS tests not otherwise addressed by the NCD is left to local Medicare Administrative Contractor (MAC) discretion. This includes, but is not necessarily limited to, tests using NGS for *RNA* sequencing and protein analysis, tests **without** FDA approval or clearance as a CDx test, and testing used for **non**-cancer related indications.

Based on Transmittal #12626 (Change Request 13596), the following CPT codes are considered appropriate for billing for the FDA-approved companion diagnostic tests that are addressed by NCD 90.2. (In the above link, go to **B. Policy**, click the URL for NCD spreadsheets, which will open a zip folder. In this zip folder, select the spreadsheet for this NCD.) ***Note: Some of the tests below may be addressed in a separate Medicare Advantage medical policy.***

NGS Test	Code(s)
FoundationOne CDx (F1CDx)	81455 (3/16/18 - 3/31/18) 0037U (4/1/18 to present)
FoundationOne®Liquid CDx	81479 (8/26/20 to 12/31/20) 0239U (1/1/21 to present)
Oncomine Dx Target Test	0022U (3/16/18 to present)
Guardant360® CDx	81479 (8/7/20-3/31/21) 0242U (4/1/21 to present)
MyChoice® CDx	0172U (7/1/20 to present)
Praxis™ Extended RAS Panel	0111U (10/1/19 to present)
Agilent Resolution ctDx FIRST	81479 (12/12/22-6/30/23) 0397U (7/1/23 to 9/30/23) Effective 9/30/2023, coverage under the NCD 90.2 ended
oncoReveal™ CDx *(Formerly, oncoReveal DX Lung and Colon Cancer Assay)*	81479 (7/30/21-3/31/2024) 0448U (4/1/2024 to 12/31/2024) 0523U (1/1/2025 to current)
xT CDx	81479 (4/28/23-6/30/2024) 0473U (7/1/24 to present)
TruSight Oncology Comprehensive	81455 (8/21/24 - 3/31/25) 0543U (4/1/25 to present)
MI Cancer Seek™	0211U

DIAGNOSTIC LABORATORY TEST JURISDICTION

The Company policy *PHA Medicare Medical Policy Development and Application* (MP# 50) describes the Plan's hierarchy with respect to Medicare medical policy development. In compliance with Medicare guidelines, some LCDs and LCAs used may be for test service areas **outside** of the Company service area. This is because Medicare's general rule regarding jurisdiction of claims furnished by an independent laboratory is that jurisdiction lies with the A/B MAC (B) (aka, Medicare Contractor) serving the **area in which the laboratory test is performed**.[10]

However, there may be exceptions to this rule. According to Medicare, while jurisdiction for laboratory services normally lies with the carrier serving the performing laboratory service area, there are situations where a regional or national lab chain jurisdiction (e.g., Quest Diagnostics, LabCorp, etc.) lies with a single carrier.[16] Therefore, tests performed by a national laboratory chain may have a single carrier established within the Company medical policies for all laboratory services they perform, regardless of the individual laboratory location. This allows for consistent outcomes for all members who receive the same test by the same lab chain.

Another exception to this rule involves "referring laboratory tests." This is when one laboratory sends the sample to another laboratory for processing. Under Medicare rules for referred tests, the location of the **billing** provider determines jurisdiction for claim payment and coverage criteria. Note, also under Medicare rules, only one laboratory is allowed to bill for the services rendered. If the performing laboratory and billing provider both submit a claim, then the performing laboratory's claim is the claim that would adjudicate according to member benefits.[18-20]

Medicare's Molecular Diagnostic (MolDX) Program Contractor

While many Medicare contractors (MACs) have adopted guidelines developed and published by the Molecular Diagnostic Services (MolDX) Program for their service areas, the program is **not** national in scope. MolDX-related reference materials only apply to genetic and molecular tests performed in the following states: OR, WA, AK, ID, UT, AZ, MT, ND, SD, WY, CA, NV, HI, NC, SC, AL, GA, TN, VA, WV, KY, OH, IA, KS, MO, NE, IN, and MI.[12]

The MolDX Program was developed by Palmetto GBA in 2011. The MolDX Contractor performs the following functions[12,14]:

- Establish clinical utility expectations.
- Complete technical assessments of published test data to determine clinical utility and coverage of individual tests.
- Develop unique test identifiers (Z-codes), adding to the DEX™ register of molecular diagnostic tests to allow for automated claims processing and to track utilization.
- Establish reimbursement.

Table 2: General MolDX Requirements by LCD

Genetic tests performed within a MolDX service area are required to undergo a technical assessment (TA) review by MolDX. The LCDs in Table 2 detail this requirement.

	LOCATION/MEDICARE CONTRACTOR				
	NORIDIAN J-F OR, WA, AK, ID, UT, AZ, MT, ND, SD, and WY	***NORIDIAN J-E*** CA and NV	***PALMETTO GBA J-J AND J-M*** NC, SC, AL, GA, TN, VA, and WV	***WPS J-5 AND J-8*** IA, KS, MO, NE, IN, and MI	***CGS J-15*** KY and OH
General MolDX Requirements	L35160		L35025	L36807	L36021

The outcome of these TA reviews is maintained in the DEX™ Diagnostics Exchange registry catalog and when possible, the coverage outcome is included within this medical policy to assist with coverage decision-making.

- Tests listed as "not covered" in this catalog have had clinical utility and analytical validity (CU/AV) reviewed and were determined to be **not medically reasonable or necessary** for Medicare under *Social Security Act, §1862(a)(1)(A)*.

- Tests which have **not yet** completed the required TA review are by default also considered to be **not medically reasonable or necessary** for Medicare under *§1862(a)(1)(A)*, based on the requirements found in the LCDs noted in Table 1 above.
- Tests listed as "covered" in this catalog have completed the required TA review and have been determined to be **medically reasonable or necessary** for Medicare under *§1862(a)(1)(A)*; however, this coverage is not automatic, as both of the following must be met:
    - Applicable NCD, LCD, and LCA criteria are met; and,
    - The member has signs/symptoms of a relevant disease or condition.

If a test is not specifically called out in this medical policy, additional research is required to determine coverage.

Note, test coverage or non-coverage positions included in this medical policy were accurate at the time of policy publication, but they are subject to change by the Medicare MolDX Program contractor at any time. Appeals to dispute non-coverage should include documentation by the MolDX Contractor which reflects a positive coverage decision (e.g., copy of the MolDX determination letter).

Non-MolDX Service Area Genetic Testing

Services areas which have **not** adopted MolDX guidelines include testing performed in the following states: FL, CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA, IL, MN, WI, CT, NY, ME, MA, NH, RI, and VT.

Table 3: Non-MolDX Service Area LCDs

The LCDs in Table 3 provide general coverage requirements for each jurisdiction area:

STATE(S)	MEDICARE CONTRACTOR	LCD	COVERAGE REQUIREMENTS
IL, MN, WI, CT, NY, ME, MA, NH, RI, and VT	***Wellpoint Federal J-6 and J-K***	L35000	This LCD requires clinical utility and analytical validity be established, but it doesn't address all tests by name specifically. For panels, this LCD also states, "testing would be covered ONLY for the number of genes or test that are reasonable and necessary to obtain necessary information for therapeutic decision making." In the absence of specific guidance in this LCD, the PHP Company policies for genetic tests provide a peer review of medical literature to evaluate clinical utility/analytical validity. When the biomarkers included in a test do not have proven clinical validity/utility, the test is not medically reasonable or necessary under *Social Security Act, §1862(a)(1)(A)* for Medicare members.
CO, NM, OK, TX, AR, LA, MI, DE, MD, NJ, and PA	***Novitas J-H and J-L***	L35062 / L35396	The LCD L35062 requires clinical utility and analytical validity be established, but it doesn't address all tests by name specifically. This LCD states Medicare coverage of biomarker testing is predicated upon three fundamental principles, which include:

			1. Must be an underlying performance of acceptable, high-quality analytical validity for all such laboratory testing. 2. Must be an appreciation of evidence-in-transition where new biomarkers should be brought on-line in harmonization with their proven clinical validity/utility (CVU). 3. Must be a recognized decision impact of such biomarkers by the clinical community. In other words, there must be acceptance/uptake of specific testing into patient management. Additionally, for multi-biomarker panel tests, the LCD L35396 requires evidence to support how "each requested biomarker can be individually contributory." In the absence of specific guidance in these LCDs, the PHP Company policies for genetic tests provide a peer review of medical literature to evaluate clinical utility/analytical validity. When the biomarkers included in a test do not have proven clinical validity/utility, the test is not medically reasonable or necessary under *Social Security Act, §1862(a)(1)(A)* for Medicare members.
FL	***First Coast Service Options J-N***	L34519	The LCD L34519 requires tests to undergo evaluation to establish clinical utility and analytical validity, based on published peer reviewed medical literature, or be FDA-approved, in order to be eligible for coverage. However, it doesn't address all tests by name specifically. For panels, this LCD also states, "testing would be covered ONLY for the number of genes or test that are reasonable and necessary to establish a diagnosis." In the absence of specific guidance in this LCD, the PHP Company policies for genetic tests provide a peer review of medical literature to evaluate clinical utility/analytical validity. When the biomarkers included in a test do not have proven clinical validity/utility, the test is not medically reasonable or necessary under *Social Security Act, §1862(a)(1)(A)* for Medicare members.

As noted in Table 3, all of the listed LCDs require tests undergo evaluation to establish clinical utility (CU) and analytical validity (AV) in order to be eligible for coverage. However, due to the large number of proprietary tests marketed and available, most genetic tests – particularly panel tests – are not specifically called out by name within an LCD or LCA, nor do LCDs or LCAs provide the outcome for the peer-reviewed CU/AV for most tests.

The Company policy *PHA Medicare Medical Policy Development and Application* (MP# 50) describes the Plan's hierarchy with respect to Medicare medical policy development. Medicare rules and regulations state that when no NCD, LCD, LCA, or other Medicare coverage guideline exists, Medicare allows Medicare Advantage Organizations (MAOs) to make coverage determinations based on an objective, evidenced-based process. Therefore, in the absence of a specific Medicare policy or reference for a test,

Company Commercial medical policy criteria may be applied to panel tests which do not have clinical utility or analytical validity documented within an LCD directly. Tests which are considered "investigational" in a Company Commercial policy will be denied as not medically reasonable or necessary under *Social Security Act, §1862(a)(1)(A)* for Medicare members.

GENETIC PANEL TESTING

According to the MolDX program, a test panel is defined as "A predetermined set of medical tests composed of individual laboratory tests, related by medical condition, specimen type, frequency ordered, methodology or types of components to aid in the diagnosis/treatment of disease."[12]

Genetic panel tests may be used for a number of indications and they may be either be proprietary, "off-the-shelf", tests with a set number of genes (subject to change without notice), or they may be customized, "a la cart", tests with genes selected by the ordering provider or genetic counselor based on a patient's symptoms.

