RETIRED
FIRST COAST SERVICE OPTIONS
MAC - PART B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L33809

First Coast Service Options, Inc.

Contractor Number
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part B

LCD Title
Chelation Therapy

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub. 100-03, Chapter 1, Section 20.21-20.22

Primary Geographic Jurisdiction

Florida
Puerto Rico/Virgin Islands
Chelation Therapy

Oversight Region

Region I

Original Determination Effective Date

10/01/2015

Original Determination Ending Date

08/11/2017

Revision Effective Date

N/A

Revision Ending Date

N/A

Indications and Limitations of Coverage and/or Medical Necessity

Chelation therapy is the administration of chelating agents to remove heavy metals from the body. The chelation therapy agents can be covered for the Food and Drug Administration (FDA) approved indication(s) and associated condition(s) as outlined. Chelation therapy is performed in cases of iron, lead, copper, and aluminum overload when the patient has the associated disorder and in certain specific cases of heavy metal toxicities.

It can be medically necessary when clinically indicated for diseases/disorders such as cystinuria; secondary hemochromatosis (due to iron overload from multiple transfusions), and Wilson’s disease. It can be medically necessary for heavy metal poisoning (such as arsenic, cadmium, copper, gold, iron, lead, and mercury) when the patient has specific signs and symptoms of heavy metal toxicity and/or a history of likely exposure to heavy metals with standard of care laboratory confirmation.

It is expected that any patient receiving chelation therapy has documented laboratory evidence of heavy metal toxicity with standard of care testing for the suspected heavy metal. For example, testing of whole blood level is the most sensitive and specific means in assessing lead toxicity. Urinary lead level is not an accurate measure of blood lead levels. Provoked testing for lead and mercury levels are not clinically appropriate. Also, any non standard of care testing of patients who demonstrate only vague, ill-defined symptoms with no history of likely heavy metal exposure for heavy metal toxicity is screening, and therefore, the testing is not a covered service as well as the chelation therapy.

Dimercaprol (BAL) (procedure code J0470):

Dimercaprol (BAL) is a useful antidote in arsenic, mercury, lead, and cadmium poisoning and is most efficient if administered immediately following exposure to the metals. Dimercaprol is administered intramuscularly.

Edetate Calcium Disodium (Calcium EDTA) (procedure code J0600):

For the purposes of this LCD, the only EDTA indicated for use as a chelating agent is Calcium Disodium Versenate (procedure code J0600)

Edetate Calcium Disodium (Calcium EDTA) is a useful antidote in lead poisoning and lead encephalopathy. Calcium EDTA is administered intravenously, subcutaneously or intramuscularly with the intramuscular route preferred. The diagnosis of lead toxicity depends on the testing of whole blood lead levels. Urinary lead level is not an accurate measure of blood lead levels and does not substantiate the medical necessity of chelation therapy.
Chelation Therapy. Part B

- Edetate Disodium (procedure code J3520), also known as Endrate, EDTA, is not covered for use as a chelating agent.

- EDTA Used as a Treatment and Prevention of Atherosclerosis is not covered.

- The application of chelation therapy using ethylenediamine-tetra-acetic acid (EDTA) for the treatment and prevention of atherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well designed, controlled clinical trials. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered.

- EDTA Used as a Mobilization Test (Provocative Chelation) is not covered.

- The administration of the chelating agent calcium EDTA as a mobilization test (provocative chelation) to determine if chelation therapy is indicated is controversial. The provocative chelation test was developed to assess the total body lead burden and efficacy of chelation treatment. The tests involve obtaining a urine collection after administering a dose of calcium EDTA. In view of a paucity of relevant clinical outcomes for studies of provocative chelation, and in view of animal studies suggesting that single doses of chelation might cause harm from mobilizing lead and redistributing it to the central nervous system, the use of provocative chelation is not indicated and therefore is not covered.

Deferoxamine Mesylate (Desferal) (procedure code J0895):

Deferoxamine mesylate (Desferal) is the chelator of choice for iron poisoning. Deferoxamine is most effective when administered intramuscularly or intravenously.

Desferal is indicated for the treatment of acute iron intoxication and of chronic iron overload due to transfusion-dependent anemias. ICD-10-CM codes E83.10-E83.19 must be used for those patients with secondary iron overload from multiple transfusions who do not meet the definition for ICD-10-CM codes D64.0-D64.3 (Sideroblastic anemia).

