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# Subject: Chelation Therapy

**THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.**



## DESCRIPTION:

Chelation therapy is an established treatment for the removal of metal toxins by converting them to a chemically inert form that can be excreted in the urine. Chelation therapy comprises intravenous or oral administration of chelating agents that remove metal ions such as lead, aluminum, mercury, arsenic, zinc, iron, copper, and calcium from the body. Specific chelating agents are used for particular heavy metal toxicities.

**Summary and Analysis of Evidence:** UpToDate review "Prevention of cardiovascular disease events in those with established disease (secondary prevention)" (Henneken, Lopez-Sendon; 2025) states, "(t)he totality of evidence does not support chelation therapy in patients with coronary artery disease (CAD). As an example, in the 2024 Trial to Assess Chelation Therapy 2 (TACT2) of 959 participants with diabetes and prior myocardial infarction (MI), ethylenediaminetetraacetic acid-based chelation reduced blood lead levels but was not superior to placebo in reducing the composite endpoint of death, recurrent MI, stroke, coronary revascularization, or hospitalization for angina (35.6 versus 35.7 percent; hazard ratio [HR] 0.93; 95% CI 0.76-1.16) or any of the individual component endpoints. UpToDate review "Autism spectrum disorder in children and adolescents: Complementary and alternative therapies" (Hale, Harris; 2025 states, "(a)utism spectrum disorder (ASD) is a neurodevelopmental disorder with an incompletely understood etiology and no known cure. Many caregivers of children with ASD seek both conventional and complementary and alternative (CAM) therapies as part of the process of understanding and accepting the diagnosis. Few CAM therapies have been proven effective/ineffective or safe/unsafe in controlled trials. Given the uncertainty, the clinician and family must weigh the unknown benefit against the potential risks, which include competition with validated treatment for time, effort, and financial resources. We strongly discourage CAM therapies with unknown benefits and potential risks in the treatment of ASD. These therapies include … chelation …" Vezzoli et al (2023) studied the efficacy of an antioxidant treatment (calcium disodium ethylenediaminetetracetic acid-EDTA) chelation therapy associated with a micronutrient complex in MS patients. A total of 20 MS patients and 20 healthy

subjects, enrolled as a control group (CTR), were recruited. They measured the plasma ROS production and total antioxidant capacity (TAC) by a direct assessment using Electron Paramagnetic Resonance; activities of the antioxidant system (thiols' redox status and enzymes); and the urinary presence of biomarkers of oxidative stress by immunoenzymatic assays. They also evaluated the levels of inflammation by plasmatic cytokines (TNFα, IL-1β, and IL-6) and assessed the sICAM levels, as well as the nitric oxide (NO) catabolism and transthyretin (TTR) concentration. Comparing CTR and MS, in the latter ROS production, oxidative damage, inflammatory biomarkers, and no metabolite concentrations results were significantly higher, while TAC was significantly lower. The authors concluded "(b)y preventing or reducing oxidative damage, we may potentially prevent or delay neurodegeneration as a core substrate of disability. The present finding of the adopted treatment causing downregulation of inflammatory expression and OxS may be considered effective. Its protective effect may be attributable to a decrease of ROS production and an increase in antioxidant activity." This study had several limitations, including low number and high interindividual variability of examined subjects; and the severity on each relapse and the time between each one was not evaluated. Rajkumar et al (2023) states, "Humans are exposed to HMs through inhalation, ingestion, or contact with the skin. Environmental pollution with HMs can result in contamination of air, water, sewage, seawater, waterways, and can accumulate in plants, crops, seafood, and meat and indirectly affect humans. Some occupations have increased risk for particular HMs exposure and toxicity. Some HMs can cause toxicity even at very low concentrations and are known as non-threshold HMs. Factors influencing the risk of toxicity include age, body weight, genetics, route of acquisition, duration of exposure, amount, health, nutritional status, and a combination of HMs. Some preparations used in complementary medicine can result in toxicity. Management includes preventing any further exposure, removal of the offending agent using chelating agents, supportive therapy, and patient education." Song, Zhang (2020) states, "Ethylene diamine tetra-acetic acid (EDTA) is a chelating agent binding to calcium, lead, iron, and copper, among other metal ions to form solvable complexes and facilitate their urinary excretion. EDTA chelation therapy has been utilized in patients with atherosclerotic cardiovascular disease on the foundation that calcium chelation could alleviate atherosclerotic plaque with calcium. However, the current pool of evidence of EDTA chelation therapy to treat in atherosclerotic cardiovascular disease remains controversial." Baldari et al (2020) states, "Unfortunately, the limited current knowledge of the complex mechanisms regulating neurodegenerative diseases, including Alzheimer's and Parkinson's diseases, and of the precise role or consequences of the mechanisms specifically dysregulated by copper imbalance in these brain pathologies have led to a minor success of the use of copper chelating agents for the treatment of these diseases. Further randomized clinical trials are necessary to confirm the benefit observed in preclinical models."

## POSITION STATEMENT:

Chelation therapy **meets the definition of medical necessity** when administered for the treatment of the following:

- Extreme conditions of metal toxicity
- Treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) or due to non-transfusion-dependent thalassemia
- Disorders of copper metabolism (e.g., Wilson's disease)
- Lead poisoning (acute or long-term)

- Control of ventricular arrhythmias or heart block associated with digitalis toxicity
- Emergency treatment of hypercalcemia
- Aluminum overload in individuals with end-stage renal disease (ESRD)

Chelation therapy is considered **experimental or investigational**, as there is insufficient scientific evidence to support the use of chelation therapy for all other indications, and specifically for the following conditions:

- Atherosclerosis (e.g., coronary artery disease, secondary prevention in individuals with myocardial infarction, cerebrovascular disease, peripheral vascular disease)*
- Multiple sclerosis
- Arthritis (includes rheumatoid arthritis)
- Hypoglycemia
- Diabetes
- Autism
- Pervasive developmental disorders (PDD)
- Cancer
- Alzheimer's disease
- Treatment of "mercury toxicity" thought to be from dental amalgam fillings

## BILLING/CODING INFORMATION:

The following codes may be used to describe chelation therapy.

