Medical Policy
Chelation Therapy

Table of Contents
• Policy: Commercial
• Policy: Medicare
• Authorization Information
• Coding Information
• Description
• Information Pertaining to All Policies
• Policy History
• References

Policy Number: 122
BCBSA Reference Number: 8.01.02 (For Plans internal use only)

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Chelation therapy in the treatment of the following conditions is **MEDICALLY NECESSARY**:
• Extreme conditions of metal toxicity
• Treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) or due to nontransfusion-dependent thalassemia (NTDT)
• Wilson's disease (hepatolenticular degeneration), OR
• Lead poisoning.

Chelation therapy in the treatment of the following conditions is **MEDICALLY NECESSARY** if other modalities have failed:
• Control of ventricular arrhythmias or heart block associated with digitalis toxicity
• Emergency treatment of hypercalcemia.

NaEDTA as chelation therapy is considered **NOT MEDICALLY NECESSARY**.

Off-label applications of chelation therapy are considered **INVESTIGATIONAL**, including, but not limited to:
• Alzheimer's disease
• Arthritis (includes rheumatoid arthritis)
• Atherosclerosis, (e.g., coronary artery disease, secondary prevention in individuals with myocardial infarction, or peripheral vascular disease)
• Autism
• Diabetes
• Multiple sclerosis.

Prior Authorization Information
Inpatient
- For services described in this policy, precertification/preauthorization **is required** for all products if the procedure is performed **inpatient**.

Outpatient
- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prior authorization is not required.</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commercial PPO and Indemnity</th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prior authorization is not required.</strong></td>
<td></td>
</tr>
</tbody>
</table>

**CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST be met** for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

**HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0470</td>
<td>Injection, dimercaprol, per 100 mg</td>
</tr>
<tr>
<td>J0600</td>
<td>Injection, edetate calcium disodium, up to 1,000 mg</td>
</tr>
<tr>
<td>J0895</td>
<td>Injection, deferoxamine mesylate, [Desferal] 500 mg</td>
</tr>
<tr>
<td>J3520</td>
<td>Edetate disodium, per 150 mg</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>

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if **medical necessity criteria are met**:

**ICD-10 Diagnosis Codes**

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D56.0</td>
<td>Alpha thalassemia</td>
</tr>
<tr>
<td>D56.1</td>
<td>Beta thalassemia</td>
</tr>
<tr>
<td>D56.5</td>
<td>Hemoglobin E-beta thalassemia</td>
</tr>
<tr>
<td>E83.00</td>
<td>Disorder of copper metabolism, unspecified</td>
</tr>
<tr>
<td>E83.01</td>
<td>Wilson's disease</td>
</tr>
<tr>
<td>E83.09</td>
<td>Other disorders of copper metabolism</td>
</tr>
<tr>
<td>E83.111</td>
<td>Hemochromatosis due to repeated red blood cell transfusions</td>
</tr>
<tr>
<td>E83.52</td>
<td>Hypercalcemia</td>
</tr>
<tr>
<td>I44.0</td>
<td>Atrioventricular block, first degree</td>
</tr>
<tr>
<td>I44.1</td>
<td>Atrioventricular block, second degree</td>
</tr>
<tr>
<td>I44.2</td>
<td>Atrioventricular block, complete</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------</td>
</tr>
<tr>
<td>I44.30</td>
<td>Unspecified atrioventricular block</td>
</tr>
<tr>
<td>I44.39</td>
<td>Other atrioventricular block</td>
</tr>
<tr>
<td>I44.4</td>
<td>Left anterior fascicular block</td>
</tr>
<tr>
<td>I44.5</td>
<td>Left posterior fascicular block</td>
</tr>
<tr>
<td>I44.60</td>
<td>Unspecified fascicular block</td>
</tr>
<tr>
<td>I44.69</td>
<td>Other fascicular block</td>
</tr>
<tr>
<td>I44.7</td>
<td>Left bundle-branch block, unspecified</td>
</tr>
<tr>
<td>I45.0</td>
<td>Right fascicular block</td>
</tr>
<tr>
<td>I45.10</td>
<td>Unspecified right bundle-branch block</td>
</tr>
<tr>
<td>I45.19</td>
<td>Other right bundle-branch block</td>
</tr>
<tr>
<td>I45.2</td>
<td>Bifascicular block</td>
</tr>
<tr>
<td>I45.3</td>
<td>Trifascicular block</td>
</tr>
<tr>
<td>I45.4</td>
<td>Nonspecific intraventricular block</td>
</tr>
<tr>
<td>I45.5</td>
<td>Other specified heart block</td>
</tr>
<tr>
<td>I49.8</td>
<td>Other specified cardiac arrhythmias</td>
</tr>
<tr>
<td>M1A.10x0</td>
<td>Lead-induced chronic gout, unspecified site, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.10x1</td>
<td>Lead-induced chronic gout, unspecified site, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1110</td>
<td>Lead-induced chronic gout, right shoulder, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1111</td>
<td>Lead-induced chronic gout, right shoulder, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1120</td>
<td>Lead-induced chronic gout, left shoulder, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1121</td>
<td>Lead-induced chronic gout, left shoulder, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1190</td>
<td>Lead-induced chronic gout, unspecified shoulder, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1191</td>
<td>Lead-induced chronic gout, unspecified shoulder, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1210</td>
<td>Lead-induced chronic gout, right elbow, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1211</td>
<td>Lead-induced chronic gout, right elbow, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1220</td>
<td>Lead-induced chronic gout, left elbow, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1221</td>
<td>Lead-induced chronic gout, left elbow, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1290</td>
<td>Lead-induced chronic gout, unspecified elbow, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1291</td>
<td>Lead-induced chronic gout, unspecified elbow, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1310</td>
<td>Lead-induced chronic gout, right wrist, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1311</td>
<td>Lead-induced chronic gout, right wrist, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1320</td>
<td>Lead-induced chronic gout, left wrist, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1321</td>
<td>Lead-induced chronic gout, left wrist, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1390</td>
<td>Lead-induced chronic gout, unspecified wrist, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1391</td>
<td>Lead-induced chronic gout, unspecified wrist, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1410</td>
<td>Lead-induced chronic gout, right hand, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1411</td>
<td>Lead-induced chronic gout, right hand, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1420</td>
<td>Lead-induced chronic gout, left hand, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1421</td>
<td>Lead-induced chronic gout, left hand, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1490</td>
<td>Lead-induced chronic gout, unspecified hand, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1491</td>
<td>Lead-induced chronic gout, unspecified hand, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1510</td>
<td>Lead-induced chronic gout, right hip, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1511</td>
<td>Lead-induced chronic gout, right hip, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1520</td>
<td>Lead-induced chronic gout, left hip, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1521</td>
