MEDICAL POLICY – 8.01.535

Chelation Therapy

BCBSA Ref. Policy: 8.01.02

Effective Date: May 1, 2018
Last Revised: Feb. 2, 2019
Replaces: 8.01.02

RELATED MEDICAL POLICIES: None

Introduction

Chelation is a process to remove certain heavy metals from the blood. In this treatment, a chemical solution is injected into the bloodstream or taken by mouth. Molecules then bind to heavy metals and/or minerals. The heavy metals are then cleared out of the body through urination. Chelation therapy has been studied and approved by the Food and Drug administration to treat certain condition. This includes removing dangerously high levels of iron, as well as lead or mercury. Thinking that the process of chelation could also remove the buildup of some other substances in the body, some doctors have tried to use it to try to treat other conditions. Examples of these other conditions include Alzheimer disease, autism, diabetes, and plaque inside of arteries (atherosclerosis). Scientific research has not proven that using chelation therapy treatment for these or other conditions is effective. For this reason, chelation therapy for many conditions is considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
## Coverage Criteria

### Service

<table>
<thead>
<tr>
<th>Medical Necessity</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chelation therapy</strong></td>
<td><strong>Off-label uses of chelation therapy that are considered investigational, include, but are not limited to:</strong></td>
</tr>
<tr>
<td>Chelation therapy may be considered medically necessary, when toxic levels are documented by standard testing methods, as a treatment for the following conditions:</td>
<td><em>Alzheimer disease</em></td>
</tr>
<tr>
<td><em>Chronic iron overload due to blood transfusions (transfusional hemosiderosis)</em></td>
<td><em>Arthritis (includes rheumatoid arthritis)</em></td>
</tr>
<tr>
<td><em>Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)</em></td>
<td><em>Atherosclerosis (eg, coronary artery disease, secondary prevention in patients with myocardial infarction, or peripheral vascular disease)</em></td>
</tr>
<tr>
<td><em>Digitalis toxicity with ventricular arrhythmias or heart block</em></td>
<td><em>Autism</em></td>
</tr>
<tr>
<td><em>Extreme conditions of metal toxicity (see Table 1 for select heavy metals)</em></td>
<td><em>Diabetes</em></td>
</tr>
<tr>
<td><em>Hypercalcemia emergency treatment</em></td>
<td></td>
</tr>
<tr>
<td><em>Lead poisoning</em></td>
<td></td>
</tr>
<tr>
<td><em>Wilson’s disease (hepatolenticular degeneration)</em></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:** For the two conditions listed below, generally other treatments are used in place of chelation therapy:

- Control of ventricular arrhythmias or heart block associated with digitalis toxicity (eg, currently treated, in most patients, with digoxin immune fragment antigen-binding [Fab] monoclonal antibodies).
- Emergency treatment of hypercalcemia using IV hydration and other pharmacologic agents is individualized based on the root cause. 

### Service

| Investigational                                                                 |
|--------------------------------------------------------------------------------|--------------------------------------------------|
| **Chelation therapy**                                                           |**Notes:** For the two conditions listed below, generally other treatments are used in place of chelation therapy:
  - Control of ventricular arrhythmias or heart block associated with digitalis toxicity (eg, currently treated, in most patients, with digoxin immune fragment antigen-binding [Fab] monoclonal antibodies).
  - Emergency treatment of hypercalcemia using IV hydration and other pharmacologic agents is individualized based on the root cause. 

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Service | Investigational
---|---
| • Multiple sclerosis
| • Other indications not listed as medically necessary above

#### Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Standard testing result showing toxic levels for the following conditions:
  - Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
  - Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
  - Digitalis toxicity with ventricular arrhythmias or heart block
  - Heavy metal poisoning (eg, arsenic, cadmium, cobalt, copper, gold, iron, lead, mercury)
  - Hypercalcemia (high levels of calcium in the blood) emergency treatment
  - Lead poisoning
  - Wilson’s disease (hepatolenticular degeneration)

#### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0068</td>
<td>Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, and/or inotropic infusion drug(s) for each infusion drug administration calendar day in the individual's home, each 15 minutes (new code effective 1/1/19)</td>
</tr>
<tr>
<td>J0470</td>
<td>Dimercaprol injection, per 100 mg</td>
</tr>
<tr>
<td>J0600</td>
<td>Edetate calcium disodium, up to 1000mg</td>
</tr>
<tr>
<td>J0895</td>
<td>Injection, deferoxamine mesylate, 500 mg</td>
</tr>
<tr>
<td>M0300</td>
<td>Chelation therapy (Chemical endarterectomy)</td>
</tr>
<tr>
<td>S9355</td>
<td>Home infusion therapy, chelation therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
Reference standards for bismuth, chromium, and manganese were not identified and are not included in Table 1.

Table 1. Toxic or Normal Concentrations of Heavy Metals\(^{1-3,5}\)

<table>
<thead>
<tr>
<th>Metal</th>
<th>Toxic Levels (Normal levels where indicated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>24-h urine: 25 µg/L urine or 100 µg/g creatinine</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Proteinuria and/or ≥15 µg/g creatinine</td>
</tr>
<tr>
<td>Cobalt</td>
<td>Normal excretion: 0.1-2.2 µg/L (urine)</td>
</tr>
<tr>
<td>Copper</td>
<td>Normal excretion: 25 µg/24 h (urine)</td>
</tr>
<tr>
<td>Iron</td>
<td>Nontoxic: &lt;300 µg/dL, Severe: &gt;500 µg/dL</td>
</tr>
<tr>
<td>Lead</td>
<td>Pediatric: Blood lead level ≥45 µg/dL, Adult: Blood lead level ≥40 µg/dL</td>
</tr>
<tr>
<td>Mercury</td>
<td>Background exposure normal limits: 1-8 µg/L (whole blood); 4-5 µg/L (urine)(^{42,a})</td>
</tr>
<tr>
<td>Nickel</td>
<td>Excessive exposure: ≥8 µg/L (blood), Severe poisoning: ≥500 µg/L (8-h urine)</td>
</tr>
<tr>
<td>Selenium</td>
<td>Mild toxicity: &gt;1 mg/L (serum), Serious toxicity: &gt;2 mg/L</td>
</tr>
<tr>
<td>Silver</td>
<td>Asymptomatic workers have mean levels of 11 µg/L (serum) and 2.6 µg/L (spot urine)</td>
</tr>
<tr>
<td>Metal</td>
<td>Toxic Levels (Normal levels where indicated)</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Thallium</td>
<td>&gt;3 µg/L (blood)</td>
</tr>
<tr>
<td></td>
<td>&gt;5 µg/L (24-hour urine)</td>
</tr>
<tr>
<td>Zinc</td>
<td>Normal range:</td>
</tr>
<tr>
<td></td>
<td>0.6-1.1 mg/L (plasma),</td>
</tr>
<tr>
<td></td>
<td>10-14 mg/L (red cells)</td>
</tr>
</tbody>
</table>

Adapted from Adal (2018).  
CDC: Centers for Disease Control and Prevention.

Hair analysis is useful to assess mercury exposure in epidemiologic studies. However, hair analysis in individual patients must be interpreted with consideration of the patient’s history, signs, and symptoms, and possible alternative explanations. Measurement of blood and urine mercury levels can exclude exogenous contamination; therefore, blood or urine mercury levels may be more robust measures of exposure in individual patients.

### Evidence Review

#### Description

Chelation therapy is an established treatment for removing metal toxins from the body by converting them to a chemically inert form that can be excreted in the urine. Therapy involves 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 (see Table 1).

#### Background

Specific chelating agents are used for particular heavy metal toxicities. For example, desferrioxamine (not FDA-approved) is used for patients with iron toxicity, and calcium-ethylenediaminetetraacetic acid (-EDTA) is used for patients 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 disease, which is associated with the disequilibrium of cerebral metals. Unlike traditional systemic chelators that bind and remove metals from tissues systemically, MPACs have subtle effects on metal homeostasis and abnormal metal interactions. In animal models of Alzheimer disease, they promote the solubilization and
clearance of beta amyloid by binding its metal-ion complex, and also inhibit redox reactions that generate neurotoxic free radicals. MPACs therefore interrupt two putative pathogenic processes of Alzheimer disease. However, no MPACs have received FDA approval for the treatment of Alzheimer disease.