In addition to targeted tumor panels, there are also comprehensive genomic profile (CGP) tests. Targeted next generation sequencing (NGS) tumor panels are "tests that identify somatic alterations known to occur in certain regions (i.e., 'hotspots') within specific genes of interest for cancer management (i.e., diagnosis, selection of molecularly targeted therapies, prognosis in a context where prognostic classification is essential for treatment selection)."[17]

CGP tests are "NGS-based molecular assays that provide additional insight beyond individual gene hotspots; these assays seek to describe the genomic makeup of a tumor and can help identify underlying mechanisms of disease to guide clinical decision making. These tests include not only mutations in individual relevant genes, but also patterns of mutations across related genes in established cancer pathways and often include an assessment of overall mutational burden."[17]

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

Some, but not all, panel tests may have a specific CPT or HCPCS code assigned (81410-81471, 815XX multianalyte assays with algorithmic analyses [MAAA] codes or newly developed proprietary laboratory analyses [PLA] codes). However, many panels may not have a specific code available. When no specific CPT or HCPCS code exists for the panel, the provider is required to bill using an unlisted code (e.g.,

81479 or 81599). It is not appropriate for the provider to bill any of the tests in a panel separately as if they were performed individually. This is a misrepresentation of services performed and is not appropriate based on either CPT or CMS guidelines. In a "Healthcare Fraud Prevention Partnership" white paper, the unbundling of claims for lab panels was identified as an area of concern for inappropriate billing.[13]

According to Noridian, under the instruction by the MolDX Contractor, to report targeted NGS gene panel services for somatic variant detection of 5 or more genes, providers are to first consider CPT® codes 81445 and 81450, with a unit of service (UOS) of one (UOS=1). Laboratories providing panel tests of 2 to 4 genes should use CPT® 81479 and one (1) UOS.[17]

Since CGP testing is not defined as a targeted panel by MolDX and it is not currently satisfactorily described by any existing CPT code, to report a CGP test, providers should use CPT® code 81479 at this time. Coverage of CGP is limited to one test per surgical specimen and precludes the use of any other molecular testing on that specimen.[17]

For NGS-based tests that do not fit under the Medicare definitions of "targeted" or "Comprehensive" panels, claims should be reported using the "Not Otherwise Classified" (NOC) code 81479. Tier 1 and/or Tier 2 individual biomarker CPT codes should not be used for a single gene or any combination of genes when testing is performed as part of a NGS or other multiplexing technology panel.[17]

Consistent with all HCPCS S-codes, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, published by Medicare[1] indicates HCPCS codes S3844 and S3870 have been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." HCPCS codes S3844 and S3870 are not covered unless allowed under a Medicare Advantage provider contract exception, as indicated in the relevant Company coding policy.

While not a complete list, please refer to the following local coverage articles (LCAs) for coding and billing assistance:

- Noridian J-E and J-F LCA: Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Testing in Cancer (A55624)

Note: Codes addressed by this policy, may include, but are not limited to, the following:

CODES*		
CPT	0003U	Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score *(Overa (Ova1 Next Generation), by Aspira Labs Inc.; Texas)*
	0004M	Scoliosis, DNA analysis of 53 single nucleotide polymorphisms (SNPs), using saliva, prognostic algorithm reported as a risk score *(ScoliScore™)*
	0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score *(ExoDx prostate, aka ExosomeDx®, EPI, or IntelliScore)*

	0006M	Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier *(HeproDX™)*
	0007M	Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index *(NETest)*
	0009U	Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin-fixed paraffin-embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified *(DEPArray™ HER2, by PacificDX; California)*
	0011M	Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk
	0012M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma *(Cxbladder™ Detect, Pacific Edge Diagnostics)*
	0013M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma *(Cxbladder™ Monitor, Pacific Edge Diagnostics)*
	0015M	Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy *(Adrenal Mass Panel, 24 Hour, Urine, Mayo Clinic Laboratories)*
	0016M	Oncology (bladder), mRNA, microarray gene expression profiling of 219 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like) *(Decipher Bladder, Veracyte Labs, SD)*
	0017M	Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin-embedded tissue, algorithm reported as cell of origin *(Lymph2Cx, Mayo Clinic, Arizona Molecular Diagnostics Laboratory)*
	0019U	Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents *(OncoTarget/OncoTreat, by Columbia University Department of Pathology and Cell Biology; New York)*
	0021U	Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score
	0022U	Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/ or absence of variants and associated therapy(ies) to consider *(Oncomine™ Dx Target Test, by Thermo Fisher Scientific; Massachusetts)*
	0023U	Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication for or against the use of midostaurin *(LeukoStrat® CDx FLT3 Mutation Assay, by LabPMM LLC; California)*

	0029U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie, CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and rs12777823) *(Focused Pharmacogenomics Panel, by Mayo Clinic; Minnesota)*
	0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2, VKORC1, rs12777823) *(Warfarin Response Genotype, by Mayo Clinic; Minnesota)*
	0031U	CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7) *(Cytochrome P450 1A2 Genotype, by Mayo Clinic; Minnesota)*
	0032U	COMT (catechol-O-methyltransferase)(drug metabolism) gene analysis, c.472G>A (rs4680) variant *(Catechol-Omethyltransferase (COMT) Genotype, by Mayo Clinic; Minnesota)*
	~~0033U~~	**TERMED 12/31/2025** ~~HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G]) *(Serotonin Receptor Genotype (HTR2A and HTR2C), by Mayo Clinic; Minnesota)*~~
	0034U	TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(eg, thiopurine metabolism) gene analysis, common variants (ie, TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5) *(Thiopurine Methyltransferase (TPMT) and Nudix Hydrolase (NUDT15) Genotyping, by Mayo Clinic; Minnesota)*
	0036U	Oncology (somatic mutations). Whole Exome 22,000 genes by Next Generation Sequencing. DNA extracted and analyzed from formalin fixed paraffin embedded tissue and Whole Blood. Algorithm result type is predictive and prognostic. Report of specific gene mutations, alterations as targets for therapeutic agents. *(EXaCT-1 Whole Exome Testing, by Weill Cornell Medicine- Clinical Genomics Laboratory; New York)*
	0037U	Broad next generation sequencing in vitro diagnostic device, solid malignant neoplasms, DNA analysis, 324 genes, detection of substitutions, insertion and deletion alterations (indels), copy number alterations (CNAs), and select gene rearrangements as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB), reported as presence/absence of variants and discrete levels of MSI and TMB, and associated therapy(ies) including multiple FDA-approved companion diagnostics, using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens *(FoundationOne CDx™ (F1CDx), by Foundation Medicine Inc.; Massachusetts)*
	0046U	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative *(FLT3 ITD MRD by NGS, by LabPMM LLC; California)*
	0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s) *(MSK-IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets), by Memorial Sloan Kettering Cancer Center; New York)*
	0049U	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative *(NPM1 MRD by NGS, by LabPMM LLC; California)*

	0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements *(MyAML NGS Panel, by LabPMM LLC; California)*
	0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma *(myTAIHEART, by TAI Diagnostics, Inc.; Wisconsin)*
	0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood *(Panorama® Twin Zygosity test, by Natera, Inc.; California)*
	0067U	Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [MMP-1], carcinoembryonic antigen-related cell adhesion molecule 6 [CEACAM6], hyaluronoglucosaminidase [HYAL1], highly expressed in cancer protein [HEC1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score *(BBDRisk Dx™, by Silbiotech, Inc.; Maryland)*
	0070U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, common and select rare variants (ie, *2, *3, *4, *4N, *5, *6, *7, *8, *9, *10, *11, *12, *13, *14A, *14B, *15, *17, *29, *35, *36, *41, *57, *61, *63, *68, *83, *xN) *(CYP2D6 Common Variants and Copy Number, by Mayo Clinic; Minnesota)*
	0071U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, full gene sequence (List separately in addition to code for primary procedure) *(CYP2D6 Full Gene Sequencing, by Mayo Clinic; Minnesota)*
	0072U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D6-2D7 hybrid gene) (List separately in addition to code for primary procedure) *(CYP2D6-2D7 Hybrid Gene Targeted Sequence Analysis, by Mayo Clinic; Minnesota)*
	0073U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D7-2D6 hybrid gene) (List separately in addition to code for primary procedure) *(CYP2D7-2D6 Hybrid Gene Targeted Sequence Analysis, by Mayo Clinic; Minnesota)*
	0074U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, non-duplicated gene when duplication/multiplication is trans) (List separately in addition to code for primary procedure) *(CYP2D6 trans-duplication/multiplication non-duplicated gene targeted sequence analysis, by Mayo Clinic; Minnesota)*
	0075U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 5' gene duplication/multiplication) (List separately in addition to code for primary procedure) *(CYP2D6 5' gene duplication/multiplication targeted sequence analysis, by Mayo Clinic; Minnesota)*
	0076U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 3' gene duplication/ multiplication) (List separately in addition to code for primary procedure) *(CYP2D6 3' gene duplication/multiplication targeted sequence analysis, by Mayo Clinic; Minnesota)*
	0080U	Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors

		(age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy *(BDX-XL2, by Biodesix, Inc.; Washington & Kansas)*
	0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score *(Molecular Microscope® MMDx—Heart, by Kashi Clinical Laboratories; Oregon)*
	0088U	Transplantation medicine (kidney allograft rejection) microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection *(Molecular Microscope® MMDx—Kidney, by Kashi Clinical Laboratories; Oregon)*
	0091U	Oncology (colorectal) screening, cell enumeration of circulating tumor cells, utilizing whole blood, algorithm, for the presence of adenoma or cancer, reported as a positive or negative result
	0092U	Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy *(REVEAL Lung Nodule Characterization, by MagArray, Inc.; California)*
	0094U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis *(RCIGM Rapid Whole Genome Sequencing, by Rady Children's Institute for Genomic Medicine (RCIGM); California)*
	0105U	Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including APOL1 genotype if available, and plasma (isolated fresh or frozen), algorithm reported as probability score for rapid kidney function decline (RKFD) *(KidneyIntelX™, by RenalytixAI; New York)*
	0108U	Gastroenterology (Barrett's esophagus), whole slide–digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalinfixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer *(TissueCypher® Barrett's Esophagus Assay, by Cernostics; Pennsylvania)*
	0111U	Oncology (colon cancer), targeted KRAS (codons 12, 13, and 61) and NRAS (codons 12, 13, and 61) gene analysis utilizing formalin-fixed paraffin-embedded tissue *(Praxis™ Extended RAS Panel, by Illumina; California)*
	0113U	Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as risk score
	0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA *(Viracor TRAC™; dd-cfDNA, by Transplant Genomics Inc.; Missouri)*
	0120U	Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter *(Lymph3Cx Lymphoma Molecular Subtyping Assay, by Mayo Clinic; Minnesota)*

	0124U	Fetal congenital abnormalities, biochemical assays of 3 analytes (free beta-hCG, PAPP-A, AFP), time-resolved fluorescence immunoassay, maternal dried-blood spot, algorithm reported as risk scores for fetal trisomies 13/18 and 21
	0153U	Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement *(Insight TNBCtype, by Insight Molecular Labs; Tennessee)*
	0154U	FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3) *(Therascreen FGFR3, by QIAGEN Sciences; Maryland)*
	0155U	PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y) *(Therascreen PIK3CA, by QIAGEN Sciences [when using tumor tissue]; Maryland)* For the Therascreen PIK3CA, by QIAGEN Sciences when using *blood plasma*, see the Medicare medical policy for *Circulating Tumor Cell and DNA Assays for Cancer Management (Medicare Only)*
	0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas *(BeScreened™-CRC, by Beacon Biomedical Inc.; Arizona)*
	0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine Smethyltransferase) (eg, drug metabolism) gene analysis, common variants *(NT [NUDT15 and TPMT] Genotyping Panel, by RPRD Diagnostics; Wisconsin)*
	0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence *(MyMRD® NGS Panel, by Laboratory for Personalized Molecular Medicine; California)*
	0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score *(myChoice® CDx, by Myriad Genetic Laboratories; Utah)*
	0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes *(Psych HealthPGx Panel, by RPRD Diagnostics; Wisconsin)*
	0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents *(LC-MS/MS Targeted Proteomic Assay, by OncoOmicDx Laboratory, LDT; Maryland)*
	0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes *(Genomind® Professional PGx Express™ CORE, by Genomind, Inc.; Pennsylvania)*

