Medica Coverage Policy

Policy Name:	**Chelation Therapy**
Effective Date:	**11/1/2021**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. 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 Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica 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: This policy is no longer scheduled for routine review of the scientific literature and is on Clinical Review Reserve.

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 secondary to transfusion dependent anemias (e.g., thalessemia,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 treatment of ~~acute~~ lead, arsenic, gold, and mercury poisoning 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 or IM]

Parenteral chelating agents for non-overload conditions: Dexrazoxane (Zinecard®, ICRF-187) is approved for: (1) nonoverload 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) Cytotoxic antibiotic adverse reaction, Anthracycline-induced injection site extravasation. [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 of lead poisoning in children over 12 months of age with blood levels above 45mcg/dL and for treatment of lead toxicity in adults.
c) Trientine (Syprine®) is approved for the treatment of Wilson's disease to remove excess copper from the body in adult and pediatric patients who are intolerant to, or experience life-threatening side effects, 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). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

Original Effective Date: 10/12/2000

Re-Review Date(s): 10/26/21, 2/1/17, 6/16/2011, 9/18/2008, 8/23/2005, 12/20/2002, 10/22/2002, 10/12/00