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1.0 Description of the Procedure, Product, or Service

The Physician's Drug Program (PDP) covers many, but not all, primarily injectable drugs that are purchased and administered in a physician's office or in an outpatient clinic setting. Intravenous (IV) iron solutions are covered through the PDP.

Intravenous iron (IV iron) solutions are products that restore the body's elemental iron supply in recipients with iron deficiency anemia. IV iron products are used in the treatment of iron deficiencies resulting from a variety of medical conditions. This policy addresses commercially available IV iron preparations administered for conditions typically treated in an outpatient setting.

There are several commercial IV iron products available including DexFerrum®, Feraheme™, Ferrlecit®, INFeD®, and Venofer®.

2.0 Eligible Recipients

2.1 General Provisions

NC Medicaid (Medicaid) recipients must be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) recipients, ages 6 through 18 years of age, must be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

2.2 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 meets all EPSDT criteria, including to 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 and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid and NC Health Choice Billing Guide:

<http://www.ncdhhs.gov/dma/basicmed/>

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

2.3 Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Recipients 6 through 18 Years of Age

EPSDT does not apply to NCHC recipients. If a NCHC recipient does not meet the clinical coverage criteria within **Section 3.0** of the clinical coverage policy, the NCHC recipient will be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes will be covered for NCHC recipients.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

3.1 General Criteria

Procedures, products, and services related to this policy are covered 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

3.2.1 Covered Indications

In the PDP, all indications approved by the Food and Drug Administration (FDA) are covered unless otherwise specified. In addition, off-label uses of an approved drug may be covered if the data on drug use are consistent with the compendia and peer-reviewed medical literature, according to 42 U.S.C. 1396r-8(g)(1)(B), and as determined by DMA.

Note: Injectable medications are covered only when oral medications are contraindicated.

3.2.2 Iron Dextran (INFeD or DexFerrum)

Medicaid and NCHC cover Iron dextran for the FDA-approved ages – 4 months of age and older.

a. FDA-approved Indication

Medicaid and NCHC cover Iron dextran for the following FDA-approved indication:

1. iron deficiency anemia for recipients in whom a trial period of oral iron was documented ineffective or infeasible.

b. Off-Label Indications

Medicaid and NCHC cover Iron dextran for the all of the following off-label indications:

1. iron deficiency anemia in hemodialysis-dependent chronic kidney disease;
2. recipients (HDD-CKD) with epoetin therapy;
3. iron deficiency anemia in peritoneal dialysis-dependent chronic kidney disease;
4. recipients (PDD-CKD) with epoetin therapy;
5. iron deficiency anemia in non dialysis dependent chronic kidney disease;
6. recipients (NDD-CKD) with or without epoetin therapy;
7. iron deficiency anemia from excessive uterine blood loss or pregnancy;
8. iron deficiency anemia of cancer and cancer chemotherapy;
9. iron deficiency anemia with comorbid heart failure;
10. iron repletion for autologous blood transfusions;
11. gastrointestinal (GI) blood loss with iron deficiency; and
12. disorders of iron metabolism.

Note: Documentation must reflect the ineffectiveness or infeasibility of oral iron.

3.2.3 Iron Sucrose (Venofer)

Medicaid and NCHC cover Iron sucrose for the FDA-approved ages – 18 years of age and older.

a. FDA-Approved Indications

Iron sucrose is covered for all of the following FDA-approved indications:

1. iron deficiency anemia in hemodialysis-dependent chronic kidney disease recipients (HDD-CKD) with epoetin therapy;
2. iron deficiency anemia in peritoneal dialysis-dependent chronic kidney disease recipients (PDD-CKD) with epoetin therapy; and
3. iron deficiency anemia in non-dialysis dependent chronic kidney disease recipients (NDD-CKD) with or without epoetin therapy.

b. Off-Label Indications

Medicaid and NCHC cover Iron sucrose for all of the following off-label indications:

1. iron deficiency anemia from cancer and cancer chemotherapy;
2. iron deficiency anemia of excessive uterine blood loss or pregnancy;
3. iron deficiency with comorbid heart failure;
4. iron repletion for autologous blood transfusions;
5. gastrointestinal (GI) blood loss with iron deficiency;
6. disorders of iron metabolism; and
7. iron deficiency where oral treatment is ineffective or infeasible.