Chelation therapy has also been discussed as a treatment for other indications including atherosclerosis and autism spectrum disorder. For example, EDTA chelation therapy has been proposed in patients with atherosclerosis as a method of decreasing obstruction in the arteries.

Summary of Evidence

Chelation therapy is an established treatment for metal toxicities and transfusional hemosiderosis. It has been investigated for a variety of off-label applications, such as treatment of atherosclerosis, Alzheimer disease, and autism. For individuals who have Alzheimer disease, cardiovascular disease, arthritis, autism spectrum disorder, diabetes, or multiple sclerosis, the evidence consists of a small number of RCTs and case series. Relevant outcomes include symptoms, change in disease status, morbid events, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One randomized controlled trial, the Trial to Assess Chelation Therapy (TACT), reported that chelation therapy reduced cardiovascular events in patients with a previous myocardial infarction and that the benefit was greater in diabetic patients compared with nondiabetic patients. However, this study had significant limitations, including high dropout rates, and therefore, the conclusions are not definitive. For other conditions, the available RCTs did not report improvements in health outcomes with chelation therapy and as evidence, the case series are not adequate to determine efficacy. The evidence is insufficient to determine the effect of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT02728843</td>
<td>Study of Parkinson’s Early Stage With Deferiprone (SKY)</td>
<td>140</td>
<td>July 2018</td>
</tr>
<tr>
<td>NCT02175225</td>
<td>Study of Deferoxamine Mesylate in Intracerebral Hemorrhage</td>
<td>294</td>
<td>Aug 2018</td>
</tr>
<tr>
<td>NCT02655315</td>
<td>Conservative Iron Chelation as a Disease-modifying Strategy in Parkinson’s Disease (FAIRPARKII)</td>
<td>338</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>NCT02733185</td>
<td>Trial to Assess Chelation Therapy 2 (TACT2)</td>
<td>1200</td>
<td>Aug 2021</td>
</tr>
</tbody>
</table>

| Unpublished  | Safety and Effectiveness Study of Deferoxamine and Xingnaojing Injection in Intracerebral Hemorrhage | 180                | Dec 2016        |
| NCT02367248  |                                                                                |                    | (unknown)       |
| NCT01741532  | A Randomized, Double-blind, Placebo-controlled Trial of Deferiprone in Patients With Pantothenate Kinase-associated Neurodegeneration (PKAN) | 89                 | Jan 2017        |

NCT: national clinical trial

* Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

American College of Physicians et al

In 2012, the American College of Physicians (ACP), American College of Cardiology Foundation (ACCF), American Heart Association (AHA), American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, and Society of Thoracic Surgeons published joint clinical practice guidelines on the management of stable ischemic heart disease (IHD). The guidelines recommended that “chelation therapy should not be used with the intent of improving symptoms or reducing cardiovascular risk in patients with stable IHD. (Grade: strong recommendation; low-quality evidence)” However, citing the Trial to Assess Chelation Therapy, a 2014 focused update of these guidelines included a revised recommendation on chelation therapy, stating that the “usefulness of chelation therapy is uncertain for reducing cardiovascular events in patients with stable IHD.” The recommendation was upgraded from class III (no benefit) to class IIb (benefit ≥ risk), and the level of evidence from C (only consensus expert opinion, case studies, or standard of care) to B (data from a single randomized trial or nonrandomized studies).
**American College of Cardiology (ACC) et al**

In 2005, the American College of Cardiology, AHA, and other medical societies stated that chelation “is not indicated for treatment of intermittent claudication and may have harmful adverse effects. (Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses).”\(^3\)

In 2013, ACCF and AHA compiled the previous ACC/AHA and ACCF/AHA recommendations issued in 2005\(^2\) and 2011\(^3\) on the management of peripheral artery disease.\(^4\) The recommendation against chelation therapy remained unchanged.

