Clinical Policy: Home Infusion Therapy

Reference Number: WNC.CP.224 Coding Implications
Last Review Date: Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description[1]

This policy describes the medical necessity criteria for Home Infusion Therapy (HIT).

Policy/Criteria[1]

I. It is the policy of WellCare of North Carolina® that HIT is covered as follows:

A. Program Criteria
1. The service can be furnished safely in the living environment.
2. The beneficiary's clinical status is stable as determined by the attending physician.
3. The service is provided in the beneficiary's private residence or in an adult care home (such as a domiciliary care or family care home).
4. The treatment is self-administered.
Note: "Self-administered" is defined as a beneficiary or an unpaid primary caregiver who is able and willing to administer the therapy following teaching and with monitoring.

B. Medical Necessity Criteria
1. HIT services must be medically necessary for the treatment of a beneficiary's illness, injury, or medical condition as documented by the physician who orders the service. The beneficiary must be under the care of the referring physician.

C. Drug Therapies
1. The treatment is self-administered.
2. The beneficiary's medical condition supports the safe administration of the therapy in the home.
3. The beneficiary has an available site for the administration of the therapy.
4. The physician has determined that the need for HIT infusion of a drug is appropriate for at least one of the reasons stated below:
   a. HIT is more effective than oral or injectable administration.
   b. The medication is not available in an oral form.
   c. The medication cannot be tolerated orally.

Note: Drug therapy services include equipment, supplies, delivery of these items, and any nursing services needed to teach, monitor, and assist the beneficiary. The drug is reimbursed separately through the Outpatient Pharmacy program as a prescription drug. The drug therapies covered by the program include the following:

- intravenous chemotherapy;
- intravenous antibiotic therapy;
- pain management therapy (including subcutaneous, epidural, intrathecal, and intravenous pain management therapy).

D. Total Parenteral Nutrition Therapies

1. The beneficiary has a medical condition that prohibits adequate oral intake of nutrients, including the inability to ingest, tolerate and absorb sufficient oral nourishment to maintain or improve health status.
2. The beneficiary has an available site for the administration of the therapy.

Note: Nutrition therapy services include:

- the rental or purchase of pumps used for TPN and the IV pole ordered by the physician;
- formulae/solutions ordered by the physician;
- medical supplies ordered by the physician;
- the cost of delivery of supplies and items to the beneficiary's residence.

E. Enteral Nutrition Therapies

1. The beneficiary has a functioning gastrointestinal tract but with the inability to physically ingest or tolerate adequate oral intake of nutriments to maintain or improve health status.
2. The beneficiary has an available site for the administration of the therapy.

Note: Oral nutrition and supplements are not covered under this policy.

Note: Nutrition therapy services include:

- the rental or purchase of pumps used for EN and the IV pole ordered by the physician;
- formulae/solutions ordered by the physician;
- medical supplies ordered by the physician;
- the cost of delivery of supplies and items to the beneficiary's residence.

F. Infusion Nursing Services

1. Assessing the beneficiary for the appropriateness of HIT;
2. Monitoring the beneficiary;
3. Teaching the beneficiary and/or primary caregiver about the HIT administration;
4. Changing intravenous (IV) sites and dressings;
5. Drawing blood for laboratory analysis;
6. Supervising the first dose.

G. Pharmacy Services

1. Monitoring the drug therapy to ensure that the drugs and related fluids are dispensed according to the physician's plan of care (POC) and standards of practice;
2. Developing a medication history and beneficiary profile;
3. Consulting with physicians and nurses on the therapy;
4. Providing drug use evaluations;
5. Providing quality assurance; **and**
6. Procuring drugs and maintaining the inventory, reconstituting drugs, preparing dosage(s), labeling drugs, and delivering to a beneficiary's residence. The reimbursement for the drug is not included as a HIT service.

II. It is the policy of WellCare of North Carolina® that HIT is **not covered** when:

A. The service duplicates another provider's service;
B. The service is experimental, investigational, or part of a clinical trial;
C. The drug therapy is provided for services other than chemotherapy, antibiotic therapy or pain management; **and/or**
D. The beneficiary is receiving Medicare-covered home health nursing services.

Note: HIT drug therapy is not allowed for beneficiaries receiving private duty nursing. The private duty nurse or the caregiver will provide the care needed if the beneficiary is receiving only EN or TPN. Nursing services for enteral and parenteral nutrition therapies are not covered.

Background[1]

The HIT program covers self-administered infusion therapy and enteral supplies provided to a beneficiary residing in a private residence or an adult care home. Covered services include the following:

- Total parenteral nutrition (TPN)
- Enteral nutrition (EN)
- Intravenous chemotherapy
- Intravenous antibiotic therapy
- Pain management therapy, including subcutaneous, epidural, intrathecal, and intravenous pain management therapy

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
No applicable codes.	

HCPCS ®* Codes	Description
S9494	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drug and nursing visits coded separately), per diem.
S9329	Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drug and nursing visits coded separately), per diem.
S9325	Home infusion therapy, pain management infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment, (drug and nursing visits coded separately), per diem.
S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drug and nursing visits coded separately), per diem. **This code can only be used for the drug therapy termination allowance.**

HCPCS ®* Codes	Description
T1030	Nursing care, in the home, by registered nurse, per diem. **This code must be billed with each therapy code billed**
T1002 SD	RN Services, up to 15 minutes. The modifier SD denotes that the service was provided by a registered nurse with specialized, highly technical home infusion training. The modifier must be used when billing this code. **This code can be used for only RN monitoring (over 2 hours) for Amphotericin B infusion therapy.**

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
No applicable codes.	

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	04/21	05/21
HCPCS codes reviewed.	07/21	08/21
HCPCS codes reviewed.	08/22	08/22
NCHC verbiage removed from NC Guidance Verbiage	04/23	04/23
Annual review. Added billing information for S9379 T1030 T1002SD.		

References

1. State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No: 3H-1 Home Infusion Therapy. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov) . Published January 6, 2020. Accessed May 16, 2023.

North Carolina Guidance

Eligibility Requirements

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.

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.

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/

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.

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).

Claims-Related Information
Provider(s) shall comply with the NC Tracks 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 - as applicable to the service provided:
   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.
   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 - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:

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

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.