

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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**NC Medicaid
Routine Patient Costs Furnished
in Connection with Participation
in Qualifying Clinical Trials**

**Medicaid
Clinical Coverage Policy No: 1A-39
Amended Date: July 1, 2023**

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Related Clinical Coverage Policies

Refer to NC Medicaid's clinical coverage policies listed at <https://medicaid.ncdhhs.gov/> to determine if Prior Approval is required.

1.0 Description of the Procedure, Product, or Service

Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg). Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage also referred to as alternative benefit plans, or ABPs with respect to items and services furnished on or after January 1, 2022.

Clinical trials are scientific investigations of treatment alternatives designed to help compare the safety and efficacy of new, untested, or non-standard treatments to standard currently accepted treatments. Clinical trials are intended to improve clinicians' knowledge about a treatment and to improve clinical outcomes for future patients.

Clinical trials are often conducted in four phases. The trials at each phase have a different purpose and help scientists answer different questions:

a. Early Phase 1 (formerly listed as Phase 0)

Pre-clinical studies are conducted to explore the effects of a drug on the body and determine whether it is safe for further testing. These studies precede traditional phase I trials and involve minimal human exposure to the drug, with no therapeutic or diagnostic objectives.

b. Phase I trials

Phase I clinical trials are designed to evaluate the safety of a drug, typically using healthy volunteers as participants. The primary objective is to identify the most common and severe adverse effects of the drug, as well as its metabolism and elimination pathways. These trials typically involve a limited number of participants.

c. Phase II trials

Phase II clinical trials are conducted to gather initial evidence on the efficacy of a drug in individuals with a specific condition or disease. Participants receiving the drug are typically compared to those receiving a placebo or an alternative treatment. These trials continue to evaluate safety and study short-term adverse events.

d. Phase III trials

Phase III clinical trials are designed to gather extensive information about a drug's safety and efficacy by studying various dosages, populations, and combinations with other drugs. These studies usually involve a larger number of participants.

e. **Phase IV trials**

Phase IV clinical trials refer to studies conducted after the FDA approves a drug for marketing. They typically include post-market requirements and commitment studies that the study sponsor is obligated to conduct or has agreed to perform. These trials are conducted to gather additional information on the drug's safety, efficacy, or optimal use.

f. **Phase Not Applicable**

Non-pharmacological trials refer to studies of devices or behavioral interventions that do not follow the FDA-defined phases used for drug clinical trials. These trials may involve different methodologies and evaluation criteria than traditional clinical trials.

An **Investigational Device Exemption (IDE)** is an unphased trial in which an investigational device is used in a clinical study in order to collect safety and effectiveness data required to support submission for approval to the FDA. This classification is divided into two sub-categories:

- a. **Category A** (experimental) device refers to a device for which the risk of the device has not been established and the FDA is unsure whether the device type can be safe and effective.
- b. **Category B** (nonexperimental-non-investigational) device refers to a device for which the incremental risk is the primary risk in question and questions of safety and effectiveness of that device type have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval (PMA) or clearance for that device type.

A **Humanitarian Use Device (HUD)** is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

A **Humanitarian Device Exemption (HDE)** is a marketing application for an HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.

An **Investigational New Drug (IND)** application is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics Product License Application.

1.1 Definitions

1.1.1 Qualifying Clinical Trial

Section 1905(gg)(2) of the Act defines the term "qualifying clinical trial" for purposes of section 1905(a)(30) of the Act 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 clauses (i)-(iii) of section 1905(gg)(2)(A) of the Act. Therefore, to meet

the statutory definition, the “qualifying clinical trial” must also be one or more of the following:

- a. A study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:
 1. The National Institutes of Health (NIH);
 2. The Centers for Disease Control and Prevention (CDC);
 3. The Agency for Health Care Research and Quality (AHRQ);
 4. The Centers for Medicare & Medicaid Services (CMS);
 5. A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs; or
 6. A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants.
- b. A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review that the Secretary determines comparable to the system of peer review of studies and investigations used by the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
 1. The Department of Energy;
 2. The Department of Veterans Affairs; or
 3. The Department of Defense.
- c. A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; or
- d. A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

1.1.2 Routine Costs

Pursuant to section 1905(a)(30) and 1905(gg)(1) of the Act, the routine patient costs that must be covered for a beneficiary participating in a qualifying clinical trial are any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Act. Such routine services and costs also include any item or service 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 or laboratory or medical imaging services that assist with prevention, diagnosis, monitoring or treatment of complications arising from clinical trial participation.

