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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 consists of the 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. For example, deferoxamine is used for individuals with iron toxicity, and calcium-ethylenediaminetetraacetic acid (EDTA) is used for individuals with lead poisoning. Note that disodium-EDTA is not recommended for acute lead poisoning due to the increased risk of death from hypocalcemia. Another class of chelating agents, called metal protein attenuating compounds (MPACs), is under investigation for the treatment of Alzheimer's disease, which is associated with the disequilibrium of cerebral metals. Chelation therapy has also been discussed as a treatment for other indications including atherosclerosis and autism. For example, EDTA chelation therapy has been proposed in individuals with atherosclerosis as a method of decreasing obstruction in the arteries.

Whole blood lead levels are considered a more specific and sensitive means of testing for lead toxicity. Urine tests for lead levels assess the plasma lead concentration and are not considered accurate measurements of blood lead levels because of rapid fluctuation in plasma lead, as compared to whole blood lead levels.

A diagnostic workup for metal toxicity must include the history, an appropriate choice of tests and testing methods, and the use of accurate and specific reference values. With regard to urine testing, the use of chelation therapy to treat heavy metal poisoning should not be performed based on post-challenge urine testing. In post-challenge, or post-provoked, urine testing, the individual is first given a chelating agent followed by urine testing for heavy metals.

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)

***NOTE:** The use of chelation therapy to treat heavy metal toxicity based on post-challenge (post-provoked) urine testing **does not meet the definition of medical necessity.**

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

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 forJ0470, J0600, J0895, and J3520:

D46.Z	Other myeolodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified
D56.0 – D56.9	Thalassemia
D57.40	Sickle-cell thalassemia without crisis
D57.411 – D57.419	Sickle-cell thalassemia with acute chest syndrome; with splenic sequestration; with crisis, unspecified
D64.0 – D64.4	Other anemias
E83.00 – E83.09	Disorders of copper metabolism
E83.10 – E83.19	Disorders of iron metabolism
E83.52	Hypercalcemia
T37.8x1A – T37.96xS	Poisoning by, adverse effect of and underdosing of other specified systemic anti-infectives and anti-parasitics
T45.4x1A – T45.4x6S	Poisoning by, adverse effect of and underdosing of 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
T56.3x1A – T56.3x4S	Toxic effect of cadmium and its compounds
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 (20.21) and Chelation Therapy (20.22), located at cms.gov.

DEFINITIONS:

Primary hemochromatosis: iron overload caused by a genetic defect that results in the overabundance of iron in the liver, brain, heart and kidneys, causing liver dysfunction, diabetes, changes in skin pigmentation, heart problems, arthritis and testicular atrophy.

Secondary hemochromatosis: iron overload which is usually the result of another condition or disease that causes the overabundance of iron; may include anemias, chronic liver diseases, and the requirement of 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 & Coverage Committee on 08/23/18.

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.