**Canadian Cardiovascular Society (CCS)**

Evidence-based, consensus guidelines from the Canadian Cardiovascular Society in 2014 included a conditional recommendation (based on moderate quality evidence) that chelation therapy should not be used to attempt to improve angina or exercise tolerance in patients with stable ischemic heart disease.\(^5\)

**National Institute for Health and Care Excellence (NICE)**

The National Institute for Health and Care Excellence issued clinical guidance reports on autism in children and young people in 2013\(^6\) and autism in adults updated in 2016.\(^7\) Both documents specifically recommend against the use of chelation therapy for the management of autism.

**Medicare National Coverage**

The Centers for Medicare & Medicare have issued 2 national coverage determinations on chelation therapy relevant to this evidence review. Section 20.21 states\(^8\).

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.
Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section.

Section 20.22 states\(^{39}\): “The use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, or similar generalized condition not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental.

These are long-standing national coverage decisions (NCD); effective dates of these versions have not been posted.

**Regulatory Status**

- In 1953, calcium-EDTA (Versenate) was FDA approved for lowering blood lead levels for both pediatric and adult patients with lead poisoning.

- In 1991, succimer (Chemet) was approved for the treatment of lead poisoning in pediatric patients only.

- Disodium-EDTA (Endrate® or Edetate Disodium) was formerly approved for use in selected patients with hypercalcemia and for use in patients with heart rhythm problems due to intoxication with the drug, digitalis. However, in 2008, FDA withdrew approval of disodium-EDTA due to safety concerns and recommended that other forms of chelation therapy be used.\(^2\)

Several iron chelating agents are FDA-approved:

- In 1968, deferoxamine (Desferal®, Novartis) for subcutaneous, intramuscular, or intravenous injections was approved to treat acute iron intoxication and chronic iron overload due to transfusion-dependent anemia.

- In 2005, deferasirox (Exjade®, Novartis) was approved by FDA, and is available as a tablet for oral suspension. It is indicated for the treatment of chronic iron overload due to blood transfusions in patients aged 2 years and older. Under the accelerated approval program, the FDA expanded the indications for deferasirox in 2013 to include treatment of patients age 10 years and older with chronic iron overload due to NTDT syndromes and specific liver iron concentration and serum ferritin levels. A generic version of deferasirox tablet for oral suspension was also approved by FDA. In 2015, an oral tablet formulation for deferasirox (Jadenu™) was approved by FDA. All formulations of deferasirox carry a black box warning because it may cause serious and fatal renal toxicity and failure, hepatic toxicity and failure,
and gastrointestinal hemorrhage. As a result, treatment with deferasirox requires close patient monitoring, including laboratory tests of renal and hepatic function.

- In 2001, deferiprone (Ferriprox®), an iron chelator was approved by FDA 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 solution. Ferriprox® carries a black box warning because it can cause agranulocytosis, which can lead to serious infections and death. As a result, absolute neutrophil count should be monitored before and during treatment.

- In a June 2014 warning to consumers, the FDA advised that FDA-approved chelating agents are available by prescription only. There are no FDA-approved over-the-counter chelation products.

References


17. Maron DJ, Hlatky MA. Trial to Assess Chelation Therapy (TACT) and equipoise: When evidence conflicts with beliefs [editorial]. Am Heart J. Jul 2014;168(1):4-5. PMID 24952853


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/01/16</td>
<td>New policy, replaces deleted policy 8.01.02. Approved March 8, 2016. Chelation therapy for FDA approved indications may be considered medically necessary when criteria are met. All other indications are considered investigational.</td>
</tr>
<tr>
<td>05/01/17</td>
<td>Annual Review, approved April 11, 2017. No change to policy statements. No references added.</td>
</tr>
<tr>
<td>11/10/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>01/01/19</td>
<td>Coding update, added new HCPCS code G0068 (new code effective 1/1/19)</td>
</tr>
<tr>
<td>02/02/19</td>
<td>Minor update, added Documentation Requirements section.</td>
</tr>
</tbody>
</table>

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Toll free 855-332-6396, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@LifeWiseHealth.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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  - Information written in other languages

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