Payment Policy: Genetic and Molecular Testing Services

Reference Number: CG.PP.551 Version C
Product Types: ALL
Date of Last Revision: 02/26/2025

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy Overview
Certain services, procedures or devices provided to members are covered in accordance with the member's coverage documents, when rendered by participating providers and, in certain circumstances, by non-participating provides, all in accordance with the treating provider's scope of practice and this policy. This policy expands the requirements for billing of molecular and genetic testing to advance the reliability of laboratory quality information and reduce variability in billing. Health plans affiliated with Centene Corporation© have contracted with Concert Concert, a leader in data and digital infrastructure for the Genetic Health Information Network, to administer this policy. Concert has developed a novel method to translate a genetic test into a single code or code combination. This method, delivered as the Concert Coding Engine, standardizes the coding process for genetic testing, allowing a single way to code each test on the market. Concert provides tools that connect, unify, and simplify the world of genetic testing and ultimately lead to insights that accelerate healing and improve health.

Application
The policy applies to billing and payment for *genetic and molecular testing* corresponding to codes within the following sections in the CPT®/HCPCS manual:

- Pathology and Laboratory Procedures (80000 Codes)
- Category III Multianalyte Assays with Algorithmic Analyses (MAAA) (M codes)
- Proprietary Lab Analysis (PLA) (U codes)
- Level II Healthcare Common Procedure Coding System (HCPCS)

To verify the accuracy of a test catalog and review coding engine standards for each molecular and genetic test, laboratories billing for genetic and molecular testing services should register using the Concert Genetics portal at https://www.concertgenetics.com/join-centene. The portal offers a quality metrics questionnaire for completion by laboratories that leverages industry-standard quality programs with customization to reflect the unique characteristics of genetic testing while being minimally burdensome on providers. Laboratories will also utilize the Concert Portal to obtain and access the Genetic Testing Unit (GTU), a unique identifier for every genetic test that will be utilized for billing and payment.

Reimbursement
All providers billing for genetic and molecular testing services (see codes in Table 1 below) must include standard, complete information on the claim, or payment for the services may be denied:

- Bill for the test performed as indicated on the test requisition form and delivered on the test result.
- Include ordering and rendering provider information on all claim transactions.

- Include appropriate and accurate diagnosis codes related to the procedure performed, per the International Classification of Diseases (ICD) coding system created by the World Health Organization (WHO). Header codes (3 digit ICDs) may lack specificity to determine coverage in some instances and may be denied for insufficient specificity.
- Include the date and place of service on all claim transactions. Place of Service codes will be used to distinguish outpatient testing from testing provided within the Emergency Department or as part of an inpatient hospital stay.

Coding must be consistent with American Medical Association coding guidelines and the National Correct Coding Initiative (NCCI) manual, or payment for the services may be denied:

