MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Chelation Therapy**
Policy Number	**8.01.03**
Category	**Technology Assessment**
Original Effective Date	**10/18/01**
Committee Approval Date	**10/18/01, 06/20/02, 04/24/03, 04/15/04, 04/21/05, 03/16/06, 01/18/07, 01/17/08**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, chelation therapy has been proven to be effective and, therefore, is considered **medically appropriate** for the following conditions:
   A. Extreme conditions of metal toxicity, including: arsenic, cadmium, copper, gold, iron, lead, and mercury;
   B. Thalassemia intermedia with hemosiderosis;
   C. Thalassemia major (Cooley's anemia);
   D. Iron overload due to chronic transfusions in sickle cell anemia patients;
   E. Patients receiving chronic transfusions (e.g. myelodysplasia, aplastic anemia);
   F. Wilson's disease (hepatolenticular degeneration); and
   G. As a cardioprotectant in women with metastatic breast cancer who have received a cumulative doxorubicin dose of at least 300 mg/m^2.

II. Based upon our criteria and assessment of the peer-reviewed literature, chelation therapy does not improve patient outcomes and, therefore, is considered **not medically necessary** in the treatment of coronary artery disease, including atherosclerosis, arteriosclerosis, and hypercholesterolemia.

III. Based upon our review of the literature and/or available information, chelation therapy as a method of treatment for digitalis toxicity and hypercalcemia is considered **not medically necessary.** With the advent of newer drug therapies such as Digibind (digitalis toxicity) and bisphosphonates (hypercalcemia) chelation therapy use has fallen out of favor.

IV. Based upon our criteria and assessment of the peer-reviewed literature, the use of post-chelator challenge/post-provocation urinary metal testing to diagnose toxic metal conditions is considered **not medically necessary.**

V. Based upon our criteria and assessment of the peer-reviewed literature, chelation therapy has not been medically proven to be effective and, therefore, is considered **investigational** in the treatment of each of the following indications, among others:
   A. Alzheimer's disease;
   B. Arthritis/arthralgia;
   C. Autism Spectrum Disorders;
   D. Diabetes;
   E. Cystinuria;
   F. Environmental allergies; and
   G. Multiple Sclerosis.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

Refer requests for Exjade (deferasirox) or other oral chelators to the pharmacy department (Pharmacy Management)

DESCRIPTION

Chelation therapy consists of the intravenous or oral administration of chelating agents, which remove toxic metal ions from the body. These heavy metal antagonists form complexes with heavy metals, rendering them physiologically inactive and enhancing their excretion in the urine. Chemical endarterectomy, a form of chelation therapy, is utilized for the removal of plaque or calcium. Chelating agents include, but are not limited to: ethylenediaminetetraacetic acid (EDTA), disodium edetate (Endrate), deferoxamine (DFO, Desferal), dimercaprol (BAL in oil), penicillamine (Cuprimine, Depen), edetate calcium disodium, dexazoxane (Zinecard), deferasirox (Exjade), trientene HCL (Syprine), and succimer (Chemet).

RATIONALE

Calcium-EDTA (Versenate) has been approved by the U.S. Food and Drug Administration (FDA) for lowering blood lead levels among both pediatric and adult patients with lead poisoning. Succimer is approved for the treatment of lead poisoning in pediatric patients only. Disodium-EDTA was FDA-approved for use in selected patients with hypercalcemia and for use in patients with heart rhythm problems due to intoxication with the drug, digitalis. In 2008, however, the FDA withdrew approval of disodium-EDTA due to safety concerns and recommended that other forms of chelation therapy be used.

Several iron-chelating agents are FDA-approved:

I. Deferoxamine for subcutaneous, intramuscular, or intravenous injections was approved to treat acute iron intoxication and chronic iron overload due to transfusion-dependent anemia.
II. Deferasirox, approved in 2005, is available as a tablet for oral suspension and is indicated for the treatment of chronic iron overload due to blood transfusions in patients age two years and older. In 2013, under the accelerated approval program, the FDA expanded the indications for deferasirox to include treatment of patients age 10 years and older with chronic iron overload due to nontransfusion-dependent thalassemia (NTDT).
III. In 2011, the FDA approved the iron chelator, deferiprone (Ferriprox), for treatment of patients with transfusional overload due to thalassemia syndromes when other chelation therapy is inadequate. Deferiprone is available in tablet form for oral use.

The position statement of the American College of Medical Toxicology states that post-chelator challenge urinary metal testing has not been scientifically validated, has no demonstrated benefit, and may be harmful when applied in the assessment and treatment of patients in whom there is a concern for metal poisoning.

Chelation therapy is an established treatment method for metal toxicity and overload conditions due to diseases such as Cooley's anemia, sickle cell anemia, and Wilson's disease. Studies investigating chelation therapy for coronary artery disease and atherosclerosis showed no significant differences in the outcomes of disease severity and subjective improvements. Therefore, there is insufficient scientific evidence to determine the effectiveness of chelation therapy in improving clinical outcomes of patients with atherosclerosis. Clinical trials have demonstrated that the use of dexrazoxane was associated with a decreased risk of clinical cardiotoxicity in women with breast cancer (e.g., cardiac events occurred

in 31% of patients receiving placebo and only in 14% of patients receiving dexrazoxane). Published trials investigating chelation therapy for other diseases such as Alzheimer's disease, arthritis, multiple sclerosis (MS), and autism have not provided evidence to support its use for these conditions.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
No specific codes	

HCPCS Codes

Code	Description
M0300 **(E/I)**	I.V. Chelation therapy (chemical endarterectomy)
J0470	Injection, dimercaprol, per 100mg
J0600	Injection, edetate calcium disodium, up to 1,000 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1190	Injection, dexazoxane HCl, per 250 mg (Zinecard)
J3520	Edetate disodium (EDTA, Disotate) per 150 mg
S9355	Home infusion therapy, chelation therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment, per diem

ICD10 Codes

Code	Description
Medically appropriate codes	
E83.00-E83.09	Disorders of copper metabolism, code range
D56.0-D56.9	Thalassemia, code range
D57.00-D57.419	Sickle cell disorders, code range
D57.80-D57.819	Other sickle cell disorders, code range
D60.0-D 60.9	Acquired pure red cell aplasia, code range
D61.01-D61.9	Aplastic anemia and other bone marrow failure syndromes
C94.6, D46.9-D46.Z	Myelodysplasia, code range
T56.0x1A -T56.0x4A	Toxic effect of lead and its compounds, code range
T56.1x1A-T56.1x4A	Toxic effect of mercury and its compounds, code range
T56.3x1A-T56.3x4A	Toxic effect of cadmium and its compounds, code range
T56.4x1A-T56.4x4A	Toxic effect of copper and its compounds, code range
T56.5x1A-T56.5x4A	Toxic effect of zinc and its compounds, code range
T56.6x1A-T56.6x4A	Toxic effect of tin and its compounds, code range
T56.811A-T56.814A	Toxic effect of thallium and its compounds, code range

Code	Description
T56.891A-T56.894A	Toxic effect of other metals, code range
T56.91xA-T56.94xA	Toxic effect of unspecified metals, code range
T57.0x1A-T57.0x4A	Toxic effect of arsenic and its compound, code range

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*Key Article

KEY WORDS

Chelation therapy, Post-chelator challenge urinary metal testing, Post-provocation urinary metal testing.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD 20.2) for chelation therapy for treatment of atherosclerosis. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=86&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAA& accessed 09/18/23.