Clinical Trials

PURPOSE

This policy defines the coverage of routine costs for ND Medicaid members participating in clinical trials.

APPLICABILITY

ELIGIBLE PROVIDERS

To receive payment from ND Medicaid, the eligible servicing and billing provider National Provider Identifiers (NPI) must be enrolled on the date of service with ND Medicaid. Servicing providers acting as a locum tenens provider must enroll in ND Medicaid and be listed on the claim form. Please refer to provider enrollment for additional details on enrollment eligibility and supporting documentation requirements.

Clinical Trial services can be provided by the following enrolled providers as allowed by their scope of licensure:

- Physicians
- Physician Assistants
- Nurse Practitioners
- Clinical Nurse Specialists
- Nurse Midwives
- Nurse Anesthetists
- Oral Surgeons
- Podiatrists

ELIGIBLE MEMBERS

Providers are responsible for verifying a member's eligibility before providing services. Eligibility can be verified using the ND Medicaid MMIS Portal or through the through the Automated Voice Response System by dialing 1.877.328.7098.

COVERED SERVICES AND LIMITS

GENERAL PROVIDER POLICIES

The General Provider Policies details basic coverage requirements for all services. Basic coverage requirements include:

- The provider must be enrolled in ND Medicaid;
- Services must be medically necessary;
- The member must be eligible on the date of service; and

If applicable, the service has an approved service authorization.

ROUTINE PATIENT COSTS

Routine patient costs are covered for recipients participating in a qualifying clinical trial.

Routine patient costs include:

- Services provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial that would otherwise be covered outside the course of participation in the qualifying clinical trial.
- Services required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service.

Some examples of routine costs in a clinical trial could include otherwise covered physician services and laboratory or medical imaging services that assist with preventing, diagnosing, monitoring, or treating complications arising from clinical trial participation.

Routine patient cost does not include any item or service:

- provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and
- not covered under North Dakota Medicaid through the state plan or waiver.

Qualifying Clinical Trial

A qualifying clinical trial is defined as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition and is described in any of the following paragraphs.

The study or investigation is approved, conducted, or supported (which may include funding through in-kind contributions) by one or more of the following:

- The National Institutes of Health.
- The Centers for Disease Control and Prevention.
- The Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- A cooperative group or center of any of the entities listed above or the Department of Defense or the Department of Veterans Affairs.
- A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
- Any of the following if the conditions described below are met:
    - The Department of Veterans Affairs.
    - The Department of Defense.

  - The Department of Energy.
- The clinical trial is conducted pursuant to an investigational new drug exemption under section 355(i) of title 21 or an exemption for a biological product undergoing investigation under section 262(a)(3) of this title.
- The clinical trial is a drug trial that is exempt from being required to have an exemption described in the preceding bulleted statement.

Conditions

The clinical trial must have been reviewed and approved through a system of peer review that the Secretary determines:

- To be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and
- Assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review.

Coverage Determinations

The health care provider and principal investigator must fill out a Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial. Health care providers must retain this attestation as part of the patient's medical record.

ONCOLOGY DRUG TRIALS
ND Medicaid will pay for chemotherapy when administered via a protocol that is registered with one of the main regional oncology research organizations provided the FDA has approved each medication in the regimen. FDA approval can be for any indication.

If the member has a primary payer, the primary payer must be billed before requesting payment from ND Medicaid. If the primary payer denies coverage of the product because they consider the use "experimental", ND Medicaid will also deny the claim.

SERVICE AUTHORIZATION REQUIREMENTS

Routine patient costs for a clinical trial that are incurred out-of-state require a service authorization. Coverage determinations for routine patient costs related to an out-of-state clinical trial must be completed within 72 hours of request. Attach the completed Medicaid Attestation Form regarding the appropriateness of the qualifying clinical trial to the service authorization documentation.

NON-COVERED SERVICES

GENERAL NON-COVERED SERVICES

The Noncovered Services Policy contains a general list of services that are not covered by North Dakota Medicaid.

Investigational items or services that are the subject of the clinical trial or items or services that are only used for data collection and analysis

DOCUMENTATION REQUIREMENTS

GENERAL REQUIREMENTS

Providers must keep legible medical and financial records that fully justify and disclose the extent of services provided and billed to ND Medicaid. Records must be retained for at least 7 years after the last date the claim was paid or denied. Providers must follow the documentation requirements in the Provider Requirements Policy.

REIMBURSEMENT METHODOLOGY AND CLAIM INSTRUCTIONS

TIMELY FILING

ND Medicaid must receive an original Medicaid primary claim within one hundred eighty (180) days from the date of service. The time limit may be waived or extended by ND Medicaid in certain circumstances. The Timely Filing Policy contains additional information.

THIRD-PARTY LIABILITY

Medicaid members may have one or more additional source of coverage for health services. ND Medicaid is generally the payer of last resort. Providers must pursue the availability of third-party payment sources. The Third Party Liability Policy contains additional information.

CLIENT SHARE (RECIPIENT LIABILITY)

Client share (recipient liability) is the monthly amount a member must pay toward the cost of medical services before the Medicaid program will pay for services received. The Client Share Policy contains additional information.

REIMBURSEMENT

A claim for services must be submitted at the provider's usual and customary charge. Payment for services is limited to the lesser of the provider's usual and customary charge or the ND Medicaid calculated reimbursement.

CLAIM FORM

Professional services must be billed using the CMS 1500 claim form or 837p, and institutional services must be billed using the CMS UB04 claim form or 837i. Detailed claim instructions are available on the ND Medicaid Provider Guidelines, Policies & Manual webpage.

REFERENCES

- North Dakota Administrative Code
- North Dakota Century Code
- Code of Federal Regulations

RELATED POLICIES

Physician Administered Drugs

CONTACT

Medical Services
600 East Boulevard Ave
Bismarck, ND 58505-0250
Phone: (701) 328-2310
Email: dhsmedicalservices@nd.gov

POLICY UPDATES

July 2025

Section	Summary
	Clinical Trials section removed from Professional Medical and Surgical Services Policy.