	0180U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-Nacetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons *(Navigator ABO Sequencing, by Grifols Immunohematology Center; California)*
	0181U	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1 *(Navigator CO Sequencing, by Grifols Immunohematology Center; California)*
	0182U	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10 *(Navigator CROM Sequencing, by Grifols Immunohematology Center; California)*
	0183U	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19 *(Navigator DI Sequencing, by Grifols Immunohematology Center; California)*
	0184U	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2 *(Navigator DO Sequencing, by Grifols Immunohematology Center; California)*
	0185U	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4 *(Navigator FUT1 Sequencing, by Grifols Immunohematology Center; California)*
	0186U	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2 *(Navigator FUT2 Sequencing, by Grifols Immunohematology Center; California)*
	0187U	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2 *(Navigator FY Sequencing, by Grifols Immunohematology Center; California)*
	0188U	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4 *(Navigator GE Sequencing, by Grifols Immunohematology Center; California)*
	0189U	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2 *(Navigator GYPA Sequencing, by Grifols Immunohematology Center; California)*
	0190U	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3 *(Navigator GYPB Sequencing, by Grifols Immunohematology Center; California)*
	0191U	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6 *(Navigator IN Sequencing, by Grifols Immunohematology Center; California)*
	0192U	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9 *(Navigator JK Sequencing, by Grifols Immunohematology Center; California)*
	0193U	Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2- 26 *(Navigator JR Sequencing, by Grifols Immunohematology Center; California)*
	0194U	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8 *(Navigator KEL Sequencing, by Grifols Immunohematology Center; California)*
	0195U	KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13) *(Navigator KLF1 Sequencing, by Grifols Immunohematology Center; California)*

	0196U	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3 *(Navigator LU Sequencing, by Grifols Immunohematology Center; California)*
	0197U	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1 *(Navigator LW Sequencing, by Grifols Immunohematology Center; California)*
	0198U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5 *(Navigator RHD/CE Sequencing, by Grifols Immunohematology Center; California)*
	0199U	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12 *(Navigator SC Sequencing, by Grifols Immunohematology Center; California)*
	0200U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (Xlinked Kx blood group) exons 1-3 *(Navigator XK Sequencing, by Grifols Immunohematology Center)*
	0201U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (Xlinked Kx blood group) exons 1-3 *(Navigator YT Sequencing, by Grifols Immunohematology Center; California)*
	0205U	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements *(Vita Risk, by Arctic Medical Laboratories; Michigan)*
	0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities *(CNGnome, by PerkinElmer Genomics; Pennsylvania)*
	0211U	Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association *(MI Cancer Seek™ NGS Analysis, by Caris Life Sciences; Arizona)*
	0212U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband *(Genomic Unity® Whole Genome Analysis, by Variantyx Inc.; Massachusetts)*
	0213U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent, sibling) *(Genomic Unity® Whole Genome Analysis – Comparator, by Variantyx Inc.; Massachusetts)*
	0214U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants,

		proband *(Genomic Unity® Exome Plus Analysis – Proband, by Variantyx Inc.; Massachusetts)*
	0215U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator exome (eg, parent, sibling) *(Genomic Unity® Exome Plus Analysis – Comparator, by Variantyx Inc.; Massachusetts)*
	0216U	Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants *(Genomic Unity® Ataxia Repeat Expansion and Sequence Analysis, by Variantyx Inc.; Massachusetts)*
	0217U	Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants *(Genomic Unity® Comprehensive Ataxia Repeat Expansion and Sequence Analysis, by Variantyx Inc.; Massachusetts)*
	0218U	Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants *(Genomic Unity® DMD Analysis, by Variantyx Inc.; Massachusetts)*
	0221U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene *(Navigator ABO Blood Group NGS, by Grifols Immunohematology Center; California)*
	0222U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3 *(Navigator Rh Blood Group NGS, by Grifols Immunohematology Center; California)*
	0228U	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer
	0229U	BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis *(Colvera, by Clinical Genomics Pathology Inc.; New Jersey)*
	0230U	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions *(Genomic Unity® AR Analysis, by Variantyx Inc.; Massachusetts)*
	0231U	CACNA1A (calcium voltage-gated channel subunit alpha 1A) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions *(Genomic Unity® CACNA1A Analysis, by Variantyx Inc.; Massachusetts)*
	0232U	CSTB (cystatin B) (eg, progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and

		intronic regions, deletions,duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions *(Genomic Unity® CSTB Analysis, by Variantyx Inc.; Massachusetts)*
	0233U	FXN (frataxin) (eg, Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions *(Genomic Unity® FXN Analysis, by Variantyx Inc.; Massachusetts)*
	0234U	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions *(Genomic Unity® MECP2 Analysis, by Variantyx Inc.; Massachusetts)*
	0236U	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions *(Genomic Unity® SMN1/2 Analysis, by Variantyx Inc.; Massachusetts)*
	0237U	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions *(Genomic Unity® Cardiac Ion Channelopathies Analysis, by Variantyx Inc.; Massachusetts)*
	0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia *(PlGF Preeclampsia Screen, by PerkinElmer Genomics; Pennsylvania)*
	0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffin-embedded tumor tissue *(Oncotype MAP™ PanCancer Tissue Test, by Paradigm Diagnostics, Inc.; Arizona)*
	0246U	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens *(Precision Blood™, San Diego Blood Bank; California)*
	0247U	Obstetrics (preterm birth), insulin-like growth factor–binding protein 4 (IGFBP4), sex hormone–binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal blood, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth *(PreTRM®, by Sera Prognostics; Utah)*
	0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report *(Theralink® Reverse Phase Protein Array (RPPA), by Theralink® Technologies, Inc.; Colorado)*
	0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden *(PGDx elio™ tissue complete, by Personal Genome Diagnostics, Inc.; Maryland)*

	0252U	Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy *(POC (Products of Conception), by Igenomix; Florida)*
	0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive) *(ERA® (Endometrial Receptivity Analysis), by Igenomix; Florida)*
	0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy, per embryo tested *(SMART PGT-A (Preimplantation Genetic Testing - Aneuploidy), by Igenomix; Florida)*
	0258U	Autoimmune (psoriasis), mRNA, next generation sequencing, gene expression profiling of 50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologic *(Mind.Px, by Mindera Corporation; California)*
	0260U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping *(Augusta Optical Genome Mapping, by Bionano Genomics Inc.; California)*
	0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping *(Praxis Optical Genome Mapping, by Praxis Genomics LLC; Georgia)*
	0265U	Rare constitutional and other heritable disorders, whole genome and mitochondrial DNA sequence analysis, blood, frozen and formalin-fixed paraffin embedded (FFPE) tissue, saliva, buccal swabs or cell lines, identification of single nucleotide and copy number variants *(Praxis Whole Genome Sequencing, by Praxis Genomics LLC; Georgia)*
	0266U	Unexplained constitutional or other heritable disorders or syndromes, tissue specific gene expression by whole transcriptome and next-generation sequencing, blood, formalin-fixed paraffin embedded (FFPE) tissue or fresh frozen tissue, reported as presence or absence of splicing or expression changes *(Praxis Transcriptome, by Praxis Genomics LLC; Georgia)*
	0267U	Rare constitutional and other heritable disorders, identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping and whole genome sequencing *(Praxis Combined Whole Genome Sequencing and Optical Genome Mapping, by Praxis Genomics LLC; Georgia)*
	0268U	Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid *(Versiti™ aHUS Genetic Evaluation, by Versiti™ Diagnostic Laboratories; Wisconsin)*
	0269U	Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 22 genes, blood, buccal swab, or amniotic fluid *(Versiti™ Autosomal Dominant Thrombocytopenia Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*

	0270U	Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes, blood, buccal swab, or amniotic fluid *(Versiti™ Coagulation Disorder Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*
	0271U	Hematology (congenital neutropenia), genomic sequence analysis of 24 genes , blood, buccal swab, or amniotic fluid *(Versiti™ Congenital Neutropenia Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*
	0272U	Hematology (genetic bleeding disorders), genomic sequence analysis of 60 genes and duplication/deletion of PLAU, blood, buccal swab, or amniotic fluid, comprehensive *(Versiti™ Comprehensive Bleeding Disorder Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*
	0273U	Hematology (genetic hyperfibrinolysis, delayed bleeding), genomic sequence analysis of 8 genes (F13A1, F13B, FGA, FGB, FGG, SERPINA1, SERPINE1, SERPINF2, PLAU), blood, buccal swab, or amniotic fluid *(Versiti™ Fibrinolytic Disorder Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*
	0274U	Hematology (genetic platelet disorders), genomic sequence analysis of 62 genes and duplication/deletion of PLAU, blood, buccal swab, or amniotic fluid *(Versiti™ Comprehensive Platelet Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*
	0276U	Hematology (inherited thrombocytopenia), genomic sequence analysis of 42 genes, blood, buccal swab, or amniotic fluid *(Versiti™ Inherited Thrombocytopenia Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*
	0277U	Hematology (genetic platelet function disorder), genomic sequence analysis of 40 genes and duplication/deletion of PLAU, blood, buccal swab, or amniotic fluid *(Versiti™ Platelet Function Disorder Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*
	0278U	Hematology (genetic thrombosis), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid *(Versiti™ Thrombosis Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*
	0288U	Oncology (lung), mRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD, TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic interpretation reported as a recurrence risk score
	0289U	Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score *(MindX Blood Test™ - Memory/Alzheimer's, by MindX Sciences™ Inc.; Indiana)*
	0290U	Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole blood, algorithm reported as predictive risk score *(MindX Blood Test™ - Pain, by MindX Sciences™ Inc.; Indiana)*
	0291U	Psychiatry (mood disorders), mRNA, gene expression profiling by RNA sequencing of 144 genes, whole blood, algorithm reported as predictive risk score *(MindX Blood Test™ - Mood, by MindX Sciences™ Inc.; Indiana)*
	0292U	Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72 genes, whole blood, algorithm reported as predictive risk score *(MindX Blood Test™ - Stress, by MindX Sciences™ Inc.; Indiana)*
	0293U	Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54 genes, whole blood, algorithm reported as predictive risk score *(MindX Blood Test™ - Suicidality, by MindX Sciences™ Inc.; Indiana)*
	0294U	Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes, whole blood, algorithm reported as predictive risk score *(MindX Blood Test™ - Longevity, by MindX Sciences™ Inc.; Indiana)*

