Subject: Genetic Testing: Next Generation Sequencing

Medical Policy #: 29.0

Original Effective Date: 01/23/2019

Status: Reviewed

Last Review Date: 05-24-2023

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. In addition, in vitro companion diagnostic laboratory tests provide a report of test results of genetic variations and are essential for the safe and effective use of a corresponding therapeutic product. Next Generation Sequencing (NGS) is one technique that can measure one or more genetic variations as a laboratory diagnostic test, such as when used as a companion in vitro diagnostic test. Patients with cancer can have recurrent, relapsed, refractory, metastatic, and/or advanced stages III or IV of cancer. Clinical studies show that genetic variations in a patient's cancer can, work in concert with clinical factors, predict how each individual respond to specific treatments.

In application, a report of results of a diagnostic laboratory test using NGS (i.e., information on the cancer's genetic variations) can contribute to predicting a patient's response to a given drug: good, bad, or none at all. Applications of NGS to predict a patient's response to treatment occurs ideally prior to initiation of such treatment.

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

For Commercial, Medicaid and Medicare.

Covered Genetic Tests:

1. **Next Generation Sequencing (NGS):**
   PHP follows, NGS, National Covered Determination (NCD 90.2); coverage indications include 1) Somatic (Acquired) Cancer and 2) Germline (inherited) Cancer.
2. **Testing for Solid Tumors**:
   PHP follows MolDX LCD L38158 and LCA A57858 for NGS for Solid Tumors. This is specific for solid tumor testing, and is **exclusive** of hematologic malignancies, circulating tumor DNA testing (ctDNA), and other cancer-related uses of NGS, such as germline testing in/for patients with cancer.
3. **Myeloid Malignancies and Suspected Myeloid Malignancies:**
   PHP follows LCD L38176 and LCA A57878 for NGS Lab-Developed Testing for Myeloid Malignancies & Suspected Myeloid Malignancies.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT CODE	CPT Description	For ICD-10 listing see the following links for each CPT codes.
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden. Includes **FoundationOne CDx™ (F1CDx)** **Effective: 04-01-2018.**	For the most recent complete listing of ICD-10 for CPT 0037U, click here for the Transmittal links related to NCD 90.2, (TN 12184, CR13278)
0022U	**Oncomine Dx Target:** Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and	For the most recent complete listing of ICD-10 for CPT 0022U, click here

CPT CODE	CPT Description	For ICD-10 listing see the following links for each CPT codes.
	RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider. **Effective 03-16-2018**	for the Transmittal links related to NCD 90.2, (TN 12184, CR13278)
0111U	**Praxis™**: Extended RAS Panel test for 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. **Effective: 10-01-2019**	For the most recent complete listing of ICD-10 for CPT 0111U, click here for the Transmittal links related to NCD 90.2, (TN 12184, CR13278)
0172U	**MyChoice CDX™** 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. **Effective 07/01/2020**	For the most recent complete listing of ICD-10 for CPT 0172U, click here for the Transmittal links related to NCD 90.2, (TN 12184, CR13278)
0239U	**FoundationOne® Liquid CDx** – Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations Effective 1/1/21	For the most recent complete listing of ICD-10 for CPT 0239U, click here for the Transmittal links related to NCD 90.2, (TN 12184, CR13278)
0242U	**Guardant360® CDx** - Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements Effective 4/1/21 **Before April 1, 2021 continue to use 81479 for **Guardant360**® CDx	For the most recent complete listing of ICD-10 for CPT 0242U, click here for the Transmittal links related to NCD 90.2, (TN 12184, CR13278)
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), 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. xT CDx (Tempus Labs, Inc.) for Colorectal Cancer (CRC) – Tissue (Matching Blood/Saliva)	For the most recent complete listing of ICD-10 for CPT 81455, click here for the Transmittal links related to NCD 90.2, (TN 12184, CR 13278) Effective 04/28/2023
81445 Solid Tumor Testing	Targeted genomic sequence analysis panel, **solid organ neoplasm**, DNA analysis, and RNA analysis when performed, **5-50 genes** (EG, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed.	For **Next Generation Sequencing for Solid Tumors** see LCA (A57858) for complete listing of ICD-10 diagnoses. See also LCA A55197.

CPT CODE	CPT Description	For ICD-10 listing see the following links for each CPT codes.
81450 Myeloid Malignancies and suspected Myeloid Malignancies Testing	Targeted genomic sequence analysis panel, **hematolymphoid neoplasm or disorder**, 5-50 genes (e.g., (EG, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS),, interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or MRNA expression levels, if performed.	See **Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies**, LCA (A57878) for complete listing of ICD-10 diagnoses. See also LCA A55197.
81451	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (EG, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mrna expression levels, if performed; rna analysis	See **Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies**, LCA (A57878) for complete listing of ICD-10 diagnoses. See also LCA A55197.
81479 Solid Tumor and Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	Unlisted molecular pathology procedure. **Effective: 02/09/2020** Note: A description of the testing performed is required in the narrative/remarks when using this code.	See also LCA (A55197). For **NGS Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Cancer** see LCA (A57878). For NGS for **Solid Tumors** see LCA (A57858) for complete listing of ICD-10 diagnoses.
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	For NGS for **Solid Tumors** see LCA (A57858) for complete listing of ICD-10 diagnoses.
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	For NGS for **Solid Tumors** see LCA (A57858) for complete listing of ICD-10 diagnoses.
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. **Effective July 1, 2022**	For NGS for **Solid Tumors** see LCA (A57858) for complete listing of ICD-10 diagnoses.
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. **Effective 10/1/2022**	For NGS for **Solid Tumors** see LCA (A57858) for complete listing of ICD-10 diagnoses.
81449	Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number	For NGS for **Solid Tumors** see LCA (A57858) for complete listing of ICD-10 diagnoses.