### HCPCS Coding:

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| J0470 | Injection, dimercaprol, per 100 mg |
| J0600 | Injection, edetate calcium disodium, up to 1000 mg |
| J0895 | Injection, deferoxamine mesylate, 500 mg |
| J3520 | Edetate disodium, per 150 mg (Endrate, EDTA) |
| M0300 | IV chelation therapy (chemical endarterectomy) |

### ICD-10 Diagnosis Codes That Support Medical Necessity for J0470, J0600, J0895, J3520, and M0300:

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| D46.Z | Other myeolodysplastic syndromes |
| D46.9 | Myelodysplastic syndrome, unspecified |
| D56.0 – D56.9 | Thalassemia |
| D57.40 – D57.459 | Sickle-cell thalassemia |
| D64.0 – D64.4 | Other anemias |
| E83.00 – E83.09 | Disorders of copper metabolism |
| E83.10 – E83.19 | Disorders of iron metabolism |
| E83.2 | Disorders of zinc metabolism |
| E83.52 | Hypercalcemia |

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| T45.4x1A – T45.4X4S | Poisoning by iron and its compounds |
| T56.0x1A – T56.0x4S | Toxic effects of lead and its compounds |
| T56.1x1A – T56.1x4S | Toxic effect of mercury and its compounds |
| T56.2x1A – T56.2x4S | Toxic effect of chromium and its compounds |
| T56.3x1A – T56.3x4S | Toxic effect of cadmium and its compounds |
| T56.4x1A – T56.4x4S | Toxic effect of copper and its compounds |
| T56.5x1A -- T56.5x4S | Toxic effect of zinc and its compounds |
| T56.6x1A -- T56.6x4S | Toxic effect of tin and its compounds |
| T56.7x1A -- T56.7x4S | Toxic effects of beryllium and its compounds |
| T56.811A -- T56.814S | Toxic effect of thallium |
| T56.891A -- T56.894S | Toxic effects of other metals |
| T56.91XA -- T56.94XS | Toxic effect of unspecified metal |
| T57.0x1A – T57.0x4S | Toxic effect of arsenic and its compounds |

## REIMBURSEMENT INFORMATION:

Refer to sections entitled POSITION STATEMENT.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage products:** The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Chelation Therapy for Treatment of Atherosclerosis (20.21) and Ethylenediamine-Tetra-Acetic (EDTA) CHELATION Therapy for Treatment of Atherosclerosis (20.22), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

## DEFINITIONS:

**Transfusional hemosiderosis:** accumulation of iron in internal organs that results from repeated blood transfusions.

**Wilson's disease:** abnormal processing of copper in the body, causing copper accumulation.

## RELATED GUIDELINES:

None applicable.

## OTHER:

None applicable.

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## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 02/27/25.

## GUIDELINE UPDATE INFORMATION:

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| 08/15/01 | Medical Coverage Guideline Reformatted. |
| 09/15/02 | Reviewed; references updated. Added Program Exception for Medicare and More. |
| 10/15/03 | Reviewed; add iron overload as a covered diagnosis. |
| 07/15/04 | Scheduled review; no changes. |
| 08/15/05 | Scheduled review; no change in coverage statement. |
| 08/15/06 | Scheduled review; revise coverage statement regarding acute iron intoxication and chronic iron overload. |
| 11/15/06 | Revision consisting of adding clarification statement regarding testing for lead toxicity. |
| 07/15/07 | Scheduled review; added ICD-9 code to Program Exception for Medicare Advantage products; reformatted guideline; updated references. |
| 09/15/08 | Scheduled review; no change in position statement. Update references. |
| 09/15/09 | Scheduled review; no change in position statement. Update references. |
| 10/01/10 | 4th Quarter HCPCS coding update: ICD-9 diagnosis code 275.0 deleted; ICD-9 diagnosis codes 275.01, 275.02, 275.03 and 275.09 added. |
| 10/15/10 | Revision; related ICD-10 codes added; Medicare Exception ICD-9 coding section updated with the addition of ICD-9 codes 275.01 – 275.09 for CPT code J0895. |
| 10/01/11 | Revision; added ICD9 codes 282.43, 282.44 and 282.45. |
| 05/15/14 | Unscheduled review. Revised MCG title, description section, position statement, ICD9 and ICD10 coding, program exceptions and definitions. Updated references. |
| 10/01/15 | Revision consisting of update to Program Exceptions section. |
| 11/01/15 | Revision: ICD-9 Codes deleted. |
| 09/15/18 | Scheduled review. Minor verbiage revisions regarding coverage of iron overload and lead poisoning. Updated program exceptions section and references. |
| 08/15/20 | Scheduled review. Maintained position statement. Revised description, ICD10 coding, and definitions. Updated references. |
| 10/01/20 | Annual ICD10 coding update. Added codes D57.42, D57.43, D57.431, D57.432, D57.433, D57.438, D57.439, D57.44, D57.45, D57.451, D57.452, D57.453, D57.458, D57.459. |
| 05/15/22 | Scheduled review. Add coverage statement for mercury toxicity and dental amalgam. Update references. |
| 05/22/23 | Update to Program Exceptions section. |
| 03/15/24 | Scheduled review. Revised description, maintained position statement, and updated references. |

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| 03/15/25 | Scheduled review. Revised description, maintained position statement and updated references. |