As described under section 1905(gg) (1) of the Act, routine patient costs within the meaning of section 1905(a)(30) of the Act **do not** include any investigational item or service that is the subject of the qualifying clinical trial and is not

otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project. Similarly, routine patient cost **does not** include any item or service that is 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 is not otherwise covered under the state plan, waiver, or demonstration project. For example, if a beneficiary has a condition that typically requires monitoring through an annual medical imaging scan and the beneficiary is participating in a clinical trial with a protocol that requires monthly medical imaging scans only to collect data on the effects of the investigational item or service, the additional monthly scans for purposes of clinical trial data collection would not be included in the beneficiary's routine patient costs to the extent they are not used for the direct clinical management of the beneficiary or are not otherwise covered under the state plan, waiver, or demonstration project.

1.1.3 Informed Consent

The process by which a beneficiary learns about and understands the purpose, benefits, and potential risks of a medical or surgical intervention, including clinical trials, and then agrees to receive the treatment or participate in the trial. Informed consent generally requires the beneficiary or responsible party to sign a statement confirming that they understand the risks and benefits of the procedure or treatment.

1.1.4 ClinicalTrials.gov Identifier (National Clinical Trial number)

The unique identification code given to each clinical study upon registration at ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419).

1.1.5 Principal Investigator

The person who is responsible for the scientific and technical direction of the entire clinical study.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term "General" found throughout this policy applies to all Medicaid policies)

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*).
- b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. **Medicaid**
None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

- a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary’s physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary’s right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider’s documentation shows that the requested service is medically necessary “to correct or ameliorate a defect, physical or mental illness, or a condition” [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary’s health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

- b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/>

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by Medicaid

Medicaid shall provide coverage of routine patient costs (**refer to Section 1.1.2**) for items and services as defined in section 1905(gg) (1) that are furnished in connection with participation in a qualified clinical trial (**refer to Section 1.1.1**) when:

- a. The beneficiary meets all eligibility criteria of the qualified clinical trial;
- b. The beneficiary is enrolled in the qualified clinical trial;
- c. The beneficiary has provided informed consent;
- d. The beneficiary is treated according to the qualified clinical trial's protocol;
AND
- e. The health care provider and principal investigator completes the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial (refer to **Subsection 7.2**).

NOTE: Routine costs associated with trials involving IDE, HUD, HDE, or IND will be covered as long as the trial meets the definition for "qualifying clinical trial" as defined in **Subsection 1.1.1**.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by Medicaid

Medicaid shall not cover any clinical trial services for which the costs have been or are funded by governmental or national agencies, foundations, commercial manufacturers, distributors, charitable grants or other such research sponsors of participants individual trials. If the service provided includes a transplant, coverage is not provided for organs sold rather than donated to a beneficiary.

In addition, Medicaid shall not cover the following clinical trial services:

- a. services that are not health care services;
- b. any item or service that is 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 is not otherwise covered under the state plan, waiver, or demonstration project;
- c. any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project;
- d. investigational drugs that do not have unrestricted market approval from the FDA for any diagnosis or treatment;
- e. after the clinical trial ends, coverage is not provided for non-FDA approved drugs that were provided or made available to an enrollee during a qualifying clinical trial; and
- f. travel, lodging and meals.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

Medicaid shall **not** require prior approval for Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials, **except** if the underlying service, product or procedure requires prior approval. The fact that the Medicaid beneficiary is enrolled in a qualifying clinical trial does not eliminate the requirement for prior approval for the underlying service, product, or procedure.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

5.3 Limitations or Requirements

None Apply.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state, and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