	0295U	Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, SIAH2), with 4 clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a recurrence risk score *(DCISionRT® test, by Prelude Corp.; California)*
	0296U	Oncology (oral and/or oropharyngeal cancer), gene expression profiling by RNA sequencing of at least 20 molecular features (eg, human and/or microbial mRNA), saliva, algorithm reported as positive or negative for signature associated with malignancy *(mRNA CancerDetect™, by Viome Life Sciences, Inc.; Washington)*
	0297U	Oncology (pan tumor), whole genome sequencing of paired malignant and normal DNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and variant identification *(Praxis Somatic Whole Genome Sequencing, by Praxis Genomics, LLC.; Georgia)*
	0298U	Oncology (pan tumor), whole transcriptome sequencing of paired malignant and normal RNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and expression level and chimeric transcript identification *(Praxis Somatic Transcriptome, by Praxis Genomics, LLC.; Georgia)*
	0299U	Oncology (pan tumor), whole genome optical genome mapping of paired malignant and normal DNA specimens, fresh frozen tissue, blood, or bone marrow, comparative structural variant identification *(Praxis Somatic Optical Genome Mapping, by Praxis Genomics, LLC.; Georgia)*
	0300U	Oncology (pan tumor), whole genome sequencing and optical genome mapping of paired malignant and normal DNA specimens, fresh tissue, blood, or bone marrow, comparative sequence analyses and variant identification *(Praxis Somatic Combined Whole Genome Sequencing and Optical Genome Mapping, by Praxis Genomics, LLC.; Georgia)*
	0313U	Oncology (pancreas), DNA and mRNA next-generation sequencing analysis of 74 genes and analysis of CEA (CEACAM5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (ie, negative, low probability of neoplasia or positive, high probability of neoplasia)
	0315U	Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result (ie, Class 1, Class 2A, Class 2B) *(DecisionDX-SCC, by Castle Biosciences; Arizona)*
	0318U	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood
	0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection
	0320U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection
	0321U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique
	0323U	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi *(Used to report*

		the Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease Diagnostics test by Johns Hopkins Medical Microbiology Laboratory)
	0326U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden *(Used to report the Guardant360® LDT test by Guardant Health, Inc.)*
	0327U	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed *(Used to report the Vasistera™ test by Natera, Inc.)*
	0329U	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations *(Used to report the Oncomap™ ExTra test by Exact Sciences, Inc. and Genomic Health Inc.)*
	0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab *(Used to report the Bridge Women's Health Infectious Disease Detection test, by Bridge Diagnostics, ThermoFisher and Hologic Test Kit)*
	0331U	Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alterations *(Used to report the Augusta Hematology Optical Genome Mapping test, by Georgia Esoteric and Molecular Labs)*
	0332U	Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint–inhibitor therapy *(Used to report the EpiSwitch® CiRT [Checkpoint-inhibitor Response Test] by Next Bio-Research Services, LLC. and Oxford BioDynamics, PLC)*
	0334U	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden *(Used to report the Guardant360® Tissue test by Guardant Health, Inc.)*
	0335U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, fetal sample, identification and categorization of genetic variants *(Used to report the IriSight™ Prenatal Analysis – Proband test by Variantyx, Inc.)*
	0336U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg,

		parent) *(Used to report the IriSight™ Prenatal Analysis – Comparator test by Variantyx, Inc.)*
	0341U	Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid *(Used to report the Single Cell Prenatal Diagnosis (SCPD) Test by Luna Genetics, Inc.)*
	0345U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6 *(Used to report the GeneSight® Pyschotropic test by Assurex health and Myriad Genetics)*
	0347U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 16 gene report, with variant analysis and reported phenotypes *(Used to report the RightMed® PGx16 Test by OneOme® LLC.)*
	0348U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes *(Used to report the RightMed® Comprehensive Test Exclude F2 and F5 by OneOme® LLC.)*
	0349U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis, including reported phenotypes and impacted gene-drug interactions *(Used to report the RightMed® Comprehensive Test by OneOme® LLC.)*
	0350U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes *(Used to report the RightMed® Gene Report by OneOme® LLC.)*
	0355U	APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2) *(Used to report the Apolipoprotein L1 [APOL1] Renal Risk Variant Genotyping by Quest Diagnostics)*
	0360U	Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy *(Used to report the Nodify CDT® by Biodesix, Inc.)*
	0363U	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of 5 genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma *(Used to report the Cxbladder™ Triage by Pacific Edge Diagnostics)*
	0365U	Oncology (bladder), 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm, including patient's age, race and gender, reported as a probability of harboring urothelial bladder cancer *(Used to report the Oncuria® Detect test by DiaCarta Clinical Lab, DiaCarta, Inc.)*
	0366U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer *(Used to report the Oncuria® Monitor by DiaCarta Clinical Lab, DiaCarta, Inc.)*
	0367U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent

		or persistent cancer following transurethral resection *(Used to report the Oncuria® Predict by DiaCarta Clinical Lab, DiaCarta, Inc.)*
	0375U	Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score *(Used to report the OvaWatch℠ test by Aspira Women's Health℠ and Aspira Labs, Inc)*
	0379U	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by next-generation sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden *(Used to report the Solid Tumor Expanded Panel by Quest Diagnostics®)*
	0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score *(Used to report the PEPredictDx test by OncoOmicsDx Laboratory)*
	0391U	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splicesite variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score *(Used to report the Strata Select™ test, by Strata Oncology, Inc)*
	0392U	Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug *(Used to report the Medication Management Neuropsychiatric Panel by RCA Laboratory Services LLC d/b/a GENETWORx)*
	0398U	Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer *(Used to report the ESOPREDICT® Barrett's Esophagus Risk Classifier Assay, Capsulomics, Inc. d/b/a Previse)*
	0400U	Obstetrics (expanded carrier screening), 145 genes by next-generation sequencing, fragment analysis and multiplex ligation dependent probe amplification, DNA, reported as carrier positive or negative *(Used to report the Genesys Carrier Panel by Genesys Diagnostics, Inc.)*
	0407U	Nephrology (diabetic chronic kidney disease [CKD]), multiplex electrochemiluminescent immunoassay (ECLIA) of soluble tumor necrosis factor receptor 1 (sTNFR1), soluble tumor necrosis receptor 2 (sTNFR2), and kidney injury molecule 1 (KIM-1) combined with clinical data, plasma, algorithm reported as risk for progressive decline in kidney function *(Used to report the kidneyintelX dkd™, by Renalytix Inc. [May also be known as the Renalytix AI test])*
	0410U	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected *(Used to report the Avantect™ Pancreatic Cancer Test, by ClearNote™ Health)*
	0411U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6 *(Used to report the IDgenetix®, by Castle Biosciences, Inc. [May also be known as the Neuro IDgenetix test])*

	0413U	Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations *(Used to report the DH Optical Genome Mapping/Digital Karyotyping Assay, by the Clinical Genomics and Advanced Technology (CGAT) Laboratory at Dartmouth Health, and Bionano Genomics)*
	0417U	Rare diseases (constitutional/heritable disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis of 335 nuclear genes, including sequence changes, deletions, insertions, and copy number variants analysis, blood or saliva, identification and categorization of mitochondrial disorder–associated genetic variants *(Used to report the Genomic Unity® Comprehensive Mitochondrial Disorders Analysis, by Variantyx Inc.)*
	0419U	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype *(Used to report the Tempus nP test, by Tempus Labs, Inc.)*
	0420U	Oncology (urothelial), mRNA expression profiling by real-time quantitative PCR of MDK, HOXA13, CDC2, IGFBP5, and CXCR2 in combination with droplet digital PCR (ddPCR) analysis of 6 single-nucleotide polymorphisms (SNPs) genes TERT and FGFR3, urine, algorithm reported as a risk score for urothelial carcinoma *(Used to report the Cxbladder Detect+ test, by Pacific Edge Diagnostics USA LTD)*
	0421U	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, EGLN2) and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer risk *(Used to report the Colosense™ test by Geneoscopy, Inc.)*
	0423U	Psychiatry (eg, depression, anxiety), genomic analysis panel, including variant analysis of 26 genes, buccal swab, report including metabolizer status and risk of drug toxicity by condition *(Used to report the Genomind® Pharmacogenetics Report – Full test by Genomind®, Inc.)*
	0425U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis, each comparator genome (eg, parents, siblings) *(Used to report the RCIGM Rapid Whole Genome Sequencing, Comparator Genome test by Rady Children's Institute for Genomic Medicine)*
	0426U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), ultra-rapid sequence analysis *(Used to report the RCIGM Ultra-Rapid Whole Genome Sequencing test by Rady Children's Institute for Genomic Medicine)*
	0433U	Oncology (prostate), 5 DNA regulatory markers by quantitative PCR, whole blood, algorithm, including prostate-specific antigen, reported as likelihood of cancer
	0434U	Drug metabolism (adverse drug reactions and drug response), genomic analysis panel, variant analysis of 25 genes with reported phenotypes *(Used to report the RightMed® Gene Test Exclude F2 and F5 test by OneOme® LLC)*
	0436U	Oncology (lung), plasma analysis of 388 proteins, using aptamer-based proteomics technology, predictive algorithm reported as clinical benefit from immune checkpoint inhibitor therapy *(Used to report the PROphet® NSCLC Test by OncoHost, Inc.)*
	0437U	Psychiatry (anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers, whole blood, algorithm reported as predictive risk score *(Used to report the MindX One™ Blood Test – Anxiety test by MindX Sciences)*

	0438U	Drug metabolism (adverse drug reactions and drug response), buccal specimen, gene-drug interactions, variant analysis of 33 genes, including deletion/duplication analysis of CYP2D6, including reported phenotypes and impacted gene-drug interactions *(Used to report the EffectiveRX™ Comprehensive Panel Test by RCA Laboratory Services LLC d/b/a GENETWORx)*
	0444U	Oncology (solid organ neoplasia), targeted genomic sequence analysis panel of 361 genes, interrogation for gene fusions, translocations, or other rearrangements, using DNA from formalin-fixed paraffin-embedded (FFPE) tumor tissue, report of clinically significant variant(s) *(Used to report the Aventa FusionPlus™ Test by Aventa Genomics, LLC)*
	0449U	Carrier screening for severe inherited conditions (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia), regardless of race or self-identified ancestry, genomic sequence analysis panel, must include analysis of 5 genes (CFTR, SMN1, HBB, HBA1, HBA2) *(Used to report the UNITY Carrier Screen™ Test by BillionToOne, Inc.)*
	0454U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping *(Used to report the Chromosome Genome Mapping test by UR Medicine Labs & Bionano Genomics, Inc.)*
	0460U	Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes *(Used to report the RightMed® Oncology Gene Report by OneOme® LLC)*
	0461U	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes *(Used to report the RightMed® Oncology Medication Report by OneOme® LLC)*
	0465U	Oncology (urothelial carcinoma), DNA, quantitative methylationspecific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative *(Used to report the UriFind® Urothelial Carcinoma Assay by DiaCarta, Inc.)*
	0469U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis for chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH), inheritance pattern that indicate uniparental disomy (UPD), and aneuploidy, fetal sample (amniotic fluid, chorionic villus sample, or products of conception), identification and categorization of genetic variants, diagnostic report of fetal results based on phenotype with maternal sample and paternal sample, if performed, as comparators and/or maternal cell contamination *(Used to report the IriSight™ CNV Analysis test by Variantyx Inc.)*
	0471U	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalin-fixed paraffin-embedded (FFPE), predictive, identification of detected mutations *(Used to report the CRCdx® RAS Mutation Detection Kit by EntroGen, Inc.)*
	0473U	Oncology (solid tumor), next-generation sequencing (NGS) of DNA from formalin-fixed paraffin-embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden *(Used to report the xT CDx test by Tempus AI, Inc.)*

