

MEDICAL POLICY



SUBJECT: CHELATION THERAPY	EFFECTIVE DATE: 10/08/99 REVISED DATE: 08/16/01, 06/20/02, 04/24/03, 04/15/04, 04/21/05, 03/16/06, 01/18/07, 01/17/08 ARCHIVED DATE: 12/18/08 EDITED DATE: 11/19/09, 11/18/10, 10/20/11, 10/18/12, 10/17/13, 10/16/14, 10/15/15, 10/20/16, 10/19/17, 10/18/18
POLICY NUMBER: 8.01.03 CATEGORY: Technology Assessment	PAGE: 1 OF: 4
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare 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.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of the peer-reviewed literature, chelation therapy has been proven to be effective and therefore **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;
 - 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/m².
- II. Based upon our criteria and assessment of the peer-reviewed literature, chelation therapy does not improve patient outcomes and is considered **not medically necessary** in the treatment of *coronary artery disease*, including *atherosclerosis, arteriosclerosis* and *hypercholesterolemia*.
- III. Based on assessment of peer-reviewed literature, chelation therapy as a method of treatment for digitalis toxicity and hypercalcemia is considered **not medically necessary**. This treatment regimen has fallen out of favor with the advent of newer drug therapies; such as Digibind (digitalis toxicity) and bisphosphonates (hypercalcemia).
- IV. Based upon our criteria and assessment of the peer-reviewed literature, chelation therapy has not been medically proven to be effective and is considered **investigational** in the treatment of, but not limited to, each of the following indications:
 - 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 # 2.01.04 regarding Clinical Ecology/ Environmental Allergies.

Refer to Corporate Medical Policy # 11.01.03 regarding Experimental and Investigational Services.

Refer requests for Exjade (deferasirox) or other oral chelators to the pharmacy department (FLRx).

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POLICY GUIDELINES:

- I. 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. Therefore, the use of post-chelator challenge/post-provocation urinary metal testing to diagnose toxic metal conditions is considered **not medically appropriate**.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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: EDTA, Disodium Edetate (Endrate), deferoxamine (DFO, Desferal), dimercaprol (BAL in oil), penicillamine (Cuprimine, Depen), edetate calcium disodium, dexazoxane (Zinecard®), deferasirox (Exjade), trientine HCL (Syprine®), and succimer (Chemet®).

RATIONALE:

FDA approved calcium-EDTA (Versenate) 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. FDA approved disodium-EDTA 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, 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 2 years and older. Under the accelerated approval program, FDA expanded the indications for deferasirox in 2013 to include treatment of patients age 10 years and older with chronic iron overload due to nontransfusion-dependent thalassemia (NTDT).
- III. In 2011, 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.

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, MS and autism have not provided evidence to support its use for these conditions.

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CODES: Number Description

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: No specific codes

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HCPCS:

M0300 (E/I)	I.V. Chelation therapy (chemical endarterectomy)
J0470	Injection, dimercaprol
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

Medically appropriate codes

ICD10:

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-D60.9	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
T56.891A-T56.894A	Toxic effect of other metals, code range

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T56.91xA-T56.94xA Toxic effect of unspecified metals, code range

T57.0x1A-T57.0x4A Toxic effect of arsenic and its compound, code range

REFERENCES:

*American Academy of Pediatrics. Policy statement. Lead exposure in children: prevention, detection and management. Pediatrics 2005 Oct;116(4):1036-46.

American College of Physicians/American College of Cardiology Foundation/American Heart Association/American Association for Thoracic Surgery/Preventive Cardiovascular Nurses Association/Society of Thoracic Surgeons. Management of stable ischemic heart disease. [www.guideline.gov] accessed 9/16/13.

BlueCross BlueShield Association. Chelation therapy for OFF-Label Uses. Medical Policy Reference Manual Policy #8.01.02. 2016 June 11.

Centers for Disease Control and Prevention. Agency for Toxic Substances and Disease Registry. Guidelines for arsenic, cadmium, chromium, lead and mercury. [http://www.atsdr.cdc.gov] accessed 9/16/13.

*National Guideline Clearinghouse. Practice parameter for the recognition, management and prevention of adverse consequences of blood transfusion. 2000 Jan.

*Schuchter LM, et al. 2002 update of recommendations for the use of chemotherapy and radiotherapy protectants: Clinical practice guidelines of the American Society of Clinical Oncology. J Clin Oncol 2002 Jun 15;20(12):2895-903.

*Villarruz MV, et al. Chelation therapy for atherosclerotic cardiovascular disease. Cochrane Database Syst Rev 2003;(4):CD002785.

*Key articles

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) 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=gAAAABAAAA&>