

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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1.0 Description of the Procedure, Product, or Service

Chemokine receptor 5 (CCR5) and chemokine receptor 4 (CXCR4) are the major chemokine coreceptors used by the human immunodeficiency virus (HIV) to enter into human cells. The HIV tropism assay is a diagnostic test used to determine the viral tropism of HIV-1. The assay can determine whether the HIV infection is CCR5, CXCR4, or dual-or mixed-tropic (D-/M-tropic). Using a small blood sample, this assay amplifies a beneficiary's HIV genome to make HIV particles specific to the individual beneficiary. These HIV particles are used to infect CCR5- and CXCR4- expressing cell lines. Once the virus infects the cell and undergoes a single round of replication, a receptor gene gives a visible signal that identifies the beneficiary's viral tropism.

A CCR5 co-receptor antagonist is indicated for combination antiretroviral treatment of a beneficiary infected with only CCR5-tropic HIV-1 detectable, who has evidence of viral replication and HIV-1 strains resistant to multiple anti-retroviral agents. CCR5 co-receptor antagonist works by binding to a specific chemokine receptor (CCR5), thus preventing HIV from entering the cell.

Note: HIV Tropism testing with a highly sensitive tropism (phenotypic) assay is required for the appropriate use of a CCR5 co-receptor antagonist.

1.1 Definitions

Co-receptor tropism is defined as the ability of a particular HIV-1 virus to infect a target cell using a specific co-receptor. HIV viruses can be characterized into three broad classifications based on which type of cell the virus can infect.

- a. CCR5 tropism: The virus infects cells that express only CCR5. Chemokine receptor 5 (CCR5) is a protein on the surface of some immune system cells. It is one of two co-receptors that HIV can use along with the CD4 receptor to bind to and enter host cells (the other co-receptor is CXCR4).
- b. CXCR4 tropism: The virus infects cells that express only CXCR4. Chemokine receptor 4 (CXCR4, also known as fusin) is a protein on the surface of some immune system cells. It is one of two co-receptors that HIV can use along with the CD4 receptor to bind to and enter host cells (the other co-receptor is CCR5).
- c. Dual- or mixed-tropic (D-/M-tropic): the virus can infect cells expressing both CCR5 and CXCR4.

Viral load (VL) is the amount of HIV RNA in a blood sample, reported as number of HIV RNA copies per milliliter of blood plasma. The VL provides information about the number of cells infected with HIV and is an important indicator of HIV progression and how well treatment is working. The VL can be measured by different techniques, including branched chain DNA (bDNA) and reverse transcriptase-polymerase chain reaction (RT-PCR) assays. VL tests are usually done when an individual is diagnosed with HIV infection and at regular intervals after diagnosis.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC 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.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

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

- a. **Medicaid**
None Apply.
- b. **NCHC**
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/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

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 and NCHC 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 both Medicaid and NCHC

Medicaid and NCHC shall cover HIV tropism (phenotypic) assay when the beneficiary meets any of the following specific criteria:

- a. Beneficiary has treatment failure of at least two other Highly Active Antiretroviral Therapy (HAART) regimens;
- b. Beneficiary has limited or no other treatment options available to them due to resistance or treatment intolerance and they must be failing to achieve adequate virologic suppression on their current regimen;
- c. The assay is used to confirm CCR5-tropic HIV-1 infection prior to initiation of CCR5 co-receptor antagonist;
- d. Viral load is at least 1,000 copies/ml; or
- e. Assay may be considered for a beneficiary exhibiting virologic failure on a CCR5 coreceptor antagonist.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC 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 and NCHC 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 both Medicaid and NCHC

Medicaid and NCHC shall not cover HIV tropism (phenotypic) assay for all of the following:

- a. the beneficiary does not meet the specific criteria in **Subsection 3.2** of this policy;
- b. when using other HIV co-receptor (genotypic) assay techniques; and
- c. to predict disease progression (irrespective of co-receptor antagonist treatment).

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 - 1. No services for long-term care.
 - 2. No nonemergency medical transportation.
 - 3. No EPSDT.
 - 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

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 and NCHC shall not require prior approval for HIV tropism (phenotypic) assay.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

5.3 Testing Requirements

CCR5 co-receptor antagonist provides a novel mechanism to inhibit the HIV viral replication cycle. HIV tropism (phenotypic) assay can help determine whether a CCR5 co-receptor antagonist may be an appropriate drug for the beneficiary.

Testing must be ordered by a qualified treating physician or other qualified treating non-physician practitioner acting within the scope of their license and in compliance with NCHC requirements.

Note: HIV Tropism testing with a highly sensitive tropism (phenotypic) assay is required for the appropriate use of a CCR5 co-receptor antagonist.

5.4 Limitations

Medicaid and NCHC will cover a maximum of 1 unit (test) per 12-month period.

6.0 Providers 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 or NCHC 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).

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 2009

Revision Information:

Date	Section Revised	Change
1/1/2009	Throughout	Initial promulgation.
7/1/2010	Throughout	Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.
8/1/2011	Sections 1.0, 3.0, 4.0, 5.0, 6.0, 7.0	Updated standard DMA Policy template language.
8/1/2011	Section 1.0, Subsection 5.2	Added “ Note: Tropism testing with a highly sensitive tropism phenotypic assay is required for the appropriate use of a CCR5 co-receptor antagonist.”
8/1/2011	Subsection 4.2	Deleted has a viral load less than 1,000 copies/ml and added (a) the recipient does not meet the specific criteria in Subsection 3.2 of this policy, (b) when using other HIV co-receptor (genotypic) assay techniques; and (c) to predict disease progression (irrespective of co-receptor antagonist treatment). Deleted note to refer for Subsection 3.2 for specific criteria when covered.
8/1/2011	Subsection 5.2	Deleted A. Added HIV and (phenotypic)
8/1/2011	Sections 1.0, 3.0, 4.0, 5.0, 6.0, 7.0	Updated standard DMA Policy template language.
3/12/2012	Throughout	To be equivalent where applicable to NC DMA’s Clinical Coverage Policy # 1S-2 under Session Law 2011-145, § 10.41.(b)
3/12/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
08/01/2014	All Sections and Attachments	Updated policy template language
08/15/2014	Attachment A: C	Added: “ Note: Providers must bill 042 on claim as the primary diagnosis along with either V09.90 or V09.91 as the secondary diagnosis.”
08/15/2014	Attachment A: C	Removed Revenue Codes as part of template update.
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.
03/15/2019	Table of Contents	Added, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.”

Date	Section Revised	Change
03/15/2019	All Sections and Attachments	Updated policy template language.
01/03/2020	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.”
01/03/2020	Attachment A	Added, “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines”.

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 and NCHC:

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.

ICD-10-CM Code(s)
B20
Z1624
Z1630
Z1633

Note: Providers must bill B20 on claim as the primary diagnosis along with one of the following as the secondary diagnosis: Z1624, Z1630; or Z1633.

C. Code(s)

Provider(s) shall select 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), ICD-9-CM procedure codes, 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.

CPT Code(s)
87999

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

1 unit = 1 test

F. Place of Service

Inpatient, Outpatient, Physician's office.

G. Co-payments

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

For NCHC refer to NCHC State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

H. Reimbursement

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

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