	0476U	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder [ADHD], schizophrenia), whole blood, buccal swab, and pharmacogenomic genotyping of 14 genes and CYP2D6 copy number variant analysis and reported phenotypes *(Used to report the RightMed® Mental Health Gene Report by OneOme, LLC.)*
	0477U	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder [ADHD], schizophrenia), whole blood, buccal swab, and pharmacogenomic genotyping of 14 genes and CYP2D6 copy number variant analysis, including impacted gene-drug interactions and reported phenotypes *(Used to report the RightMed® Mental Health Medication Report by OneOme, LLC.)*
	0478U	Oncology (non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes (EGFR, KRAS, BRAF, ALK, ROS1, RET, NTRK 1/2/3, ERBB2, and MET) in formalin-fixed paraffin-embedded (FFPE) tissue, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and reported as actionable detected variants for therapy selection *(Used to report the Lung HDPCR™ test, by Protean BioDiagnostics)*
	0480U	Infectious disease (bacteria, viruses, fungi, and parasites), cerebrospinal fluid (CSF), metagenomic next-generation sequencing (DNA and RNA), bioinformatic analysis, with positive pathogen identification *(Used to report the Bacteria, Viruses, Fungus, and Parasite Metagenomic Sequencing, Spinal Fluid (MSCSF) test, by Mayo Clinic)*
	0481U	IDH1 (isocitrate dehydrogenase 1 [NADP+]), IDH2 (isocitrate dehydrogenase 2 [NADP+]), and TERT (telomerase reverse transcriptase) promoter (eg, central nervous system [CNS] tumors), next-generation sequencing (single-nucleotide variants [SNV], deletions, and insertions) *(Used to report the IDH1, IDH2, and TERT Mutation Analysis, Next-Generation Sequencing, Tumor (IDTRT) test, by Mayo Clinic)*
	0482U	Obstetrics (preeclampsia), biochemical assay of soluble fmslike tyrosine kinase 1 (sFlt-1) and placental growth factor (PlGF), serum, ratio reported for sFlt1/PlGF, with risk of progression for preeclampsia with severe features within 2 weeks *(Used to report the Preeclampsia sFlt1/PlGF Ratio (PERA) test, by Mayo Clinic)*
	0488U	Obstetrics (fetal antigen noninvasive prenatal test), cellfree DNA sequence analysis for detection of fetal presence or absence of 1 or more of the Rh, C, c, D, E, Duffy (Fya), or Kell (K) antigen in alloimmunized pregnancies, reported as selected antigen(s) detected or not detected *(Used to report the UNITY Fetal Antigen™ NIPT test, by BillionToOne Laboratory)*
	0489U	Obstetrics (single-gene noninvasive prenatal test), cellfree DNA sequence analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants, and relative mutation-dosage analysis based on molecular counts to determine fetal inheritance of maternal mutation, algorithm reported as a fetal risk score for the condition (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia) *(Used to report the UNITY Fetal Risk Screen™ test, by BillionToOne Laboratory)*
	0493U	Transplantation medicine, quantification of donor-derived cell-free DNA (cfDNA) using next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA *(Used to report Prospera™, by Natera)*

	0494U	Red blood cell antigen (fetal RhD gene analysis), next-generation sequencing of circulating cell-free DNA (cfDNA) of blood in pregnant individuals known to be RhD negative, reported as positive or negative *(Used to report the Rh Test, by Natera)*
	0495U	Oncology (prostate), analysis of circulating plasma proteins (tPSA, fPSA, KLK2, PSP94, and GDF15), germline polygenic risk score (60 variants), clinical information (age, family history of prostate cancer, prior negative prostate biopsy), algorithm reported as risk of likelihood of detecting clinically significant prostate cancer
	0497U	Oncology (prostate), mRNA gene-expression profiling by real-time RT-PCR of 6 genes (FOXM1, MCM3, MTUS1, TTC21B, ALAS1, and PPP2CA), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer
	0498U	Oncology (colorectal), next-generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood, and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation *(Used to report the OptiSeq™ Colorectal Cancer NGS Panel test, by DiaCarta, Inc.)*
	0499U	Oncology (colorectal and lung), DNA from formalin-fixed paraffin-embedded (FFPE) tissue, next-generation sequencing of 8 genes (NRAS, EGFR, CTNNB1, PIK3CA, APC, BRAF, KRAS, and TP53), mutation detection *(Used to report the OptiSeq™ Dual Cancer Panel Kit test, by DiaCarta, Inc.)*
	0500U	Autoinflammatory disease (VEXAS syndrome), DNA, UBA1 gene mutations, targeted variant analysis (M41T, M41V, M41L, c.118-2A>C, c.118-1G>C, c.1189_118-2del, S56F, S621C) *(Used to report the QClamp® Plex VEXAS UBA1 Mutation test, by DiaCarta, Inc.)*
	0507U	Oncology (ovarian), DNA, whole-genome sequencing with 5hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as cancer detected or not detected *(Used to report the Avantect Ovarian Cancer test, by ClearNote® Health)*
	~~0508U~~	**TERMED 12/31/2025** ~~Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single-nucleotide polymorphisms (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cellfree DNA with risk for active rejection *(Used to report the VitaGraft™ Kidney Baseline + 1st Plasma test, by Oncocyte Corporation)*~~
	~~0509U~~	**TERMED 12/31/2025** ~~Transplantation medicine, quantification of donor-derived cell-free DNA using up to 12 single-nucleotide polymorphisms (SNPs) previously identified, plasma, reported as percentage of donor-derived cell-free DNA with risk for active rejection *(Used to report the VitaGraft™ Kidney Subsequent test, by Oncocyte Corporation)*~~
	0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA whole-transcriptome data, reported as probability of predicted molecular subtype *(Used to report the PurIST^{SM} test, by Tempus AI, Inc.)*
	0511U	Oncology (solid tumor), tumor cell culture in 3D microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug *(Used to report the PARIS test, by Tempus AI, Inc.)*
	0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased

		probability of MSI-high (MSI-H) *(Used to report the Tempus p-MSI test, by Tempus AI, Inc.)*
	0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) and homologous recombination deficiency (HRD) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of each biomarker *(Used to report the Tempus p-Prostate test, by Tempus AI, Inc.)*
	0516U	Drug metabolism, whole blood, pharmacogenomic genotyping of 40 genes and CYP2D6 copy number variant analysis, reported as metabolizer status *(Used to report the MyGenVar Pharmacogenomics test, by Geisinger Medical Laboratories)*
	0523U	Oncology (solid tumor), DNA, qualitative, next-generation sequencing (NGS) of single nucleotide variants (SNV) and insertion/deletions in 22 genes utilizing formalin-fixed paraffin-embedded tissue, reported as presence or absence of mutation(s), location of mutation(s), nucleotide change, and amino acid change *(Used to report the oncoReveal™ CDx test, by Pillar Biosciences, Inc.)*
	0524U	Obstetrics (preeclampsia), sFlt-1/PlGF ratio, immunoassay, utilizing serum or plasma, reported as a value *(Used to report the PreClara™ Ratio (sFlt-1/PlGF), by Thermo Fisher Scientific)*
	0529U	Hematology (venous thromboembolism [VTE]), genome-wide single-nucleotide polymorphism variants, including F2 and F5 gene analysis, and Leiden variant, by microarray analysis, saliva, report as risk score for VTE *(Used to report the Lifetime Genomics Risk Assessment, VTE by GenomicMD, Inc.)*
	0532U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome and mitochondrial DNA sequencing for single-nucleotide variants, insertions/deletions, copy number variations, peripheral blood, buffy coat, saliva, buccal or tissue sample, results reported as positive or negative *(Used to report the Rapid Genome Sequencing Test, by Univ. of California San Francisco Genomic Medicine Laboratory)*
	0533U	Drug metabolism (adverse drug reactions and drug response), genotyping of 16 genes (ie, ABCG2, CYP2B6, CYP2C9, CYP2C19, CYP2C, CYP2D6, CYP3A5, CYP4F2, DPYD, G6PD, GGCX, NUDT15, SLCO1B1, TPMT, UGT1A1, VKORC1), reported as metabolizer status and transporter function *(Used to report the UCSF Pharmacogenomics Panel, by Univ. of California San Francisco Genomic Medicine Laboratory)*
	0534U	Oncology (prostate), microRNA, single-nucleotide polymorphisms (SNPs) analysis by RT-PCR of 32 variants, using buccal swab algorithm reported as a risk score
	0536U	Red blood cell antigen (fetal RhD), PCR analysis of exon 4 of RHD gene and housekeeping control gene GAPDH from whole blood in pregnant individuals at 10+ weeks gestation known to be RhD negative, reported as fetal RhD status *(Used to report the Prenatal Detect RhD test, by Devyser Genomic Laboratories)*
	0537U	Oncology (colorectal cancer), analysis of cell-free DNA for epigenomic patterns, next-generation sequencing, >2500 differentially methylated regions (DMRs), plasma, algorithm reported as positive or negative *(Used to report Shield™, by Guardant Health Inc.)*
	0538U	Oncology (solid tumor), next-generation targeted sequencing analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis of 600 genes, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and copy number alterations, microsatellite instability, tumor

		mutation burden, reported as actionable variant *(Used to report the PredicineATLAS™ Assay test, by Predicine Inc.)*
	0540U	Transplantation medicine, quantification of donor-derived cell-free DNA using next-generation sequencing analysis of plasma, reported as percentage of donor-derived cell-free DNA to determine probability of rejection *(Used to report the AlloSure® test, by CareDx)*
	0543U	Oncology (solid tumor), next-generation sequencing of DNA from formalin-fixed paraffin-embedded (FFPE) tissue of 517 genes, interrogation for single-nucleotide variants, multi-nucleotide variants, insertions and deletions from DNA, fusions in 24 genes and splice variants in 1 gene from RNA, and tumor mutation burden *(Used to report the TruSight™ Oncology Comprehensive test, by Illumina, Inc.)*
	~~0544U~~	**TERMED 12/31/2025** ~~Nephrology (transplant monitoring), 48 variants by digital PCR, using cell-free DNA from plasma, donor-derived cell-free DNA, percentage reported as risk for rejection *(Used to report the VitaGraft™ Kidney 2.0, test, by Oncocyte Corporation)*~~
	0549U	Oncology (urothelial), DNA, quantitative methylated real-time PCR of TRNA-Cys, SIM2, and NKX1-1, using urine, diagnostic algorithm reported as a probability index for bladder cancer *(Used to report the Bladder CARE™ test, by Pangea Laboratory LLC)*
	0552U	Reproductive medicine (preimplantation genetic assessment), analysis for known genetic disorders from trophectoderm biopsy, linkage analysis of disease-causing locus, and when possible, targeted mutation analysis for known familial variant, reported as low-risk or high-risk for familial genetic disorder *(Used to report the PGT-M test, by Igenomix)*
	0553U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, and a mitochondrial DNA score, results reported as normal/balanced (euploidy/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, or mosaic, per embryo tested *(Used to report the Smart PGT-A test, by Igenomix)*
	0554U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from trophectoderm biopsy for aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal (euploidy), monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or inconsistent cohort when applicable, per embryo tested *(Used to report the Smart PGT-SR test, by Igenomix)*
	0572U	Oncology (prostate), high-throughput telomere length quantification by FISH, whole blood, diagnostic algorithm reported as risk of prostate cancer
	0591U	Oncology (prostate cancer), biochemical analysis of 3 proteins (total PSA, free PSA, and HE4), serum, prognostic algorithm incorporating 3 proteins and digital rectal examination, results reported as a probability score for clinically significant prostate cancer
	0597U	Oncology (breast), RNA expression profiling of 329 genes by targeted next-generation sequencing and 20 proteins by multiplex immunofluorescence, formalin-fixed paraffin-embedded (FFPE) tissue, algorithmic analyses to determine tumor-recurrence risk score

