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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 co-receptors 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 recipient's HIV genome to make HIV particles specific to the individual recipient. 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 recipient's viral tropism.

A CCR5 co-receptor antagonist is indicated for combination antiretroviral treatment of a recipient 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.

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).

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).

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 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service. EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

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 recipients 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 clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/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 recipient'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 recipient's right to a free choice of providers.

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

- a. that is unsafe, ineffective, or experimental/investigational.
- b. 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/or 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 will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/basicmed/>

EPSDT provider page: <http://www.ncdhhs.gov/dma/epsdt/>

3.0 When the Procedure, Product, or Service Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

3.1 General Criteria

Medicaid covers procedures, products, and services related to this policy when they are 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 recipient'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 recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Medicaid covers HIV tropism (phenotypic) assay when any of the following criteria are met:

- a. Recipient has treatment failure of at least two other Highly Active Antiretroviral Therapy (HAART) regimens;
- b. Recipient 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 recipient exhibiting virologic failure on a CCR5 co-receptor antagonist.

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

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health

in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily 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

HIV tropism (phenotypic) assay is not covered for all of the following:

- 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).

5.0 Requirements for and Limitations on Coverage

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

5.1 Prior Approval

Prior approval is not required.

5.2 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 recipient.

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 Medicaid requirements.

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

5.3 Limitations

Medicaid will reimburse for up to 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 procedures, products, and services related to this policy, providers shall

- a. meet Medicaid's qualifications for participation;
- b. be currently enrolled with N.C. Medicaid; 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.

7.0 Additional Requirements

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

7.2 Hospital Inpatient Testing

Payment to the hospital includes all necessary laboratory services.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 2009

Revision Information:

Date	Section Revised	Change
1/1/2009	Throughout	Initial promulgation
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)

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

ICD-9-CM Code	Description
V09.90	Infection with drug-resistant microorganisms, unspecified; without mention of multiple drug resistance
V09.91	Infection with drug-resistant microorganisms, unspecified; with multiple drug resistance
042	Human immunodeficiency virus [HIV] disease

C. Procedure Code(s)

CPT Code	Description
87999	Unlisted microbiology procedure

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

1 unit = 1 test

F. Place of Service

Inpatient, outpatient, physician's office

G. Co-Payments

Co-payment is not required for HIV tropism assay.

H. Reimbursement

Providers must bill their usual and customary charges.