Note: Per the FDA circular, Desferal is specifically not indicated for the treatment of primary hemochromatosis. Phlebotomy is the treatment of choice for this condition and the patient’s medical record would need clear support for any off-label use of chelation therapy in lieu of phlebotomy.

Limitations

Chelation therapy is not covered for a myriad of alternative medicine uses that are not medically necessary and reasonable for treatment of an illness or injury since treatment outcomes have not been consistently demonstrated as well as the diagnostic criteria for treatment. Examples of clinical situations where chelation therapy is not covered since heavy metal toxicity is not clinically apparent and not consistent with standards of diagnostic testing (this is not an all-inclusive list) are as follows: the prevention and treatment of cancer, cardiovascular disease (CAD), peripheral vascular disease, individuals at risk from drug-eluting stents, neurodegenerative diseases (such as Alzheimer’s disease), autism, attention deficit hyperactivity disorder, fungal disease, progressive renal insufficiency in Type II diabetic nephropathy, Parkinson’s disease, and hypercholesterolemia.

CPT/HCPCS Codes

J0470 Injection, dimercaprol, per 100 mg

J0600 Injection, ededate calcium disodium, up to 1000 mg

J0895 Injection, deferoxamine mesylate, 500 mg

ICD-10 Codes that Support Medical Necessity

Dimercaprol (BAL) (procedure code J0470)
Chelation Therapy.

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>T56.0X1A-T56.0X4S</td>
<td>Toxic effects of lead and its compounds</td>
</tr>
<tr>
<td>T56.1X1A-T56.1X4S</td>
<td>Toxic effects of mercury and its compounds</td>
</tr>
<tr>
<td>T56.3X1A-T56.3X4S</td>
<td>Toxic effects of cadmium and its compounds</td>
</tr>
<tr>
<td>T57.0X1A-T57.0X4S</td>
<td>Toxic effect of arsenic and its compounds</td>
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Edetate Calcium Disodium (Calcium EDTA) (procedure code J0600)

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Deferoxamine Mesylate (Desferal) (procedure code J0895)

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
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<tbody>
<tr>
<td>D46.0-D46.21</td>
<td>Myelodysplastic syndromes</td>
</tr>
<tr>
<td>D46.A</td>
<td>Refractory cytopenia with multilineage dysplasia</td>
</tr>
</tbody>
</table>
| D46.B | Refractory cytopenia with multilineage dysplasia and ring sideroblasts  
Refractory anemia, unspecified |
| D64.0-D64.3 | Other anemias |
| E83.10-E83.19 | Disorders of iron metabolism |
| T45.4X1A-T45.4X4S | Poisoning by, adverse effect of and underdosing of iron and its compounds |

Diagnoses that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Associated Information

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician or the nonphysical practitioner must substantiate the medical need for the use of these drugs by clearly indicating the condition for which the drug is being used. The medical record must indicate that the treatment is based on diagnostic information, including the appropriate laboratory testing (such as whole blood for lead toxicity), completed to confirm the need to remove unwanted metal ions from the body for the treatment of metal intoxication. In addition, specific signs and symptoms of heavy metal poisoning must be documented to substantiate that the Food and Drug Administration (FDA) indications for chelating drug usage is followed. Documentation that the service was performed must also be included in the patient’s medical record. This documentation is usually found in the history and physical or in the office/progress notes of the medical record.

Utilization Guidelines

It is expected that these services would be performed as indicated by current literature and/or standards of practice and should follow the guidelines for administration and safety found in the FDA approved labels for these drugs. When services are performed in excess of established parameters, they may be subject to medical review for medical necessity.
Sources of Information and Basis for Decision

FCSO reference LCD number – L29113


Ferri: Ferri’s Clinical Advisor: Instant Diagnosis and Treatment 2006 ed. Mosby, An Imprint of Elsevier


Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

04/01/2014

Revision History

Revision History Number: R1

Revision Number: 1
Publication: August 2017 Connection
LCR B2017-010

Explanation of revision: Based on data analysis review of the local coverage determination (LCD), it was determined that the LCD is no longer required and, therefore, is being retired. The effective date of this LCD retirement is based on date of service.

Revision Number: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

Related Documents

N/A

LCD Attachments
Chelation Therapy.1 Part B

N/A