Note: Documentation must reflect details of the ineffectiveness or infeasibility of oral iron.

3.2.4 Sodium Ferric Gluconate Complex in Sucrose (Ferrlecit)

Medicaid and NCHC cover Sodium ferric gluconate complex in sucrose for the FDA-approved ages – 6 years of age and older.

a. FDA-Approved Indication

Medicaid and NCHC cover Sodium ferric gluconate complex in sucrose for the following FDA-approved indication:

1. iron deficiency anemia in recipients undergoing chronic hemodialysis (HDDCKD) who are receiving epoetin therapy.

b. Off-Label Indications

Medicaid and NCHC cover Sodium ferric gluconate complex in sucrose for all of the following off-label indications:

1. iron deficiency anemia in recipients with chronic kidney disease who are on peritoneal dialysis (PDD-CKD);
2. iron deficiency anemia in recipients who are non-dialysis dependent with chronic kidney disease (NDD-CKD);
3. iron deficiency anemia of excessive uterine blood loss or pregnancy;
4. iron deficiency anemia in recipients with cancer or who have chemotherapy- associated anemia;
5. iron deficiency anemia with comorbid heart failure;
6. iron repletion for autologous blood transfusions;
7. gastrointestinal (GI) blood loss with iron deficiency;
8. disorders of iron metabolism; and
9. iron deficiency where oral treatment is ineffective or infeasible.

Note: Documentation must reflect details of the ineffectiveness or infeasibility of oral iron.

3.2.5 Ferumoxytol (Feraheme)

Ferumoxytol is covered for the FDA-approved ages – 18 years of age and older.

a. FDA-Approved Indications

Ferumoxytol is covered for all of the following FDA-approved indications:

1. iron deficiency anemia in adult recipients who are hemodialysis dependent with chronic kidney disease (HDD-CKD);
2. iron deficiency anemia in adult recipients who are non-dialysis dependent with chronic kidney disease (NDD-CKD); and
3. iron deficiency anemia in adult recipients who are peritoneal dialysis dependent with chronic kidney disease (PDD-CKD).

b. Off-Label Indications

No off-label indications for ferumoxytol are covered. Refer to **Subsection 4.2.f.**

3.2.6 Dosage Recommendations for IV Iron Products

Medicaid and NCHC cover iron products for infusion according to their individualized recommendations published by the FDA and compendia and peer-reviewed medical literature, according to 42 U.S.C. 1396r-8(g)(1)(B), and as determined by DMA.

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

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

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 Non-Covered Criteria

Medicaid and NCHC do not cover IV Iron therapy for a recipient who does not meet the criteria in **Section 3.0** including the following:

- a. IV iron is contraindicated in recipients with anemias not caused by iron deficiency.
- b. IV iron is contraindicated in recipients with iron overload.
- c. IV iron sucrose is contraindicated in recipients with known hypersensitivity to iron.
- d. sucrose or any of its inactive components. Contraindication is related to iron sucrose.
- e. (Venofer) products.
- f. IV iron dextran is contraindicated in recipients with known hypersensitivity to dextran. Contraindication is related to iron dextran (INFeD, DexFerrum) products.
- g. IV sodium ferric gluconate complex in sucrose is contraindicated in recipients with known hypersensitivity to sodium ferric gluconate complex in sucrose (Ferrlecit) or any of its inactive components. Contraindication is related to sodium ferric gluconate complex in sucrose (Ferrlecit) products.
- h. off-label indications for ferumoxytol.

4.3 NCHC Non-Covered Criteria

Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Health Choice program shall be equivalent to coverage provided for dependents under the NC Medicaid Program except for the following:

- a. no services for long-term care;
- b. no non-emergency medical transportation;
- c. **no EPSDT**; and
- d. dental services shall be provided on a restricted basis.

4.4 Medicaid Non-Covered Criteria

No additional non-covered criteria.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

5.1 Prior Approval

Prior approval is not required for Medicaid and NCHC recipients.