	0609U	Oncology (prostate), immunoassay for total prostate-specific antigen (PSA) and free PSA, serum or plasma, combined with clinical features, algorithm reported as a probability score for clinically significant prostate cancer
	0630U	Oncology (breast), mRNA, gene expression profiling by microarray of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffin-embedded tissue (FFPE), algorithm reported as an index that is diagnostic of a molecular subtype (luminal, basal, Her2) *(Used to report the BluePrint® test, by Agendia)*
	0666U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal/balanced (euploidy/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or inconsistent cohort when applicable, per embryo tested *(Used to report the Smart PGT-SR Plus test, by Igenomix)*
	0565U	Oncology (hepatocellular carcinoma), next-generation sequencing methylation pattern assay to detect 6626 epigenetic alterations, cell-free DNA, plasma, algorithm reported as cancer signal detected or not detected *(Used to report the EarlyDx MethylScan™ HCC test, by EarlyDiagnostics Laboratory)*
	0567U	Rare diseases (constitutional/heritable disorders), whole-genome sequence analysis combination of short and long reads, for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy-number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variants *(Used to report the Genomic Unity® 2.0, by Variantyx, Inc.)*
	0575U	Transplantation medicine (liver allograft rejection), miRNA gene expression profiling by RT-PCR of 4 genes (miR-122, miR-885, miR-23a, spike-in control), serum, plasma, or blood, algorithm reported as risk of liver allograft rejection *(Used to report the HepatoTrack™ test, by LuminoDx Laboratory)*
	0576U	Transplantation medicine (liver allograft rejection), quantitative donor-derived cell-free DNA (cfDNA) by whole genome next-generation sequencing, plasma and mRNA gene expression profiling by multiplex real-time PCR of 56 genes, whole blood, combined algorithm reported as a rejection risk score *(Used to report the OmniGraf® Liver test, by Eurofins Transplant Genomics)*
	0577U	Oncology (ovarian), serum, analysis of 39 glycoproteins by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in multiple reaction monitoring mode, reported as likelihood of malignancy *(Used to report the GycoKnow™ Ovarian test, by InterVenn Biosciences)*
	0582U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome DNA sequencing for single-nucleotide variants, insertions/deletions, copy number variations, blood, saliva, tissue sample, variants reported *(Used to report the Rapid Whole Genome Sequencing test, by Mayo Clinic)*
	0583U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome comparator DNA sequencing for single-nucleotide variants, insertions/deletions, copy number variations, blood, saliva, tissue sample, variants reported with proband results *(Used to report the Rapid Genome Sequencing Family Member Comparator test, which is an add-on test to 0583U, also by Mayo Clinic)*

	0586U	Oncology, mRNA, gene expression profiling of 216 genes (204 targeted and 12 housekeeping genes), RNA expression analysis, formalin-fixed paraffin-embedded (FFPE) tissue, quantitative, reported as log2 ratio per gene *(Used to report the RNA Salah Targeted Expression Panel test, by Moffitt Cancer Center Advanced Diagnostics Laboratory)*
	0588U	Infectious disease (bacterial or viral), 32 genes (29 informative and 3 housekeeping), immune response mRNA, gene expression profiling by splitwell multiplex reverse transcription loop-mediated isothermal amplification (RTLAMP), whole blood, reported as continuous risk scores for likelihood of bacterial and viral infection and likelihood of severe illness within the next 7 days *(Used to report the TriVerity™ test, by Inflammatix™, Inc.)*
	0592U	Oncology (hematolymphoid neoplasms), DNA, targeted genomic sequence of 417 genes, interrogation for gene fusions, translocations, rearrangements, utilizing formalin-fixed paraffin-embedded (FFPE) tumor tissue, results report clinically significant variant(s) *(Used to report the Aventa Lymphoma test, by Aventa Genomics, LLC)*
	0593U	Infectious disease (genitourinary pathogens), DNA, 46 targets (28 pathogens, 18 resistance genes), RT-PCR amplified probe technique, urine, each analyte reported as detected or not detected *(Used to report the Taq Array Card Urinary Tract Infection PCR Panel test, by SoftCell Laboratories LLC)*
	0605U	Allergy and immunology (hereditary alpha tryptasemia), DNA, analysis of TPSAB1 gene copy number variation using digital PCR, whole blood, results reported with genotype-specific interpretation of alpha-tryptase copy number and algorithmic classification as normal or abnormal *(Used to report the Tryptase Gene Copy Number Analysis by dPCR test, by Virant Diagnostics Inc.)*
	0613U	Oncology (urothelial carcinoma), DNA methylation and mutation analysis of 6 biomarkers (TWIST1, OTX1, ONECUT2, FGFR3, HRAS, TERT promoter region), methylation-specific PCR and targeted next-generation sequencing, urine, algorithm reported as a probability index for bladder cancer and upper tract urothelial carcinoma *(Used to report the AssureMDx™ test, by Vesica Health® Inc.)*
	0616U	Neurology (dementia), DNA methylation analysis of more than 30,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS Alzheimer's & MCI test, by TruDiagnostic™, Inc.)*
	0617U	Cardiovascular (atherosclerotic cardiovascular disease [ASCVD]), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS ASCVD test, by TruDiagnostic™, Inc.)*
	0618U	Psychiatry (bipolar disorder), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS Bipolar test, by TruDiagnostic™, Inc.)*
	0619U	Pulmonary (chronic obstructive pulmonary disease [COPD]), DNA methylation analysis of more than 18,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS COPD test, by TruDiagnostic™, Inc.)*
	0620U	Oncology (hepatocellular carcinoma), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS Hepatocellular Carcinoma test, by TruDiagnostic™, Inc.)*
	0621U	Infectious disease (Lyme borreliosis), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS Lyme Disease test, by TruDiagnostic™, Inc.)*

	0622U	Psychiatry (major depressive disorder), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS Major Depressive Disorder test, by TruDiagnostic™, Inc.)*
	0623U	Autoimmune (multiple sclerosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS Multiple Sclerosis test, by TruDiagnostic™, Inc.)*
	0624U	Hepatology (nonalcoholic steatohepatitis [NASH]), DNA methylation analysis of 5,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS NASH test, by TruDiagnostic™, Inc.)*
	0625U	Endocrinology (osteoporosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS Osteoporosis test, by TruDiagnostic™, Inc.)*
	0626U	Neurology (Parkinson disease), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS Parkinson's test, by TruDiagnostic™, Inc.)*
	0627U	Psychiatry (schizophrenia), DNA methylation analysis of more than 15,000 sites, whole blood, algorithm reported as positive or negative risk *(Used to report the TruD MDS Schizophrenia test, by TruDiagnostic™, Inc.)*
	0628U	Nephrology (kidney disease-related genetic conditions), genomic analysis, renal disease panel, saliva, DNA, next-generation sequencing of 449 genes, reported as pathogenic or likely pathogenic variants of uncertain significance or risk alleles *(Used to report the RenaDx™: Comprehensive Renal Disease Panel test, by Personalized Medicine Care Diagnostics)*
	0632U	Red blood cell antigen (fetal RhD gene analysis), multiplex polymerase chain reaction (PCR) and next-generation circulating cell-free DNA (cfDNA), plasma from pregnant individuals known to be RhD negative, reported as detected or not detected sequencing (NGS) of circulating cell-free DNA (cfDNA), plasma from pregnant individuals known to be RhD negative, reported as detected or not detected *(Used to report the UNITY Fetal RhD NIPT™ test, by BillionToOne Laboratory)*
	0633U	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA (cfDNA), nextgeneration sequencing (NGS) analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants and to determine fetal inheritance of maternal mutation, using maternal blood sample, algorithm reported as a fetal risk score *(Fetal Focus test, by Natera)*
	0635U	Autoimmune (atopic dermatitis), mRNA, next-generation sequencing (NGS), gene expression profiling of 487 genes, noninvasive skinsurface scraping, algorithm reported as likelihood of response to therapy *(AdvanceAD-Tx™ test, by Castle Biosciences, Inc.)*
	0640U	Oncology (leptomeningeal metastases), tumor cell selection, identification, detection and enumeration based on differential CD318(CDCP1), SUSD2, CD340(erbB2/HER2), HGFR/cMET, FOLR1, EGFR, N cadherin, MUC1, EpCAM, and TROP2 antibody biomarkers, cerebrospinal fluid, reported as detection and quantification of tumor cells *(CNSide CSF Tumor Cell Enumeration (TCE) test, by CNSide® Diagnostics LLC)*
	0648U	Oncology (solid tumor), targeted genomic sequencing analysis, to detect deletions, insertions, and substitutions in 42 genes, copy number amplifications in 10 genes, and fusions and splice variants in 18 driver genes from DNA and RNA extracted

		from formalin fixed paraffin-embedded (FFPE) tissue *(Oncomine Dx Express Test, by Thermo Fisher Scientific, Inc .)*
	0650U	Drug metabolism (adverse drug reactions and drug response), genotyping of 9 genes (ie, CYP2D6, CYP2C19, G6PD, SLCO1B1, HLA-B*58:01, NAT2, CYP2C9, VKORC1, ABCG2), reported as metabolizer status and transporter function *(CKM PGx™ Panel (Hypertension and Cardiovascular-kidney-metabolic pharmacogenetic panel) test, by Personalized Medicine Care Diagnostics)*
	0652U	Drug metabolism (adverse drug reactions), DNA analysis of 13 genes by targeted genotyping, using saliva or buccal swab, reported as diplotype and metabolizer status *(RenaPGx™ (Renal Pharmacogenetic Test), by Personalized Medicine Care Diagnostics)*
	0653U	Nephrology (inherited kidney disorders), DNA, analysis of approximately 700 genes associated with inherited kidney diseases by exome sequencing, using whole blood, saliva, or nail clipping, reported as an interpretive clinical report classifying pathogenic and likely pathogenic variants *(RenaXome™ (Renal Disease Whole Exome Sequencing) test, by Personalized Medicine Care Diagnostics)*
	0654U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by western blot analysis, using cultured skin fibroblasts, diagnostic qualitative result *(Complex I Assembly Western Blot Assay, by Children's Hospital Colorado Laboratory)*
	0655U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by spectrophotometric kinetic assay, using cultured skin fibroblasts, diagnostic quantitative result *(Complex V Hydrolysis Enzyme Assay, by Children's Hospital Colorado Laboratory)*
	0656U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by radioactive activity assay, using cultured skin fibroblasts, diagnostic quantitative result *(Pyruvate Dehydrogenase (PDH) Enzyme Assay, by Children's Hospital Colorado Laboratory)*
	0657U	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of comparator nuclear and mitochondrial DNA by next-generation sequencing (NGS), using blood or buccal sample, relevant variants reported with proband results *(GenomeDx Rapid, Comparator test, by GeneDx)*
	0658U	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for single-nucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants *(GenomeDx Rapid, Proband test, by GeneDx)*
	0659U	Rare diseases (constitutional/heritable disorders), ultrarapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for single nucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants *(GenomeDx ultraRapid, Proband test, by GeneDx)*
	0662U	Transplantation medicine (kidney allograft rejection), mRNA, gene-expression profiling by real-time quantitative PCR of 12 genes (11 content and 1 housekeeping), urine, algorithm reported as a rejection risk score *(Exosome Kidney Transplant Report (EkTRA), by One Lambda™ Laboratories, part of Thermo Fisher Scientific)*

