State of New Jersey
Department of Human Services
Division of Medical Assistance & Health Services

NEWSLETTER

Volume 32 No. 22 **August 2022**

TO: All Providers **– For Action**
Managed Care Organizations **– For Information Only**

SUBJECT: **Billing and Coding of Laboratory Services**

- **Genomic Sequencing Procedures**
- **Molecular Pathology Procedures (Tier 1 and Tier 2)**
- **Gene Assays**

EFFECTIVE: Immediately

PURPOSE: To notify all providers of proper billing and coding procedures related to gene assay testing services.

BACKGROUND: The Division of Medical Assistance and Health Services is experiencing an increasing volume of claim requests for gene assay tests, specifically molecular multianalyte assays, multianalyte assays with algorithmic analyses, Proprietary Laboratory Analyses (PLA) and gene assays. For gene assay testing, the Division applies principles of correct coding and general guidelines found in the National Correct Coding Initiative (NCCI) Policy Manual for Medicaid Services (Revised quarterly). Providers may access the NCCI Manual at https://www.medicaid.gov/medicaid/program-integrity/national-correct-coding-initiative/medicaid-ncci-reference-documents/index.html

The Centers for Medicare & Medicaid Services (CMS) publishes coding instructions in its rules, manuals, and notices. Medicaid/NJ FamilyCare requires physicians/laboratories to use the instructions, specifically CMS' National Correct Coding Initiative program, when reporting services.

ACTION: DMAHS is providing important correct billing procedures and general guidelines for providers to use for gene assay testing claims as detailed below.

General Guidelines

- Selection of a procedure code is based on the specific gene(s) that are being analyzed. Procedure codes that describe assay tests to assess for the presence of gene variants use common gene variant names. All of the listed variants would usually be tested; however, **these lists are not exclusive**. If additional variants for the same

gene are also tested in the analysis, they should be included in the procedure and **should not be reported separately**.

- When multiple procedure codes are submitted on a claim (for example, a unique procedure code and an unlisted procedure code), **documentation supporting each procedure code being billed must be easily identifiable**. If on review the reviewer cannot link a billed procedure code to the submitted documentation, the billed procedure code shall be denied payment based on Title XVIII of the Social Security Act, Section 1833(e).

- It is not expected that a provider would routinely bill a procedure code for more than one (1) distinct gene assay for the same beneficiary on the same date of service. In the rare circumstance that more than one (1) distinct gene assay is medically reasonable and necessary for the same beneficiary on the same date of service, the provider must attest that each additional service billed is distinct using the 59-procedure code modifier. Documentation must support the use of modifier 59. **Laboratories submitting claims and reporting modifier 59 for many individual genes rather than appropriately reporting a gene panel may be subject to medical review by the Division of Medical Assistance and Health Services.**

Genomic Sequencing Procedures

- All genomic sequencing procedures, **molecular multianalyte assays** (e.g., CPT codes 81410-81471), many **multianalyte assays with algorithmic analyses** (e.g., CPT codes found in the NCCI Medicaid Manual, revised 1/1/2022, 81490-81599, 0004M-XXXXM), and many **Proprietary Laboratory Analyses (PLA)** (e.g., CPT codes 0001U – XXXXU) are DNA or RNA analytic methods that simultaneously assay multiple genes or gene regions. **A provider shall not additionally separately report testing for the same gene or gene region by a different methodology** (e.g., CPT codes 81105-81408, 81479, 88364- 88377). **CMS policy does not allow separate payments for multiple methods testing for the same analyte.**

- A Tier 1 or Tier 2 molecular pathology CPT code **shall not be reported** with a genomic sequencing procedure, molecular multianalyte assay, multianalyte assay with algorithmic analysis, or PLA CPT code **where the CPT code descriptor includes testing for the analyte described by the Tier 1 or Tier 2 molecular pathology code**. Procedures reported together must be both medically reasonable and necessary (e.g., sequencing procedures) and ordered by the provider who is treating the beneficiary and using the results in the management of the member's care.

- Full gene sequencing should not be reported using codes that assess for the presence of gene variants unless the CPT code specifically states “full gene sequence” in the descriptor.

