

# Medica Coverage Policy



<b>Policy Name:</b>	<b>Chelation Therapy</b>
<b>Current Policy Effective Date:</b>	1/1/2009

## Product Application

The policy applies to all fully insured Medica Health Plans, Medica Insurance Company, and Medica Health Plans of Wisconsin products, unless a specific limitation or exception exists. For self-insured plans, consult individual plan sponsor benefit documents. If there is a discrepancy between a coverage policy and a self-insured benefit plan, the provisions of the benefit plan will govern. With respect to Medicare and Medicaid members, this policy will apply unless Medicare or Medicaid policies require different coverage.

## Important Information - Please Read Before Using This Policy

Medica updates its Coverage Policies regularly, and reserves the right to amend these policies without notice to Medica members. Medica also reserves the right to amend these policies without notice to contracted health care providers unless the amendment materially alters the policy. If the amendment materially alters the policy, Medica will disclose the change to contracted health care providers not less than 45 days prior to implementation of the policy. Medica's Coverage Policies contain general information only and do not guarantee coverage. Receipt of benefits is subject to all terms and conditions of the member's coverage document. Members should consult their Certificates of Coverage or Plan Documents/Summary Plan Descriptions, to review the provisions relating to a specific coverage determination. If there is a conflict between a Coverage Policy and the applicable coverage document, the coverage document will govern. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Medica's Provider Service Center toll free at 1-800-458-5512.

Medica's Coverage Policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

## Coverage Policy

Chelation therapy, using FDA-approved chelating agents, is COVERED when used as a treatment for metal poisoning or iron overload in transfusion dependent hemoglobinopathies. Use is limited to FDA-approved indications for each chelation agent, as referenced in a generally recognized drug compendium (e.g., American Hospital Formulary Services Drug Information® or DrugDex® System). Laboratory analysis must demonstrate current metal levels greater than or equal to the listed critical values.

Chelation therapy with dexrazoxane is COVERED when used for the following FDA-approved indication: Treatment to reduce the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose equal to or greater than 300 milligrams per square meter.

Non-FDA approved indications are investigative and therefore NOT COVERED. Examples include, but are not limited to: the treatment of cardiovascular disease; re-perfusion injury incurred during coronary angioplasty or cardiopulmonary bypass surgery; mercury release from dental amalgam; rheumatoid arthritis; Alzheimer's disease; and behavior, learning, mood and thought disorders, including autism spectrum disorder.

Note: See also related Medica coverage policy Pfeiffer Treatment Center Protocols.

Note: This policy is no longer scheduled for routine review of the scientific literature.

## Description

Chelation therapy is the administration of a drug to reduce the accumulation of essential metal ions, such as iron, in organs and tissues. Chelators bind to the metal ions to form a water soluble, ring-like complex, which is then excreted in the urine or feces. Chelating agents can be administered intravenously, subcutaneously, intramuscularly, or orally. Treatment is administered in either an outpatient or inpatient setting dependent on the compound administered, route of administration, and/or clinical presentation. Several treatment sessions may be required. Baseline levels and course of treatment are monitored by blood and/or urine laboratory tests.

Chelation therapy is used for certain metal overload conditions, such as lead poisoning, and for transfusion dependent hemoglobinopathies (e.g., sickle cell anemia and the beta thalassemias). Chelation therapy reduces potentially dangerous levels of heavy metal ions within organs and tissues.

Chelation therapy is proposed as a treatment for a number of non-overload conditions in which the removal of heavy metal ions is hypothesized to reduce oxidative damage caused by production of hydroxyl radicals. Oxidation damage in non-overload conditions is a consequence of an underlying disease. Chelation therapy is under investigation for the treatment of a number of non-overload conditions, including (but not limited to) atherosclerotic cardiovascular disease (where it is also referred to as 'chemical endarterectomy/ chemoendarterectomy'), reperfusion injury during coronary angioplasty or cardiopulmonary bypass surgery, Alzheimer's disease, and rheumatoid arthritis.

## FDA Approval

Parenteral chelating agents for overload conditions:

- a. Deferoxamine/DFO (Desferal®, deferoxamine mesylate, deferoxamine B mesylate, desferrioxamine) is approved for the treatment of acute iron intoxication and chronic iron overload (e.g., thalassemia, transfusion-dependent anemias, hemoglobin sickle cell disease) in adults and children 3 years of age or older. [Administration routes: intravenous (IV), intramuscular (IM), or subcutaneous (SubQ)]
- b. Dimercaprol (BAL® in Oil) is approved for the chelation of lead, arsenic, gold, and mercury in adult and pediatric patients. [Administration route: IM]
- c. Edetate (EDTA) calcium disodium (Edetate Calcium Versenate®) is approved for chelation therapy for lead poisoning in adult and pediatric patients. [Administration routes: IV, IM, or SubQ]
- d. Edetate (EDTA) disodium (Disotate®) is approved for treatment of hypercalcemia and digitalis toxicity in adults. (Note: the mode of action in digitalis toxicity is not chelation.) [Administration route: IV]

Parenteral chelating agents for non-overload conditions: Dexrazoxane (Zinecard®, ICRF-187) is approved for: (1) non-overload treatment to reduce the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose equal to or greater than 300 milligrams per square meter, and (2) anthracycline-induced cytotoxic antibiotic adverse reaction. [Administration route: IV]

Oral chelating agents:

- a. Penicillamine (Cuprimine®, Depen®) is approved for the treatment of rheumatoid arthritis and Wilson's disease in adults and cystinuria in both adults and pediatric patients. Penicillamine is intended to be used only after failure to respond to conventional treatment regimens. (Note: the mode of action for the treatment of cystinuria and rheumatoid arthritis is not chelation.)
- b. Succimer (CHEMET®, meso-2,3-dimercaptosuccinic acid, DMSA) is approved for the treatment

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- of lead overload poisoning in adults and children over 12 months of age.
- c. Trientine (Syprine®) is approved for the treatment of adult and pediatric patients with Wilson's disease who cannot tolerate or are inadequately responsive to penicillamine.

### **Prior Authorization**

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

### **Coding Considerations**

Use the current applicable CPT/HCPCS code(s).

Decision Date: 9/18/2008  
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