	0664U	Transplantation medicine (kidney allograft failure), RNA expression transcriptome by next-generation sequencing (NGS), profiling of 13 genes, post-transplant peripheral blood, algorithm reported as a risk score for predicting progressive fibrosis in the kidney allograft *(Protega™, by Verici Dx)*
	0690U	Transplantation medicine (allograft rejection), quantification of donor-derived cell-free DNA (cfDNA) using digital PCR analysis of 45 single-nucleotide polymorphisms, plasma, reported as quantity of donorderived cfDNA in plasma to determine the probability of allograft rejection *(GraftAssure™, by Insight Molecular Diagnostics Inc. – used for the laboratory developed or LDT test. This code is NOT used for GraftAssureIQ or GraftAssureDx)*
	0696U	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, RNA analysis, 350 or more genes for RNA alterations (eg, gene rearrangements and splice isoforms) *(Guardant360® Tissue RNA, by Guardant Health, Inc.)*
	0697U	Obesity, DNA genotyping, analysis of up to 41 genes, buccal swab or blood specimen, patient biometrics, risk-score algorithm to identify a predisposition to up to 4 phenotypes, reported as likelihood to benefit from therapeutics *(MyPhenomeRx™, by Phenomix Sciences Clinical Laboratory)*
	81105	Human Platelet Antigen 1 genotyping (HPA-1), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-1a/b (L33P)
	81106	Human Platelet Antigen 2 genotyping (HPA-2), GP1BA (glycoprotein Ib [platelet], alpha polypeptide [GPIba]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-2a/b (T145M)
	81107	Human Platelet Antigen 3 genotyping (HPA-3), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex], antigen CD41 [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-3a/b (I843S)
	81108	Human Platelet Antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-4a/b (R143Q)
	81109	Human Platelet Antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant (eg, HPA-5a/b (K505E))
	81110	Human Platelet Antigen 6 genotyping (HPA-6w), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa, antigen CD61] [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-6a/b (R489Q)
	81111	Human Platelet Antigen 9 genotyping (HPA-9w), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex, antigen CD41] [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-9a/b (V837M)
	81112	Human Platelet Antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-15a/b (S682Y)

	81120	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)
	81121	IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)
	81161	DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed
	81168	CCND1/IGH (t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed
	81170	ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain
	81171	AFF2 (AF4 transcription elongation factor 2 [FMR2]) (eg, fragile X intellectual disability 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
	81172	AFF2 (AF4 transcription elongation factor 2 [FMR2]) (eg, fragile X intellectual disability 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)
	81173	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence
	81174	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant
	81175	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence
	81176	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; targeted sequence analysis (eg, exon 12)
	81177	ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81178	ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81179	ATXN2 (ataxin 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81180	ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81181	ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81183	ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
	81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence
	81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant
	81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

	81188	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
	81189	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; full gene sequence
	81190	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; known familial variant(s)
	81191	NTRK1 (neurotrophic receptor tyrosine kinase 1) (eg, solid tumors) translocation analysis
	81192	NTRK2 (neurotrophic receptor tyrosine kinase 2) (eg, solid tumors) translocation analysis
	81193	NTRK3 (neurotrophic receptor tyrosine kinase 3) (eg, solid tumors) translocation analysis
	81194	NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (eg, solid tumors) translocation analysis
	81195	Cytogenomic (genome-wide) analysis, hematologic malignancy, structural variants and copy number variants, optical genome mapping (OGM)
	81200	ASPA (aspartoacylase) (eg, Canavan disease) gene analysis, common variants (eg, E285A, Y231X)
	81204	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)
	81205	BCKDHB (branched-chain keto acid dehyrogenase E1, beta polypeptide) (e.g., Maple syrup urine disease) gene analysis, common variants (e.g., R183P, G278s, E422X)
	81206	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative
	81207	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative
	81208	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative
	81209	BLM (Bloom syndrome, RecQ helicase-like) (e.g., Bloom syndrome) gene analysis 2281 del6ins7 variant
	81210	BRAF(v-raf murine sarcoma viral oncogene homolog B1) (e.g. Colon Cancer) gene analysis, V600E variant
	81218	CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence
	81219	CALR (calreticulin)(eg myeloproliferative disorders, gene analysis, common variants in exon 9)
	81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)
	81221	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; known familial variants
	81222	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants
	81223	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; full gene sequence
	81224	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; intron 8 poly-T analysis (eg, male infertility)

	81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)
	81226	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)
	81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
	81228	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number variants, comparative genomic hybridization [CGH] microarray analysis
	81229	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and single nucleotide polymorphism variants, comparative genomic hybridization [CGH] microarray analysis
	81230	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis, common variant(s) (eg, *2, *22)
	81231	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *7)
	81232	DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism), gene analysis, common variant(s) (eg, *2A, *4, *5, *6)
	81233	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)
	81234	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles
	81235	EGFR (Epidermal growth factor receptor)(EG, non-small cell lung cancer) gene analysis, common variants (EG, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)
	81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence
	81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)
	81238	F9 (coagulation factor IX) (eg, hemophilia B), full gene sequence
	81239	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)
	81240	F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant
	81241	F5 (coagulation factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant
	81242	FANCC (Fanconi anemia, complementation group C) (e.g., Fanconi Anemia, type C) gene analysis, common variant (e.g., IVS4=4A>T)
	81243	FMR1 (Fragile X messenger ribonucleoprotein 1) (e.g., fragile X syndrome, X-linked intellectual disability [XLID]) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles
	81244	FMR1 (Fragile X messenger ribonucleoprotein 1) (e.g., fragile X syndrome, X-linked intellectual disability [XLID]) gene analysis; characterization of alleles (e.g., expanded size and methylation status)

	81245	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15)
	81246	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (eg, D835, I836)
	81247	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-)
	81248	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s)
	81249	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; full gene sequence
	81250	G6PC (glucose-6-phosphatase, catalytic subunit) (e.g., Glycogen storage disease, type 1a, von Gierke disease) gene analysis, common variants (e.g., R83C, Q347X)
	81251	GBA (glucosidase, bets, acid) (e.g., Gaucher disease) gene analysis, common variants (e.g., N370S, 84GG, L444P, IVS2=1G>A)
	81252	GJB2 (gap junction protein, beta 2, 26kDa, connexin 26) (eg, nonsyndromic hearing loss) gene analysis; full gene sequence
	81253	GJB2 (gap junction protein, beta 2, 26kDa, connexin 26) (eg, nonsyndromic hearing loss) gene analysis; known familial variants
	81254	GJB6 (gap junction protein, beta 6, 30kDa, connexin 30) (eg, nonsyndromic hearing loss) gene analysis, common variants (eg, 309kb [del(GJB6-D13S1830)] and 232kb [del(GJB6-D13S1854)])
	81255	HEXA (hexosaminidase A [alpha polypeptide]) (e.g. Tay-Sachs disease) gene analysis common variants (e.g., 1278insTATC, 1421+1G>C, G269S)
	81256	HFE (hemochromatosis) (e.g. hereditary hemochromatosis) gene analysis, common variants (e.g. C282Y, H63D)
	81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2)(e.g. alpha thalsemmia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (e.g., Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha20.5, and Constant Spring)
	81258	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant
	81259	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence
	81260	IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex- associated protein)(e.g. familial dysautonomia) gene analysis, common variants
	81261	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology (eg, polymerase chain reaction)
	81262	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); direct probe methodology (eg, Southern blot)
	81263	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemia and lymphoma, B-cell), variable region somatic mutation analysis
	81264	IGK@ (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma, B-cell), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
	81265	Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing,

		post-transplant non-hematopoietic recipient germline [eg, buccal swab or other germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)
	81266	Comparative analysis using Short Tandem Repeat (STR) markers; each additional specimen (eg, additional cord blood donor, additional fetal samples from different cultures, or additional zygosity in multiple birth pregnancies) (List separately in addition to code for primary procedure)
	81267	Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; without cell selection
	81268	Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; with cell selection (eg, CD3, CD33), each cell type
	81269	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants
	81270	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant
	81271	HTT (huntingtin) (eg, Huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
	81272	KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (eg, exons 8, 11, 13, 17, 18)
	81273	KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, mastocytosis), gene analysis, D816 variant(s)
	81274	HTT (huntingtin) (eg, Huntington disease) gene analysis; characterization of alleles (eg, expanded size)
	81275	KRAS ((V-KI-RAS2 Kirsten Rat Sarcoma Viral Oncogene)(EG carcinoma) gene analysis, variants in codons 12 and 13
	81276	KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)
	81277	Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-ofheterozygosity variants for chromosomal abnormalities
	81278	IGH@/BCL2 (t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative
	81279	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)
	81283	IFNL3 (interferon, lambda 3) (eg, drug response), gene analysis, rs12979860 variant
	81284	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles
	81285	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)
	81286	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence
	81287	MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme) promoter methylation analysis
	81289	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; known familial variant(s)

	81290	MCOLN1 (mucolipin 1) (e.g., Mucolipidosis, Type IV) gene analysis, common variants (e.g. IVS3-2A>G, del6.4b)
	81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (e.g., hereditary hypercoagulability) gene analysis, common variants (e.g., 677T, 1298C)
	81301	Microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (e.g., BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed
	81302	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; full sequence analysis
	81303	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; known familial variant
	81304	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; duplication/deletion variants 6 or exon 6), qualitative or quantitative
	81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant
	81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)
	81309	PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20)
	81310	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants
	81311	NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61)
	81312	PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81314	PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18)
	81315	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative
	81316	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative
	81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)
	81324	PMP22 (peripheral myelin protein 22)(e.g., Charcot-Marie-Tooth hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis
	81325	PMP22 (peripheral myelin protein 22)(e.g., Charcot-Marie-Tooth hereditary neuropathy with liability to pressure palsies) gene analysis; full sequence
	81326	PMP22 (peripheral myelin protein 22) (e.g., Charcot-Marie-Tooth hereditary neuropathy with liability to pressure palsies) gene analysis; know familial variant
	81327	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis
	81328	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (eg, adverse drug reaction), gene analysis, common variant(s) (eg, *5)