CPT CODE	CPT Description	For ICD-10 listing see the following links for each CPT codes.
	variants or rearrangements, if performed; RNA analysis. **Effective 01/01/2023**	

Reviewed by / Approval Signatures

Clinical Quality & Utilization Mgmt. Committee: Gray Clarke MD
Senior Medical Director: David Yu MD
Medical Director: Ana Maria Rael MD
Date Approved: 05-24-2023

References

1. CMS, National Coverage Determination (NCD) for Next Generation Sequencing, (90.2), Version 2, Effective date 01/27/2020, Implement Date: 11/13/2020. [Cited 04-07-2023].
    a. CMS Manual, Pub 100-20 One Time Notification, Change Request (CR) (related to NCD 90.2) 06/2022 - Transmittal 11400, dated May 4, 2022, is being rescinded and replaced by Transmittal 11460, dated, June 17, 2022, to update NCD 90.2, NGS, spreadsheet to conform with changes in CR 12124, and change the implementation date for all business requirements except 12705.6 to 30 days from issuance of this correction. All other information remains the same.(TN 11460) (CR12705) [Cited 03-29-2023]
2. CMS, Local Coverage Determination, (LCD): MolDX: Next-Generation Sequencing for Solid Tumor (L38158), Effective date: 02-09-2020, Revision History Date: 06-24-2021, R2. Related Article (A57858), Effective date: 02-09-2020. Revision 01/01/2023 R8. [Cited 03-29-2023]
3. CMS, Local Coverage Determination, (LCD): MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38176), Effective Date: 02-09-2020, Revision date: 07/08/2021, R2. Related Article A5787**7**8, Effective Date 02-09-2020, Revision date: 01/01/2023, R5. [Cited 03-29-2023]
4. CMS, Local Coverage Determination, (LCD): MolDX: Molecular Diagnostic Tests (MDT), (L36807), [TA information], Revision date 12/30/2021, R14. [Cited 04-07-2023]
5. CMS, Local Coverage Article: Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next Generation Sequencing Testing in Cancer (A55197), Revision date: 03/31/2022, R13. [Cited 03-29-2022]

Publication History

01-23-20 Policy created 01/23/2019
03-25-20 Annual review. NCD 90.2 remains the same, however Transmittal 214, dated March 6, 2019 was rescinded and replaced by Transmittal 215, dated April 10, 2019. Added new Local Coverage Determination: LCD L38158/LCA A57858 for Solid Tumor; LCD L38176/LCA A57878 for Myeloid Cancer; LCD L36807 for MolDX-Technical Assessment guidance; and LCA A55197 for Billing and Coding Guideline. Removed F1CDx test, CPT 81455 due to expiration of usage from DOS 03/16/18 thru 03/31/2018. During this review, the title changed to remove Medicaid and Medicare.
05-05-20 Update only for new CPT code 0171U released by CMS for NGS NCD 90.2

08-25-20 CPT code update only. CMS rescinded CR 11749 for CPT 0171U. Released new code 0172U on July 31, 2020. CPT 0171U removed and added 0172U.

05-26-21 Annual review. Reviewed on 04/13/2021. No criteria change. Added language statement "For Commercial, Medicaid and Medicare." Two new codes added to policy: 0239U, 0242U. PA will be required for new codes:0239U (FoundationOne® Liquid CDx) and 0242U (Guardant360® CDx). Continue PA for: 0022U, 0172U and 0111U. Removed CPT code 0048U from policy but will be in MPM 7.1. Title changed to add "Genetic Testing" to beginning of title.

05-25-22 Annual review. Reviewed by PHP Medical Policy Committee on 04/13/2022. Continue to follow NGS, (NCD 90.2) and continue Prior authorization for related codes: 0037U, 0022U, 0111U, 0172U, 0239U and 0242U. For Testing of Solid Tumors, continue to follow LCD (L38158) and LCAs (A57858/A55197); and continue PA for related codes 81445 and 81479. New codes 0244U and 0250U added to policy which will require Prior Auth. For testing for Myeloid Malignancies and Suspected Myeloid Malignancies, continue to follow LCD L38176 and the two related LCAs (A57858 and A55197). The coverage determination guideline language removed from policy and reformatted to only include CMS LCD and NCD weblinks.
CPT codes added to policy on 01-25-2023: MPC approved on 11-11-22 to add these codes to policy and to require PA (81449, 0329U, 0334U).

05-24-23 Annual review. Reviewed by PHP Medical Policy Committee on 03-28-2023. For NGS: continue to follow NCD 90.2 and TN **11460** (CR#12705) for update of CPT & ICD-10 codes. For Testing of Solid Tumors, continue to follow LCD (L38158) and LCAs (A57858/A55197). For myeloid testing: continue to follow LCD L38176 and LCAs (A57878/A55197). Add code 81451 to policy which will require PA for ALOB (code also listed in MPM 7.1). Update description to code 81450. PA will continue for all related codes in policy.
Update 10-20-2023: CR13278: Add xT CDx (Tempus Labs, Inc.) using CPT 81455 and its indications related to Colorectal Cancer (CRC) effective FDA approval date 4/28/2023. Continue PA requirement for 81455.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.