

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

The specialty pharmacy program implementation for hemophilia drugs was mandated by the General Assembly [Session Law 2012-142, Section 10.48. (a2)]. Based on that mandate, the following applies to NC Medicaid (Medicaid) and NC Health Choice (NCHC) covered hemophilia drugs. Pharmacy providers furnishing hemophilia drugs or services to Medicaid and NCHC beneficiaries with a diagnosis of hemophilia or blood clotting factor related diseases shall follow all clinically appropriate standards of care.

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

The Medicaid and NCHC Outpatient Pharmacy Programs cover hemophilia drugs when they meet the following guidelines which are the same as other prescribed drugs:

- a. The prescribed drug must have Federal Drug Administration (FDA) approved indications.
- b. The prescribed drug must bear the federal legend statement.
- c. A legend drug must be manufactured by a company that has signed a National Medicaid Drug Rebate Agreement with the Centers for Medicare and Medicaid Services (CMS).
- d. The prescription must be written for whom the claim is billed.

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

None Apply.”

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 Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Prior approval is not required.

5.2 Initial and Annual On-Site Assessment

An initial and subsequent yearly on-site assessment must be performed by an individual trained in blood clotting factor related diseases. All materials used in training must be made available to NC Medicaid, or its designee upon request. A nurse or pharmacist is preferred for these assessments but not required. This written assessment shall be of the beneficiary, family or caregiver, and the beneficiary's home environment.

- a. Initial On-Site Assessment Report. An initial on-site assessment shall be conducted within 30 calendar days of first dispensing of a blood clotting factor drug to a new beneficiary. The provider shall determine any client specific needs, including any education needed to optimize self-care, and a physical inventory of factor products in the home shall be taken. All recordings of the details of the visit shall be kept as an initial assessment report.
- b. Annual On-Site Assessment Report. An annual on-site assessment for each beneficiary shall be conducted. The provider shall determine any client specific needs, address compliance and adherence issues, provide education as needed to optimize self-care, and conduct a physical inventory of the in-home factor product. All recording of the details of the visit shall be kept as an annual assessment report.

5.3 Monthly Contact Record

The provider shall maintain telephone contact with the beneficiary, family or caregiver, at least monthly, and record the details of each conversation as a contact record. These records may be required to be provided on a quarterly basis to NC Medicaid and/or its designee.

The following items must be assessed monthly and documented within the contact record, a signed and dated written log organized by beneficiary:

- a. beneficiary's compliance/adherence and persistence with treatment plan;
- b. factor utilization and infusion logs;
- c. each incidence of adverse events, including number of reported bleeds and infusions since the previous shipment and level of care needed to treat or resolve the event (i.e., provider visit, Emergency Department (ED) visit, hospitalization). The provider shall use information from the prior shipment as well as beneficiary self-report of factor utilization to validate the need for additional product or non-compliance with the treatment plan;
- d. any scheduled medical or dental procedures in the upcoming month. The provider shall coordinate with the hemophilia product prescriber of the upcoming procedures and obtain a prescription for any change in hemophilia product(s) orders that may be needed;
- e. each incidence of supply or equipment malfunctions;

- f. product quantity and inventory management including the dates of the home inventory check of factor and supplies and the beneficiary's current stock (including earliest expiration date). The provider shall discourage stockpiling of product;
- g. the beneficiary's expected next product delivery date.

Additionally, the pharmacist shall discuss and/or review on a monthly basis the information available with the beneficiary's medical provider and/or medical record in order to evaluate available medication fill history, laboratory data, and provider, emergency department, and hospital visit histories with the goal of identifying potential interactions, duplicate therapy, contraindications, or opportunities to optimize medication therapy. When opportunities to optimize therapy, untreated or unresolved adverse events, and upcoming medical/dental procedures are identified, the pharmacist shall communicate this information to relevant providers (i.e., primary care provider/medical home and/or specialist(s)). The pharmacist shall also collaborate and coordinate with the beneficiary's medical providers and care managers on care provided to the beneficiary, as needed.

5.4 Assay Management

A provider shall perform assay management. Variance in assay to prescription or target dose must not exceed +/- 5% in aggregate for all prescriptions dispensed within the reporting period regardless if the order from the licensed physician provides an assay range exceeding 5%. Providers shall have a policy and procedure describing their assay management program that must be provided to NC Medicaid or its designee upon request.

5.5 Delivery of Services

A provider delivering blood clotting supplies and services to a location requested by beneficiary that has been determined by the pharmacy provider to be appropriate and safe must render the service as follows:

- a. Routine orders from established beneficiaries must be correctly filled and delivered within 48 hours from the time the order is placed or within 48 hours of an agreed upon dispensing date.
- b. The full range of commercially available concentrates, including all commercially available assays and vial sizes.
- c. Shipments and deliveries of blood clotting factor. Providers must use appropriate cold chain management and packaging practices to ensure proper temperature, drug stability, integrity, and efficacy are maintained during shipment or delivery.
- d. Emergency delivery of blood clotting factor. When a physician authorizes an emergency fill for a hemophilia drug, the pharmacy provider shall dispense and ship the drug within 12 hours for receipt by the beneficiary no later than 18 hours.

5.6 Ancillary Supplies

A provider shall dispense and deliver all medically necessary ancillary products and supplies required for the administration of blood clotting factor used in the treatment of hemophilia and other congenital bleeding disorders including:

- a. Supplies needed to perform the actual intravenous administration of the clotting factor.
- b. Sharps containers and any other necessary biohazards waste containers.
- c. Provide for the pickup and disposal of waste containers according to national, state and local bio hazardous waste ordinances.