7.2 Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial

NC Medicaid will not require an attestation be submitted with claims associated with routine costs, however, a completed attestation form must be in the beneficiary's health record. Records are subject to audit for compliance at any time. If a completed attestation form is not in the record and signed by the Principal Investigator (refer to **Subsection 1.1.6**) and Health Care Provider (provider who has referred beneficiary to qualifying clinical trial) prior to participation in the study, all associated costs will be recouped. Electronic signatures will be allowed on the attestation form. The form is available at <https://www.medicaid.gov/resources-for-states/downloads/medicaid-attest-form.docx>.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 2004 – Phases III and IV

Revision Information:

Date	Section Revised	Change
09/01/2013	All sections and attachment(s)	New policy, effective June 1, 2013, documenting current Medicaid and NCHC coverage of routine costs in clinical trials for life threatening conditions in Phases III and IV of qualifying clinical trials. The policy developed according to SL 2011-145 Section 10.31. (d).
09/01/2013	All sections and attachment(s)	Coverage of routine costs in clinical trials for life threatening conditions for Phase II qualifying clinical trials effective November 15, 2010.
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
07/01/2019	Section 1.0	Added descriptions for clinical trials, clinical trial phases, investigational device exemptions, investigational new drug applications, humanitarian use device, and humanitarian device exemption.
07/01/2019	Subsection 1.1	Added or updated definitions for qualifying clinical trial, routine costs, life-threatening conditions, informed consent, ClinicalTrials.gov identifier, and Institutional Review Boards.
07/01/2019	Subsection 3.2.1(a)	Removed criteria that beneficiary must have a current diagnosis with a grave prognosis (life expectancy less than 2 years) and replaced with “beneficiary must have a life-threatening condition.”
07/01/2019	Subsection 3.2.1(d)	Added criteria that beneficiary must meet all eligibility criteria of qualifying clinical trial.
07/01/2019	Subsection 4.2.1	Added the following to non-coverage: after the clinical trial ends, coverage is not provided for non-FDA approved drugs that were provided or made available to an enrollee during a qualifying clinical trial; services related to Phase 0-I clinical trials; travel, lodging and meals; the experimental intervention itself (except medically necessary Category B investigational devices).
07/01/2019	Subsection 4.2.1(e)	Removed “services related to investigational drugs and devices” from non-coverage and replaced with “investigational drug costs for drugs that do not have unrestricted market approval from the FDA for any diagnosis or treatment.”
12/12/2019	Table of Contents	Updated policy template language, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.”
12/12/2019	Attachment A	Added, “Unless directed otherwise, Institutional Claims

Date	Section Revised	Change
		must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
05/01/2023	Section 1.0	Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg). Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage also referred to as alternative benefit plans, or ABPs with respect to items and services furnished on or after January 1, 2022.
05/01/2023	Section 1.0	Phase definitions updated.
05/01/2023	Section 1.1.1	Definition of “qualifying clinical trial” updated based on Section 1905(gg)(2) of the Act.
05/01/2023	Section 1.1.2	Definition of “routine costs” updated based on Section 1905(a)(30) and 1905(gg)(1) of the Act.
05/01/2023	Section 1.1.6	Definition added for “principal investigator.”
05/01/2023	Section 3.2.1	Section revised to meet new criteria in the Act. Requirement added that provider and principal investigator complete the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial.
05/01/2023	Section 4.2.1	Section revised to meet new criteria in the Act.
05/01/2023	Section 7.2	Requirement added that the provider and principal investigator must complete the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial and maintain in the beneficiary’s health record.
07/01/2023	Section 7.2	Added statement that electronic signatures will be allowed on the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial.
07/01/2023	All Sections and Attachments	Updated policy template language due to North Carolina Health Choice Program’s move to Medicaid. Policy posted 7/1/2023 with an effective date of 4/1/2023.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Refer to the applicable clinical coverage policy or manual on NC Medicaid's website <https://medicaid.ncdhhs.gov/>.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions for Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Inpatient, Outpatient, Office.

G. Co-payments

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices>

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

In the event a claim contains charges related to covered clinical trial services, but those charges have not been or cannot be separated from costs related to non-covered services, those charges are not reimbursable.