Molecular Pathology Procedures (Tier 1 and Tier 2)

- Molecular pathology procedures (Tier 1 and Tier 2) may be eligible for coverage when **ALL of the following criteria are met**:

  - A clinically valid test is available, based on published peer reviewed medical literature;
  - Testing assay(s) are Food and Drug Administration (FDA) approved/cleared (or if the assay is a Lab Developed Test (LDT) or an LDT protocol or FDA modified test(s)), the laboratory documentation should support assay(s) of analytical validity and clinical utility;
  - The results of the testing directly impact treatment or management of the Medicaid/NJ FamilyCare member;
  - Alternative laboratory or clinical tests to definitively diagnose the disorder/identify the condition are unavailable.
  - Testing panels, including but not limited to multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, are reasonable and medically necessary.
  - The test(s) are necessary to obtain necessary information for therapeutic decision making; and
  - An individual has not previously received gene testing for the same disease/condition, since diagnostic gene testing for a disease should be performed once in a lifetime. Exceptions may include clinical scenarios whereby repeat testing of somatically-acquired mutation (for example, pre- and post- therapy) may be required to inform appropriate therapeutic decision-making.

- Providers are required to use a procedure code that most accurately describes the gene assay test being rendered. If the analyte being tested is not accurately represented by a Tier 1 or Tier 2 code, the unlisted molecular pathology procedure code 81479 should be reported. However, when reporting CPT code 81479, the specific gene being tested must be entered. Failure to include this information on the claim may result in the claim being returned to provider or rejected. In addition, medical records may be requested when 81479 is billed.

The specific gene being tested must be entered in Box 19 of a CMS 1500 paper claim; OR the shaded area located in Box 24; OR in Block 80 of the UB04; OR an equivalent field found in an electronic claim. In addition, medical records may be requested for review by DMAHS. The medical record must clearly identify the unique molecular pathology procedure performed, its analytic and clinical utility, and why the CPT code billed was reasonable and necessary.

- If billing utilizing Tier 2 codes 81400 - 81408, additional information will be required to identify the specific analyte/gene(s) tested in the narrative of the claim or the claim will be rejected. Additional information can be provided in any of the appropriate fields mentioned in the box above.

Gene Assays

- Genes may be assayed serially or in parallel. Genes **assayed on the same date of service** are considered to be performed **in parallel** if the result of one assay does not affect the decision to complete the assay on another gene, and the other gene(s) are being tested for the same indication. Genes **assayed on the same date of service** are considered to be performed **serially** if there is a reflexive decision component wherein the results of the analysis of one gene determines whether or not the results of additional analyses are reasonable and necessary.

  If laboratory assays for two or more genes are performed **in parallel,** then those assays are considered to be part of the same panel. A panel constitutes a single procedural service, so only one (1) HCPCS code must be submitted for the panel. If the laboratory assays genes **serially**, then the laboratory should submit claims for the assays individually.

The order by the treating clinician must reflect whether it is for a panel or single gene assay, and, additionally, the patient's medical record must reflect why it is reasonable and medically necessary. A clinician's order is not sufficient to indicate that a test was reasonable and necessary without supporting evidence. The medical record must reflect that the test is being used appropriately in accordance with 42 CFR Section 410.32.

- A gene panel is a distinct procedural service which includes a series of individual gene assays. All services billed must be reasonable and medically necessary. As such, if a provider submits a claim for a panel, then the patient's medical record must reflect that the panel is reasonable and necessary. Alternatively, if a provider bills for a number of individual gene assays, then the patient's medical record must reflect that each individual gene assay is reasonable and necessary.

Attached is a new **Genetic Testing Supporting Information Form (FD-143)** which should be attested to and attached to claims for genetic testing requiring the submission of supporting documentation.

For additional information, providers may visit the following links:

https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58917&ver=23&bc=0

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35000&ver=133&bc=CAAAAAAAAAAA

If you have any questions concerning this Newsletter, please contact the Gainwell Technologies Provider Services Unit at 800-776-6334.

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State of New Jersey
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

GENETIC TESTING SUPPORTING INFORMATION FORM

This form must be completed by the ordering provider. Forms completed by laboratories will not be accepted.

PROVIDER INFORMATION

Provider Name _____

Medicaid/NJ FamilyCare Provider ID _____

Provider Address _____

Provider Contact Name _____ **Provider Contact Phone No.** _____

MEMBER INFORMATION

Member Name _____

Member Identification Number _____

Member Date of Birth _____

GENE ASSAY TESTING INFORMATION

Date of Service _____ **CPT/HCPCS Code(s)** _____

ICD-10 Diagnosis Code(s) _____

Gene(s) Tested _____

Type of Test (e.g., Common Variants, Full Sequence, Del/Dup): _____

Reason for Testing (e.g., clinical findings, family history, previous test results)

How will the results of this genetic test change/impact future medical management of the patient?

To the best of my knowledge, the above information is true, accurate, and complete and the requested services are medically indicated and necessary to the health of the patient

Authorized Signature	Title	Date