

# UPMC Health Plan POLICY AND PROCEDURE MANUAL

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**PAGE NUMBER: 1 of 7**

**SUBJECT:** Chelation Therapy  
**INDEX TITLE:** Medical Management  
**ORIGINAL DATE:** April 2006

**This policy applies to the following lines of business: (Check those that apply.)**

<b>Commercial:</b>					
HMO ( )		POS ( )		PPO ( )	
Fully Insured ( )		Self-funded/ASO ( )		HSA ( )	
Medicare Select ( )		Medicare Supplement ( )			
<b>DPW-MA:</b>					
Health Choices ( )			Voluntary ( )		All ( X )
<b>CMS-MA:</b>					
OH ( )		WV ( )		PA ( )	All ( X )
HMO ( X )	PPO ( X )	Specialty Needs Plan ( X )		Part D ( )	PFFS ( )
<b>PID-CHIP:</b>					
Free ( )			Sub ( )		All ( X )
<b>APPLICABLE TO:</b>					
Community Care ( )			Work Partners ( )		

## I. POLICY

It is the policy of UPMC Health Plan to cover Chelation Therapy when it is medically necessary as detailed in this policy and covered under the member's specific benefit plan.

## II. DEFINITIONS

**Hemochromatosis:** A rare genetic disease that results in the overabundance of iron to the liver, brain, heart and kidneys causing dysfunction, diabetes, changes in skin pigmentation, heart problems, arthritis and testicular atrophy.

**Sickle Cell Disease:** An inherited genetic disorder that causes red blood cells to take on a characteristic crescent or sickle-like shape with decreased ability to carry oxygen.

**Sideroblastic Anemia:** A condition in which there is excess iron in the bone cells.

**Thalassemia Intermedia:** A genetic form of anemia in which there is an abnormality in the oxygen carrying portion of red blood cells.

**Wilson's Disease:** An inherited (autosomal recessive) disorder where excessive quantities of copper build up in the body, particularly in the liver and central nervous system.

### III. PURPOSE

The purpose of this policy is to define the indications for coverage of Chelation Therapy with chelating agents that are FDA approved.

### IV. SCOPE

This policy applies to various UPMC Health Plan Departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

### V. PROCEDURE

#### A. Medical Description

Chelation Therapy involves the administration of drugs that bind heavy metal ions such as lead, arsenic, iron and mercury in the blood stream preventing their interaction with vital organs, which include the nervous system and kidneys. Such drugs are known as chelating agents. The presence of heavy metals in the blood stream can be the result of several factors including environmental exposure. Additionally, many medical conditions may lead to excess iron in the blood stream causing health problems.

Chelation therapy has been proposed as a treatment for the removal of heavy metal ions to reduce cellular oxidative damage caused by the production of hydroxyl radicals. This therapy is being investigated for the treatment of numerous non-over-load conditions, including, cardiovascular disease, reperfusion injury during coronary angioplasty or cardiopulmonary bypass surgery, anthracycline-associated cardiac damage, Alzheimer's disease, Autism and rheumatoid arthritis. Specific chelation agents are used to treat certain kinds of poisonings.

Common chelating agents include:

1. **Desfuroxamine Mesylate:** used for acute iron toxicity, and acute iron intoxication and chronic iron overload due to transfusion-dependent anemias. Intravenous preferred.
2. **Dimercaprol (BAL):** indicated in the treatment of arsenic, gold and mercury (soluble inorganic compounds) poisoning, and as an adjunct in the treatment of lead toxicity, given intramuscularly.
3. **DMSA:** an analogue of Dimercaprol that can be given orally for lead and arsenic poisoning.
4. **D-penicillamine:** an oral chelating agent used for lead, arsenic or mercury.
5. **Calcium Disodium Versante (CaNa2-EDTA):** can be used in conjunction with BAL in lead toxicity. It should never be used alone in treating lead toxicity because it chelates only extracellular and not intracellular lead.
6. **Edetate calcium disodium:** is indicated for treatment of lead toxicity. It reduces the blood concentrations and depot stores of lead, and increases urinary excretion of zinc, when therapy is continued for more than five (5) days or zinc stores are low prior to treatment. It has also been found to chelate iron, copper, calcium and manganese.

Patients with heavy metal toxicity usually require chelation therapy 2-6 times a day, for 2-5 days (depending on the level, agent, and condition of the patient). In addition, they require close monitoring of their physical signs and symptoms and heavy metal levels. Additionally chelation therapy and its resultant sequelae must be continuously monitored.

The American College of Cardiology (ACC) has stated that there is inadequate scientific evidence to justify the application of Chelation Therapy for atherosclerosis on a clinical basis.

The American Medical Association (AMA) indicates that there is no scientific documentation that Chelation Therapy is effective in the treatment of cardiovascular disease, atherosclerosis, rheumatoid arthritis and cancer.

### **B. Indications**

The administration of FDA-approved chelating agents is considered medically necessary in the treatment of **any** of the following conditions:

1. Secondary hemochromatosis due to chronic iron overload due to transfusion-dependent anemias (e.g. thalassemias, Cooley's anemia, sickle cell anemia, sideroblastic anemia).
2. Heavy metal toxicity, includes the following:
  - Lead overload in cases of acute or long-term lead exposure
  - Copper overload in members with Wilson's Disease
  - Arsenic, mercury, iron, copper or gold poisoning when long-term exposure to and toxicity has been confirmed through lab results (i.e., blood, plasma, and/or urine results) or clinical findings (i.e. symptoms consistent with metal toxicity).
  - Aluminum overload in chronic hemodialysis members
  - Emergency treatment of hypercalcemia.

**Note:** for metals not listed above, additional documentation must be maintained in the medical record.

3. Chelation therapy is covered only in places of service that can provide the level of care and monitoring required for the procedure, i.e., hospital, hospital-based ambulatory setting, outpatient hospital, emergency room, renal dialysis facilities, and skilled nursing facilities.

### **C. Limitations**

1. Chelation therapy is considered **investigational and not medically necessary** for the treatment of any of the following conditions:
  - Atherosclerosis,
  - Rheumatoid arthritis

- Cancer
  - Prevention and treatment of cardiovascular disease.
  - Peripheral vascular disease
  - Treatment of Alzheimer's Disease
  - Treatment of rheumatoid arthritis
  - Treatment of Parkinson's Disease
  - Treatment of cadmium exposure
  - Treatment of autism
  - Chemical Endarterectomy with Edetate Disodium
2. Chelation therapy is not covered in locations that cannot provide the level of care and monitoring required i.e., office setting, home setting, or certain ambulatory surgical centers, because it requires close monitoring.

#### **D. Variations**

N/A

#### **F. Quality Audit**

Quality Audit may monitor policy compliance or billing accuracy at the request of the UPMC Health Plan's Technology Assessment Committee or the Benefits Reimbursement Committee.

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