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Reviewed: 02/22/24

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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.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

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: 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
- Wilson’s disease (hepatolenticular degeneration)
- Lead poisoning
- 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:

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:

D46.Z	Other myelodysplastic 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
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 02/22/24.

GUIDELINE UPDATE INFORMATION:

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.