- Procedure codes are determined based on the attributes of the testing performed, not based on the clinical indication of the member.
- If the laboratory has obtained an approved Proprietary Laboratory Analyses (PLA) code or the test has a Multianalyte Algorithmic Assay (MAAA) code, the PLA/MAAA code must be used to bill for the service.
- Proprietary codes may be used to bill only for the specific test to which the code is assigned.
- If a test qualifies for panel code(s), the panel code(s) must be used.
    - Per the NCCI Manual, Chapter 10, Section F-8, if one laboratory procedure evaluates multiple genes using a next generation sequencing procedure, the laboratory shall report only one unit of service of one genomic sequencing procedure.
    - If a test evaluates multiple analytes (e.g. drugs, pathogens, metabolites, genes) using a procedure that consolidates at least one part of the testing process (e.g., tandem mass spectrometry), the laboratory shall report only one unit of service of one appropriate level II HCPCS, CPT, or PLA code.
- If a panel code is not appropriate, a limited number of individual components from multi- gene tests may be billed.
- Only one unit of the non-specific procedure codes, CPT code 81479 and 81599, may be billed per test.
- Codes may be used when the date of service falls after the listed effective date and prior to the date of retirement.
- Modifier codes should be used when billing multiple service units of a code is appropriate. This includes but is not limited to repeat testing, testing performed on multiple specimens, and testing for multiple species.
- When interpretation of existing data resulting from a separate test is conducted, the provider may bill at an adjusted rate using Modifier 52 to indicate that the wet lab procedures were not performed.
- Procedure-to-Procedure (PTP) and Medically Unlikely Edit (MUE) Requirements:
    - If a code(s) falls under a NCCI procedure-to-procedure edit, the code must be billed in alignment with the edit. PTP edits prohibit certain codes billed in presence of other codes as they are "mutually exclusive procedures."
    - If a code(s) falls under an NCCI procedure-to-procedure edit, modifiers must ONLY be used when appropriate and Modifier 59 may be used only if no other appropriate modifier describes the service.
    - If a code(s) falls under a Medically Unlikely Edit (MUE), which defines the maximum units of service (UOS), the units billed must not exceed the maximum UOS. Per the NCCI Manual, the MUE is the maximum units of service (UOS) reported for a HCPCS/CPT code on the vast majority of appropriately reported claims by the same provider/supplier for the same beneficiary on the same date of service. Not all HCPCS/CPT codes have an MUEs.

Additional Requirements- All providers must follow these additional requirements when

submitting claims or prior authorization requests:

- Register on the Concert website (https://app.concertgenetics.com) to:
  - Verify accuracy of the lab's genetic test catalog
  - Access Concert GTUs
  - Complete a brief quality profile
- Bill for services according to the Concert coding engine standards.
- When CPT code 81479, 81599 or a Tier 2 code is used, a claim procedure description is required. Including the Concert GTU satisfies this requirement, and it is the recommended way to do so.
- When any procedure codes in Table 1 other than CPT code 81479 are used, including a claim procedure description is optional. Including the Concert GTU in the claim procedure description is recommended.
- All providers requesting prior authorization for genetic and molecular testing services are required to add the appropriate Concert Genetics GTU descriptor to all prior authorization requests.

Coding and Modifier Information

This payment policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT® codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from current 2024 manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this payment policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Table 1: Molecular/Genetic testing codes subject to Genetic Testing Units (GTU) Requirements in Table 2

Molecular/Genetic Testing Code	Description
81105-81383	Tier 1 CPT Codes
81400-81408, 81479	Tier 2 CPT Codes
81410-81471	Genomic Sequencing Procedures and Other Molecular Multianalyte Assays CPT Codes
81490-81599	Multianalyte Assays with Algorithmic Analyses CPT Codes
HCPCS Codes for Genetic/Molecular Testing	
Proprietary Laboratory Analyses (PLA) Codes for Genetic/Molecular Testing	

Table 2: GTU Requirements

Procedural Code(s)	Genetic Testing Unit (GTU) Requirements	Claim Type and Field or Segment	GTU Format
81479, other Tier 2 codes, and 81599	Claim procedure description is required. Including the Concert GTU in the claim procedure description satisfies this requirement.	• Electronic Professional– 837P Transaction: Loop 2400 Segment SV101-7 • Electronic Institutional– 837I Transaction: Loop 2400 Segment SV202-7 • Paper Professional – CMS-1500: Item/block 19 • Paper Institutional – CMS-1450: Item/block 80	Insert the exact GTU or the GTU preceded by "GTU-." For example, insert either: • 6V98G • GTU-6V98G
All other molecular /genetic testing codes noted in Table 1	Claim procedure description is optional. Recommend including the Concert GTU in the claim procedure description		

