LABORATORY AND PATHOLOGY SERVICES

PURPOSE
To define coverage criteria and billing requirements for laboratory and pathology services to enrolled providers.

APPLICABILITY
Enrolled ND Medicaid providers who provide laboratory or pathology services to ND Medicaid members, including;

- Physicians and Other Licensed Providers (OLPs)
- Clinics
- Hospitals
- Independent Laboratories

DEFINITIONS
CLIA **-** Clinical Laboratory Improvement Amendments Certificate

Reference Lab – A laboratory that receives a specimen from another laboratory and performs one or more tests on such specimen.

COVERED SERVICES & LIMITS
North Dakota Medicaid covers medically necessary laboratory tests for diagnostic and treatment purposes. Services must:

- Be ordered and provided under the direction of a recipient's treating physician or other licensed practitioner who gives a consultation or treats a specific medical problem within his or her scope of practice as defined by state law;
- The service must yield results that are used by the treating physician or other licensed practitioner in the screening, diagnosis, or management of a recipient's specific medical problem and
- Be allowed under the laboratory's CLIA certification if the service is classified under the CLIA program.

<u>Genetic Testing</u>
When requesting a genetic test, the provider must document at least one specific disease that, if diagnosed, will result in an evidence-based change in the active treatment plan. The provider must document the exact changes in the treatment plan that would not otherwise occur without the genetic test results. A change in the treatment plan does not include covered routine screenings for potential diseases or knowledge of risk for acquiring an associated disease (for example, risk of cardiac or ophthalmologic problems or increased risk for development of malignancies). Genetic testing is not covered to determine the risk of occurrence in other family members (for example, genetic testing for family planning purposes).

Most Molecular Pathology, Genomic Sequencing, and Multianalyte Assays require an approved Service Authorization (SA) before being performed. Please see the Service Authorization policy and the SA section below for details.

Newborn Metabolic Screening
North Dakota Medicaid covers the newborn metabolic screening panel. The screening must include the tests specified in the NBS List of Conditions under ND Newborn Screening Laws. Services are covered under the hospital's inpatient reimbursement if provided while the newborn is inpatient and must not be billed separately.

Specimen Collecting and Handling
ND Medicaid will cover the following specimen collecting and handling when performed for a covered lab service.

- Routine venipuncture (36415)
- Collection of capillary blood specimen, finger, heel, ear stick (36416)
- Collection of blood specimen from a completely implantable venous access device (36591)
- Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified (36592)

MEDICAL NECESSITY
Medical or remedial services or supplies required for treatment of illness, injury, disease condition, or impairment; consistent with the recipient's diagnosis or symptoms; appropriate according to generally accepted standards of medical practice; not provided only as a convenience to the recipient or provider; not investigational, experimental, or unproven; clinically appropriate in terms of scope, duration, intensity, and site; and provided at the most appropriate level of service that is safe and effective.

National and Local Coverage Determinations (NCDs and LCDs)
North Dakota Medicaid edits claims for medical necessity against the following NCDs and LCDs.
The Centers for Medicare and Medicaid Services (CMS) uses local coverage determinations (LCDs) and national coverage determinations (NCDs) to determine whether Medicaid covers a service or item.

CMS National Coverage Determinations (NCDs)

- 190.12 Urine Culture, Bacterial
- 190.15 Blood Counts
- 190.16 Partial Thromboplastin Time (PTT)
- 190.17 Prothrombin Time (PT)
- 190.18 Serum Iron Studies
- 190.21 Glycated Hemoglobin / Glycated Protein
- 190.22 Thyroid Testing
- 190.23 Lipid Testing
- 190.27 Human Chorionic Gonadotropin

Local Coverage Determinations (LCDs)

- L34051 Vitamin D Assay Testing
- L36707 Lab: Controlled Substance Monitoring and Drugs of Abuse Testing
- L36700 Serum Magnesium
- L36074 Lab: Flow Cytometry
- L34038 B-type Natriuretic Peptide (BNP) Testing

SERVICE AUTHORIZATION
See the Service Authorization Policy for a detailed list of lab services that require SA.

NON-COVERED LABORATORY SERVICES
- Routine handling charges (99000-90001)
- Stat fees (S3600-S3601)
- Paternity testing
- Postmortem examinations
- Reproductive medicine procedures
- Pharmacogenetic testing
- Drug testing for members undergoing Medicated Opioid Use Disorder treatment; testing is included in the MOUD bundle paid to MOUD providers.

BILLING & REIMBURSEMENT
Reference and Outside Lab Services
The laboratory that performed the test must submit the claim for the test. However, a laboratory participating in North Dakota Medicaid that did not perform the test may submit the claim for the test only when the participating lab cannot complete the test as ordered by the referring physician and the outside lab receiving the applicable test is not enrolled in North Dakota Medicaid. The date of service is the date the specimen was drawn.

Laboratory Panels
The laboratory tests listed under each panel identify its defined components, and all listed tests must be performed to bill for that panel. Tests conducted in addition to those specifically indicated for a particular panel can be billed separately from the panel code. Lab panels should be reported as one line item, with a single service unit per panel. If a panel is submitted and one of the lab procedures/tests is repeated, that single repeat component may be billed with the individual service code and will require the submission of modifier 91. Do not report two or more panel codes comprising the same tests; report the panel with the highest number of tests to meet the code's definition and report the remaining tests individually.

Unbundling is the submission of multiple procedure codes for a group of specific procedures that are components of a single comprehensive code. BCBSND will reject the individual component codes related to the extensive procedure code for payment.

Ordering, Referring Prescribing (ORP) Requirements
All lab services required the ordering, referring, or prescribing provider's NPI to be listed on the 837P claim. Please see the ORP Policy for further details.

Out of State Labs
Labs that are sent out of state for processing from North Dakota do not require an out of state authorization. Providers should complete Box 19 or the electronic equivalent that the labs were drawn in ND.

Labs that are performed as part of approved out of state services will be matched against the out of state approval.

Test Components
- Professional component—The professional component includes examining the patient when indicated, performing, or supervising the procedure, and interpreting and writing a report of the examination. Professional components should be reported by appending modifier 26 to the usual procedure code number.
- Technical component - Refers to the facility and equipment costs of performing a study, including supplies and a technologist or technician to conduct the exam. It is represented by appending the modifier -TC to the procedure code.
- Total component - Represents the complete study, including both technical and professional components. It is represented by reporting the procedure code without the 26 or TC modifiers.
    - Clinics billing for lab services performed on clinic-owned equipment should not separate services into professional and technical components.

National Correct Coding Initiative (NCCI) Editing
The Medicaid National Correct Coding Initiative (NCCI) program allows states to reduce improper payments in Medicaid and the Children's Health Insurance Program (CHIP).

The Medicaid NCCI methodologies must be applied to Medicaid fee-for-service (FFS) claims, which are submitted with and reimbursed based on Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes. This includes claims reimbursed on an FFS basis in state Medicaid Primary Care Case Management (PCCM) managed care programs. Application of NCCI methodologies to FFS claims processed by limited benefit plans or Managed Care Organizations (MCOs) is desirable but optional. The Medicaid NCCI program has certain edits unique to the Medicaid NCCI program (e.g., edits for codes that are noncovered or otherwise not separately payable by the Medicare program).

REFERENCES
42 CFR section 441.17 – Laboratory Services
North Dakota Administrative Code
Medicaid National Correct Coding Initiative

RELATED POLICIES
Noncovered Services
Ordering/Referring/Prescribing Providers
Service Authorizations

POLICY UPDATES