

**This policy is being terminated for no utilization. Medicaid covers codes in the same manner as Health Choice. This does not impact the State's treatment of lead poisoning which has a separate policy.**

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## **1.0 Description of the Procedure, Product, or Service**

Chelation therapy is the use of chelating agents, such as edetate calcium disodium (EDTA), dimercaprol, deferoxamine, penicillamine, and succimer, to rid the body of toxic levels of iron, lead, or other heavy metals. After the chelating agent is introduced into the body, it takes the metal from the organs or tissues and binds it firmly to a new compound that can be eliminated from the body. In cases of severe poisoning, a process of parenteral infusion of the chelating agents (for example: EDTA, dimercaprol, or deferoxamine) is used to speed up the elimination process. Chelating agents may be given by mouth or by parenteral infusion.

### **1.1 Medical Term Definitions**

- a. Digitalis: a drug that strengthens the contraction of the heart muscle, slows the heart rate and promotes the elimination of fluid from body tissues. It is often used to treat congestive heart failure, some kinds of congenital heart defects, and also to treat certain arrhythmias. It is derived from the foxglove plant.
- b. Genetic: hereditary; transferred through the genes from parent to child.
- c. Hereditary: the genetic transfer of a specific trait from parent to offspring.
- d. Parenteral: not through the digestive tract but by injection through some other route (Example: intramuscular, intravenous or subcutaneous).
- e. Parenteral infusion: process of injecting a solution into the vein.
- f. Phlebotomy: needle puncture of a vein to withdraw blood.
- g. Subcutaneous: under the skin.
- h. Ventricular arrhythmias: a cardiac arrhythmia that originates within the ventricles (chambers) of the heart.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

To be eligible, NCHC recipients must be enrolled on the date of service.

## **3.0 When the Procedure, Product, or Service Is Covered**

### **3.1 General Criteria**

NCHC 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; **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

Chelation therapy may be covered by the NC Health Choice Program when the following criteria are met:

Parenteral chelation therapy may be considered medically necessary for the treatment of documented systemic iron overload (hemochromatosis), lead poisoning, or other heavy metal toxicity as defined below:

- a. Hemochromatosis: Clinical symptoms of chronic iron toxicity should correlate with an elevated serum ferritin. Parenteral chelation therapy is not medically necessary in genetic or hereditary hemochromatosis. Subcutaneous infusion of desferoxamine via a portable pump may be considered medically necessary for acquired hemochromatosis complicating a chronic hemolytic anemia such as thalassemia or sideroblastic anemia or when hypoproteinemia precludes phlebotomy as treatment.
- b. Acute iron poisoning: Parenteral deferoxamine is medically necessary in recipients with serum iron level greater than 50umol/L (300ug/dL) or in whom a deferoxamine challenge test is positive.
- c. Lead: parenteral chelation therapy may meet medical necessity requirements in adults with blood lead levels greater than 1.7umol/L (35ug/dL) or in children with levels greater than 25 ug/dL. Parenteral EDTA and/or dimercaprol may be allowed until blood lead levels decrease (usually one to two 5-day courses of therapy).
- d. Other heavy metals: arsenic, cadmium, gold, mercury, and thallium poisoning are generally suspected based upon a positive urine screen for heavy metals in a symptomatic recipient. Toxic levels should be confirmed with blood levels where appropriate. Parenteral chelation agents are not always appropriate and should be reviewed for approved indications against the specific heavy metal identified.
- e. Parenteral chelation therapy may also be medically necessary for the following indications:
  1. Control of ventricular arrhythmias or heart block associated with digitalis toxicity
  2. Emergency treatment of hypercalcemia
  3. Wilson's Disease (Hepatolenticular degeneration)

### 3.3 Policy Guidelines

In general, parenteral chelation therapy is short term. Home parenteral chelation therapy may be allowed in sub-acute situations; for example, thalassemia, where therapy is likely to be lengthy and hospitalization is not required.

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

### **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 or investigational.

### **4.2 Specific Criteria**

Chelation therapy is considered investigational and non-covered by the NC Health Choice Program when used to treat the following conditions:

- a. Peripheral arterial occlusive disease
- b. Heavy metal toxicity or iron or lead poisoning where toxic levels are not documented by standard testing methods
- c. Multiple sclerosis
- d. Arthritis
- e. Hypoglycemia
- f. Diabetes
- g. Arteriosclerosis
- h. Other indications not listed.

## **5.0 Requirements for and Limitations on Coverage**

### **5.1 Prior Approval**

Prior approval is not required for chelation therapy.

### **5.2 Documentation Requirements**

Laboratory results must be provided by a certified lab.

## **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 NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **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

### 7.1 Compliance

Providers must 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: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
February 29, 2012	Throughout	Policy Termination

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P transaction)

### B. Diagnosis Codes

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

### C. Procedure Code(s)

HCPSC Codes
J0470
J0600
J3520
S9355

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

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

### F. Place of Service

Outpatient Hospital, Office and Home

### G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

### H. Reimbursement

Providers must bill their usual and customary charges.