References

1. American Medical Association. CPT® Code Book. Last updated April, 2024
2. World Health Organization. (2019). International statistical classification of diseases and related health problems (11th ed.). https://icd.who.int/
3. Centers for Medicare and Medicaid Services, "NCCI Policy Manual", Chapter 10 https://www.cms.gov/ncci-medicare/medicare-ncci-policy-manual
4. Medicare NCCI FAQ Library. https://www.cms.gov/ncci-medicare/medicare-ncci-faq-library
5. Centers for Medicare and Medicaid Services,"Medicare NCCI Procedure to Procedure (PTP) Edits"https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-procedure-procedure-ptp-edits
6. Centers for Medicare and Medicaid Services, "Medically Unlikely Edits" https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html

Revision History	
02/12/2024	Payment policy version C developed.
02/23/2024	Under "application," removed reference to "independent" providers and their contract status with health plans affiliated with Centene. Added to the "reimbursement" section that a description is required for 81599 and Tier 2 codes as well as 81479. Added Tier 1 and Tier 2 codes to Table 1 and removed molecular pathology codes as a separate category. Added Table 2, with claim and code types and description requirements.
02/26/2025	Annual Review. Minor rewording throughout. Removed "Policy Description" header. In Policy Overview, updated vendor name to "Concert". In "Application": replaced first sentence regarding "molecular pathology, genomic sequencing…" with Pathology and Laboratory Procedures (80000 Codes), Category III Multianalyte Assays with Algorithmic Analyses (MAAA) (M codes), Proprietary Lab Analysis (PLA) (U codes), Level II Healthcare Common Procedure Coding System (HCPCS);" updated URL to https://www.concertgenetics.com/join-centene. In the Reimbursement section reworded "Laboratories should adhere…" to "All providers of genetic and molecular testing services…". In the Reimbursement section, added: requirement that billing should be

Revision History	
	consistent with what is delivered on the test result; requirement to add rendering provider information on the claim; requirements to add appropriate ICD-10 codes and place of service codes to claims; that coding must be consistent with NCCI guidelines; that if coding is not consistent with AMA and NCCI guidelines, payment may be denied; if a test has a PLA or MAAA code assigned, it must be billed, and PLA codes should only be billed for the specific test to which they are assigned; requirement for "if a test analyzes multiple analytes…"; 81599 as a non-specific procedure that may only be billed once per claim; requirement "codes may be used…"; requirement "modifier should be used…"; statement regarding use of Modifier 52; PTP and MUE requirements; requirement to "Bill for services according to the Concert coding engine standards". Reordered GTU requirements to end of Reimbursement section under "Additional Requirements". In "Additional Requirements": added "All providers must follow these additional requirements…" and registration requirements. In the Reimbursement section, removed qualifier regarding the interpretation of AMA correct coding per the Concert Genetics Coding engine on the following verbiage: "the coding must be consistent with American Medical Association coding guidelines". Table 1: Labeled table as codes for tests subject to GTU requirements; removed specific code range limits for PLA codes; added HCPCS codes for genetic and molecular testing. Table 2: labeled Table 2 as GTU Requirements; minor rewording to procedure codes in table 2 to reflect that 81479 is a Tier 2 code. References updated.

Important Reminder

For the purposes of this payment policy, "Health Plan" means a health plan that has adopted this payment policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any other of such health plan's affiliates, as applicable.

The purpose of this payment policy is to provide a guide to payment, which is a component of the guidelines used to assist in making coverage and payment determinations and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage and payment determinations and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable plan-level administrative policies and procedures.

This payment policy is effective as of the date determined by Health Plan. The date of posting may not be the effective date of this payment policy. This payment policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy

between the effective date of this payment policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. Health Plan retains the right to change, amend or withdraw this payment policy, and additional payment policies may be developed and adopted as needed, at any time.

This payment policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This payment policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this policy are independent contractors who exercise independent judgment and over whom Health Plan has no control or right of control. Providers are not agents or employees of Health Plan.

 Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this payment policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this payment policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this payment policy. Refer to the CMS website at http://www.cms.gov for additional information.