5.2 Limitations

Providers who determine that the indications or dosing for a particular IV iron product is medically necessary for a recipient, but those parameters fall outside of the guidelines for that drug, may submit medical record information to the DMA Assistant Director for Clinical Policy and Programs for a case-by-case review. The address to send this information is:

Assistant Director for Clinical Policy and Programs
Division of Medical Assistance
2501 Mail Service Center
Raleigh, NC 27699-2501

5.3 Medical Record Documentation

Documentation in the recipient's medical record must include all of the following elements:

- a. support for the medical necessity of the IV iron therapy injection;
- b. a covered diagnosis;
- c. a trial period of oral iron was ineffective or infeasible;
- d. dosage and frequency of the doses administered;
- e. support of the clinical effectiveness of the IV iron therapy; and
- f. specific site(s) injected.

5.4 Age Range for NCHC Recipients

The age range for eligibility of NCHC recipients is 6 years through 18 years of age.

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 or NCHC qualifications for participation;
- b. be currently Medicaid - enrolled; 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

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

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.

8.0 Policy Implementation/Revision Information

Original Effective Date: September 1, 1994

Revision Information:

Date	Section Revised	Change
07/01/2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
08/1/2011	Subsection 3.2	Initial promulgation of current coverage. Added coverage for off-label indications for iron dextran, iron sucrose and ferric gluconate complex in sucrose. Removed the requirement for epoetin from Venofer and Ferrlecit.
3/1/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.

Attachment A: Claims-Related Information

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

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

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

C. Billing Code(s)

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

HCPCS Codes	Description
Q0138	Injection, ferumoxitol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)
Q0139	Injection, ferumoxitol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)
J1750	Injection, iron dextran, 50 mg
J1756	Injection, iron sucrose, 1 mg
J2916	Injection, sodium ferric gluconate complex in sucrose injection, 12.5 mg

ICD-9-CM Diagnosis Code	Description
Primary diagnosis (280.x) and a secondary diagnosis (555.x, 556.x, 579.x, V12.79)	Iron deficiency anemias where oral treatment is not suitable
275.0x	Disorders of iron metabolism
Primary diagnosis (285.22 or 285.3). Must also be billed with the ICD-9-CM code indicative of the specific malignancy for which the patient is undergoing treatment (140.0 through 239.9 except for 205.00 through 205.92 [myeloid malignancies]).	Anemia in neoplastic disease or antineoplastic chemotherapy induced anemia
Primary diagnosis (280.x) and a secondary diagnosis (626.2, 626.3, 627.0, 627.1, V22)	Iron deficiency anemias of excessive uterine blood loss or pregnancy
Primary diagnosis (285.21). Must be also billed with the appropriate chronic kidney disease ICD-9 CM code (585.2; 585.3; 585.4; 585.5; 585.6; 585.9) indicative of the patient's condition.	Anemia in chronic kidney disease
V59.01, V59.09	Iron repletion for autologous blood transfusions
Primary diagnosis (280.x) and secondary diagnosis (285.1)	Gastrointestinal (GI) blood loss with iron deficiency
Primary diagnosis (280.x) and a secondary diagnosis (425.4, 428.x)	Iron deficiency with comorbid heart failure

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

1. Ferumoxytol (Feraheme) and iron sucrose (Venofer): 1 billing unit = 1 mg.
2. Iron dextran (INFeD and DexFerrum): 1 billing unit = 50 mg.
3. Sodium ferric gluconate complex in sucrose (Ferrelecit): 1 billing unit = 12.5 mg.
4. Medicaid covers appropriate administration codes when billed with Q0138, Q0139, J1750, J1756, or J2916 on the same day of service.

F. Place of Service

Outpatient, Office.

G. Co-payments

Medicaid recipients 21 years of age and older may be subject to co-payment for office visits.

NCHC recipients may be subject to co-payment for office visits.

H. Reimbursement

Providers shall bill their usual and customary charges.

Providers are required to bill applicable revenue codes.

For a schedule of rates, see: <http://www.ncdhhs.gov/dma/fee/>.