	81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed
	81330	SMPD1 (sphingomyelin phosphodiesterase 1, acid lysomal) (e.g., Niemann-Pick disease Type A) gene analysis, common variants (e.g., R496L, L302P, fsP330)
	81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and Ubiquitin protein ligase E3A) (e.g., Prader-Willi syndrome and/or Angelman syndrome methylation analysis
	81332	SERPINA 1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase variants (e.g., *S and *Z)
	81333	TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)
	81334	RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis (eg, exons 3-8)
	81335	TPMT (thiopurine S-methyltransferase) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3)
	81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence
	81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)
	81338	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)
	81339	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10
	81340	TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (eg, polymerase chain reaction)
	81341	TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using direct probe methodology (eg, Southern blot)
	81342	TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
	81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81344	TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analabnormal (eg, expanded) alleles
	81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)
	81346	TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism), gene analysis, common variant(s) (eg, tandem repeat variant)
	81347	SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)
	81348	SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L)
	81349	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-pass sequencing analysis

	81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, *28, *36, *37)
	81354	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of structural and copy number variants, optical genome mapping (OGM)
	81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variant(s) (eg, -1639G>A, c.173+1000C>T)
	81357	U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)
	81360	ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs)
	81361	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (eg, HbS, HbC, HbE)
	81362	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s)
	81363	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)
	81364	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); full gene sequence
	81370	HLA Class I and II typing, low resolution (eg, antigen equivalents); HLA-A, -B, -C, -DRB1/3/4/5, and -DQB1
	81371	HLA Class I and II typing, low resolution (eg, antigen equivalents); HLA-A, -B, and -DRB1 (eg, verification typing)
	81372	HLA Class I typing, low resolution (eg, antigen equivalents); complete (ie, HLA-A, -B, and -C)
	81373	HLA Class I typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-A, -B, or -C), each
	81374	HLA Class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, B*27), each
	81375	HLA Class II typing, low resolution (eg, antigen equivalents); HLADRB1/3/4/5 and -DQB1
	81376	HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
	81377	HLA Class II typing, low resolution (eg, antigen equivalents); one antigen equivalent, each
	81378	HLA Class I and II typing, high resolution (ie, alleles or allele groups), HLA-A, -B, -C, and -DRB1
	81379	HLA Class I typing, high resolution (ie, alleles or allele groups); complete (ie, HLA-A, -B, and -C)
	81380	HLA Class I typing, high resolution (ie, alleles or allele groups); one locus (eg, HLA-A, -B, or -C), each
	81381	HLA Class I typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, B*57:01P), each
	81382	HLA Class II typing, high resolution (ie, alleles or allele groups); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each

	81383	HLA Class II typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, HLA-DQB1*06:02P), each
	81400	Molecular pathology procedure, Level 1 (e.g., identification of single germline variant [e.g., SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
	81401	Molecular pathology procedure, Level 2 (e.g., 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
	81402	Molecular pathology procedure, level 3 (e.g.,>10 SNPs, 2-10 methylated variants, or 2-10 somatic variants [typically using non-sequencing target variant analysis], immunoglobulin and T-cell receptor gene rearrangements, duplication/deletion variants 1 exon)
	81403	Molecular pathology procedure, level 4 (e.g. analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons
	81404	Molecular pathology procedure, level 5 (e.g., analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder /triplet repeat by southern blot analysis
	81405	Molecular pathology procedure, level 6 (e.g., analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons)
	81406	Molecular pathology procedure, Level 7 (e.g., analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)
	81407	Molecular pathology procedure, level 8 (e.g., analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of >50 exons, sequence analysis of multiple genes on one platform)
	81408	Molecular pathology, level 9 (e.g., analysis of >50 exons in a single gene by DNA sequence analysis)
	81410	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis panel, must include sequencing of at least 9 genes, including FBN1, TGFBR1, TGFBR2, COL3A1, MYH11, ACTA2, SLC2A10, SMAD3, and MYLK
	81411	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); duplication/deletion analysis panel, must include analyses for TGFBR1, TGFBR2, MYH11, and COL3A1
	81412	Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1
	81413	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A
	81414	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia);

		duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1
	81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
	81416	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (List separately in addition to code for primary procedure)
	81417	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)
	81418	Drug metabolism (eg, pharmacogenomics) genomic sequence analysis panel, must include testing of at least 6 genes, including CYP2C19, CYP2D6, and CYP2D6 duplication/deletion analysis
	81419	Epilepsy genomic sequence analysis panel, must include analyses for ALDH7A1, CACNA1A, CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B, SCN2A, SCN8A, SLC2A1, SLC9A6, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2
	81420	Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21
	81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood
	81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
	81426	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)
	81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)
	81430	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel, must include sequencing of at least 60 genes, including CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3, USH1C, USH1G, USH2A, and WFS1
	81431	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); duplication/deletion analysis panel, must include copy number analyses for STRC and DFNB1 deletions in GJB2 and GJB6 genes
	81434	Hereditary retinal disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, and USH2A
	81440	Nuclear encoded mitochondrial genes (eg, neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes, including BCS1L, C10orf2, COQ2, COX10, DGUOK, MPV17, OPA1, PDSS2, POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, SUCLA2, SUCLG1, TAZ, TK2, and TYMP
	81441	Inherited bone marrow failure syndromes (IBMFS) (eg, Fanconi anemia, dyskeratosis congenita, Diamond-Blackfan anemia, Shwachman-Diamond syndrome, GATA2 deficiency syndrome, congenital amegakaryocytic thrombocytopenia) sequence analysis panel, must include sequencing of at least

		30 genes, including BRCA2, BRIP1, DKC1, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, GATA1, GATA2, MPL, NHP2, NOP10, PALB2, RAD51C, RPL11, RPL35A, RPL5, RPS10, RPS19, RPS24, RPS26, RPS7, SBDS, TERT, and TINF2
	81442	Noonan spectrum disorders (eg, Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, and SOS1
	81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)
	81445	Solid organ neoplasm, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants and copy number variants or rearrangements, if performed; DNA analysis or combined DNA and RNA analysis
	81448	Hereditary peripheral neuropathies (eg, Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include sequencing of at least 5 peripheral neuropathy-related genes (eg, BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, SPTLC1)
	81449	Solid organ neoplasm, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis
	81450	Hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis
	81451	Hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis
	81455	Solid organ or hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 51 or greater genes, interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis
	81456	Solid organ or hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 51 or greater genes, interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis
	81457	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability
	81458	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants and microsatellite instability

	81459	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements
	81460	Whole mitochondrial genome (eg, Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERFF], neuropathy, ataxia, and retinitis pigmentosa [NARP], Leber hereditary optic neuropathy [LHON]), genomic sequence, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection
	81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed
	81470	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2
	81471	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2
	81479	Unlisted molecular pathology procedure
	81500	Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score
	81503	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score
	81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores
	81506	Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adiponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score
	81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy
	81508	Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
	81509	Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score
	81510	Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
	81511	Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)
	81512	Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score
	81524	Oncology (central nervous system tumor), DNA methylation analysis of at least 10,000 methylation sites, utilizing DNA extracted from formalin-fixed tumor tissue, algorithm(s) reported as probability of matching a reference tumor family and

		class, and MGMT (O-6-methylguanine-DNA methyltransferase) promoter methylation status, if performed
	81525	Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score
	81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival
	81540	Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype
	81554	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])
	81558	Transplantation medicine (allograft rejection, kidney), mRNA, gene expression profiling by quantitative polymerase chain reaction (qPCR) of 139 genes, utilizing whole blood, algorithm reported as a binary categorization as transplant excellence, which indicates immune quiescence, or not transplant excellence, indicating subclinical rejection
	81595	Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score
	81599	Unlisted multianalyte assay with algorithmic analysis
	84999	Unlisted chemistry procedure
	88299	Unlisted cytogenetic study
	89398	Unlisted reproductive medicine laboratory procedure
HCPCS	G9143	Warfarin responsiveness testing by genetic technique using any method, any number of specimen(s)
	S3844	DNA analysis of the connexin 26 gene (GJB2) for susceptibility to congenital, profound deafness *(CMS-assigned Status "I" code – See above billing guidelines)*
	S3870	Comparative genomic hybridization (cgh) microarray testing for developmental delay, autism spectrum disorder and/or intellectual disability *(CMS-assigned Status "I" code – See above billing guidelines)*

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.

- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)
4/2023	Q2 2023 code updates
7/2023	Interim update; no policy changes, but updated PA requirements on select codes. Q3 2023 code updates
8/2023	Interim update; added Decipher Bladder with relevant LCD/LCA (code already in policy), updated CMS LCD/LCA references for several tests (Colvera, PancraGEN (aka Pathfinder® Pancreas), PancreaSeq Genomic Classifier and CxBladder tests)
10/2023	Q4 2023 code updates
1/2024	Q1 2024 code updates and annual review. Add LCD for genetic testing related to rheumatoid arthritis treatment decision-making. Update tests as needed, including Colvera criteria. Add LCAs for germline testing for PARP inhibitors
4/2024	Interim update; Remove liquid biopsy tests and codes addressed in separate policy. Q2 2024 code updates
7/2024	Interim update and Q3 2024 code updates; update configuration for cardiomyopathy testing; removed tests not expected to be used for general Medicare population; added criteria that are used to review tests not called out by name in a plan policy; removed retired MolDX LCAs
8/2024	Interim update; Update criteria for the KidneyIntelX™ and kidneyintelX.dkd™ tests
9/2024	Interim update; Add Percepta Genomic Sequencing Classifier test with LCD information, update code for epi proColon, and add Guardant Shield™ test
10/2024	Q4 2024 code updates

1/2025	Annual review; add BDX-XL2 to the policy with relevant criteria; add criteria for Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease Diagnostics test; Q1 2025 code updates
3/2025	Interim update to align with updated LCDs
4/2025	Q2 2025 code updates
7/2025	Interim update and Q3 2025 code updates
9/2025	Interim update; moved inherited cancer syndrome testing to new Medicare policy
10/2025	Interim update and Q4 2025 code updates (10/24/2025: Replaced L37062 with L37054 due to Noridian JF consolidation with JE LCD policies)
11/2025	Annual review; no changes
1/2026	Q1 2026 code updates (1/27/2026: Replaced multiple MolDX LCDs and LCAs due to Noridian JF consolidation with JE LCD policies) (2/13/2026: Replaced multiple MolDX LCDs and LCAs due to Noridian JF consolidation with JE LCD policies) (3/6/2026: Replaced LCD L38337 with L38335 due to Noridian JF consolidation with JE LCD policies)
4/2026	Interim update and Q2 2026 code updates; Add *APOE* gene testing criteria for non-cardiac screening indications and update criteria for the PGDx elio™ Tissue Complete test
5/2026	Interim update; Add breast gene expression profile tests, as well as prostate protein biomarker and genetic tests, from prior policies
7/2026	Interim update and Q3 2026 code updates
9/2026	Interim update; remove hereditary cardiomyopathy testing and the Guardant360® LDT test (addressed in separate policies)
10/2026	Q4 2026 code updates; replaced National Government Services with new brand name, Wellpoint Federal; update criteria for hereditary thrombophilia (F2, F5) testing; update non-coverage language for hereditary hearing loss criteria
11/2026	Annual review