5.7 Emergency Support

A provider shall provide 24-hour, 7-day-a-week emergency telephone support to ensure that beneficiaries are directed appropriately for care in emergency situations.

Providers shall assist beneficiaries and caregivers with developing emergency plans for beneficiary access to factor treatments in case of emergency, whether it occurs at school, home, work, or while traveling.

Providers shall have a plan in place to meet delivery requirements in the event of a natural disaster.

5.8 Beneficiary Education

Providers shall discuss or provide educational information about congenital bleeding disorders, self-care, and treatment to beneficiaries and their family or caregivers to support awareness and promote compliance with treatment.

5.9 Product Recalls and Withdrawals

A provider shall handle product recalls and withdrawals of hemophilia medication as follows:

- a. Any stock of recalled hemophilia product shall be removed from the pharmacy's inventory.
- b. Beneficiaries shall be notified within 24 hours of any recall affecting hemophilia products dispensed to them and recalled hemophilia product dispensed to a beneficiary shall be retrieved.
- c. The prescribing physician shall be notified within 24 hours of a hemophilia product recall and a prescription for an alternative product shall be obtained, if necessary.
- d. Participation in the Patient Notification System for the plasma-derived recombinant analog industry is required.

5.10 Discontinuation of Services

Prior to a pharmacy provider discontinuing a beneficiary's hemophilia drugs or services, the provider shall:

- a. coordinate the beneficiary's care with another provider qualified to provide hemophilia services within 10 business days; or
- b. continue to provide services and supplies to a beneficiary until the beneficiary obtains an alternate source of services and supplies.

Note: When a provider has been unsuccessful and has exhausted all alternatives to link the beneficiary with a new pharmacy provider qualified to provide hemophilia drugs or services within 10 business days, the provider or the beneficiary may contact the NC Medicaid Pharmacy Program for assistance.

5.11 Provider Accreditation

To provide hemophilia drugs to Medicaid or NCHC beneficiaries, a pharmacy provider shall have a current national accreditation as a specialty pharmacy by one of the following organizations:

- a. Utilization Review Accreditation Commission (URAC)
- b. Accrediting Commission for Health Care (ACHC)
- c. The Joint Commission (TJC)

Pharmacy providers who are dispensing hemophilia medications to beneficiaries prior to the effective date of this policy have one year to obtain accreditation. Pharmacy providers who are not dispensing hemophilia medications to beneficiaries prior to the effective date of this policy must be accredited prior to initiating factor product dispensing and hemophilia related care for NC Medicaid and NC Health Choice beneficiaries.

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 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).

7.2 Quarterly Reporting Requirements

NC Medicaid will determine and refine reporting requirements. NC Medicaid's designee may monitor any or all of the following on a quarterly basis, (at least every three months) for providers dispensing hemophilia drugs to NC Medicaid and NC Health Choice beneficiaries:

- a. beneficiaries receiving service, including the number of active, new and pending beneficiaries, and the monthly and yearly reports related to each beneficiary;
- b. dispensed hemophilia drugs per beneficiary;
- c. provided supplies and other hemophilia-related services (i.e. nursing care) per beneficiary;
- d. assay management summary per beneficiary;
- e. status of any hemophilia drug recall;
- f. report of adverse event(s) and level of care needed to treat/resolve event(s) for each beneficiary;
- g. distribution accuracy, errors, and failures including missed 48-hour delivery windows
- h. dispensing accuracy and errors, including label and dispensing accuracy, drug, dosage, and dosage form;
- i. inquiry and complaint statistics including number and type of inquiries;
- j. written, verbal, and electronic communication(s) sent to provider(s) regarding opportunities to optimize therapy, untreated/unresolved adverse events, and upcoming medical or dental procedures.
- k. any quarterly report deemed necessary by NC Medicaid and/or its designee. Any changes required for quarterly reporting will be communicated in the monthly NC Medicaid Pharmacy Newsletter and/or by email to hemophilia providers at least one quarter prior to the start of the quarter the changes are required.

7.3 Pharmacy Audits

The designee appointed by NC Medicaid shall facilitate, monitor, and provide feedback to NC Medicaid regarding providers' compliance with this policy to ensure clinically appropriate services are being provided to beneficiaries. The designee shall work closely with NC Medicaid to determine appropriate corrective action including education, other types of support and care coordination, or referral to Program Integrity.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 31, 2013

Revision Information:

Date	Section Revised	Change
01/31/2013	All sections and attachment(s)	New coverage policy for Medicaid and NCHC.
06/21/2013	Section 8.0	Added Original Effective Date: "January 31, 2013"
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.
02/01/2019	All Sections and Attachments	Removed all reference to CCNC; replaced CCNC with NC Medicaid's designee. Updated DMA to NC Medicaid
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."
03/15/2019	All Sections and Attachments	Updated policy template language.
01/12/2020	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."
01/12/2020	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

D Claim, NCPDP Claim Format.

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)

Not Applicable.

C. Code(s)

Not Applicable.

D. Modifiers

Not Applicable.

E. Billing Units

Microgram, milligram or unit(s).

F. Place of Service

Not Applicable.

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>

The pharmacy provider shall not present any bill or collect any monies for a covered NC Medicaid or NC Health Choice Beneficiary with whom the provider agreed to the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia, except as follows:

- a. collect the copayment/coinsurance amounts the beneficiary is required to pay under the terms defined by Medicaid or NCHC; or
- b. when the service/product is deemed “non-covered” and the beneficiary has been notified in advanced.

H. Reimbursement

Reimbursement information for the Hemophilia Specialty Pharmacy Program is available on NC Medicaid’s Outpatient Pharmacy Program website at: <https://medicaid.ncdhhs.gov/>.