<td>Lead-induced chronic gout, left hip, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1590</td>
<td>Lead-induced chronic gout, unspecified hip, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1591</td>
<td>Lead-induced chronic gout, unspecified hip, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1610</td>
<td>Lead-induced chronic gout, right knee, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1611</td>
<td>Lead-induced chronic gout, right knee, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1620</td>
<td>Lead-induced chronic gout, left knee, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1621</td>
<td>Lead-induced chronic gout, left knee, with tophus (tophi)</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>M1A.1690</td>
<td>Lead-induced chronic gout, unspecified knee, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1691</td>
<td>Lead-induced chronic gout, unspecified knee, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1710</td>
<td>Lead-induced chronic gout, right ankle and foot, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1711</td>
<td>Lead-induced chronic gout, right ankle and foot, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1720</td>
<td>Lead-induced chronic gout, left ankle and foot, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1721</td>
<td>Lead-induced chronic gout, left ankle and foot, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1790</td>
<td>Lead-induced chronic gout, unspecified ankle and foot, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.1791</td>
<td>Lead-induced chronic gout, unspecified ankle and foot, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.18x0</td>
<td>Lead-induced chronic gout, vertebrae, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.18x1</td>
<td>Lead-induced chronic gout, vertebrae, with tophus (tophi)</td>
</tr>
<tr>
<td>M1A.19x0</td>
<td>Lead-induced chronic gout, multiple sites, without tophus (tophi)</td>
</tr>
<tr>
<td>M1A.19x1</td>
<td>Lead-induced chronic gout, multiple sites, with tophus (tophi)</td>
</tr>
<tr>
<td>Q24.6</td>
<td>Congenital heart block</td>
</tr>
<tr>
<td>R00.1</td>
<td>Bradycardia, unspecified</td>
</tr>
<tr>
<td>T46.0x1A</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, accidental (unintentional), initial encounter</td>
</tr>
<tr>
<td>T46.0x1D</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, accidental (unintentional), subsequent encounter</td>
</tr>
<tr>
<td>T46.0x2A</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm, initial encounter</td>
</tr>
<tr>
<td>T46.0x2D</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm, subsequent encounter</td>
</tr>
<tr>
<td>T46.0x2S</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm, sequela</td>
</tr>
<tr>
<td>T46.0x3A</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, assault, initial encounter</td>
</tr>
<tr>
<td>T46.0x3D</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, assault, subsequent encounter</td>
</tr>
<tr>
<td>T46.0x3S</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, assault, sequela</td>
</tr>
<tr>
<td>T46.0x4A</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, undetermined, initial encounter</td>
</tr>
<tr>
<td>T46.0x4D</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, undetermined, subsequent encounter</td>
</tr>
<tr>
<td>T46.0x4S</td>
<td>Poisoning by cardiac-stimulant glycosides and drugs of similar action, undetermined, sequela</td>
</tr>
<tr>
<td>T46.0x5A</td>
<td>Adverse effect of cardiac-stimulant glycosides and drugs of similar action, initial encounter</td>
</tr>
<tr>
<td>T46.0x5D</td>
<td>Adverse effect of cardiac-stimulant glycosides and drugs of similar action, subsequent encounter</td>
</tr>
<tr>
<td>T46.0x5S</td>
<td>Adverse effect of cardiac-stimulant glycosides and drugs of similar action, sequela</td>
</tr>
<tr>
<td>T56.0x1A</td>
<td>Toxic effect of lead and its compounds, accidental (unintentional), initial encounter</td>
</tr>
<tr>
<td>T56.0x2A</td>
<td>Toxic effect of lead and its compounds, intentional self-harm, initial encounter</td>
</tr>
<tr>
<td>T56.0x3A</td>
<td>Toxic effect of lead and its compounds, assault, initial encounter</td>
</tr>
<tr>
<td>T56.0x4A</td>
<td>Toxic effect of lead and its compounds, undetermined, initial encounter</td>
</tr>
<tr>
<td>T56.4x1A</td>
<td>Toxic effect of copper and its compounds, accidental (unintentional), initial encounter</td>
</tr>
<tr>
<td>T56.4x2A</td>
<td>Toxic effect of copper and its compounds, intentional self-harm, initial encounter</td>
</tr>
<tr>
<td>T56.4x3A</td>
<td>Toxic effect of copper and its compounds, assault, initial encounter</td>
</tr>
<tr>
<td>T56.4x4A</td>
<td>Toxic effect of copper and its compounds, undetermined, initial encounter</td>
</tr>
<tr>
<td>T56.5x1A</td>
<td>Toxic effect of zinc and its compounds, accidental (unintentional), initial encounter</td>
</tr>
<tr>
<td>T56.5x2A</td>
<td>Toxic effect of zinc and its compounds, intentional self-harm, initial encounter</td>
</tr>
<tr>
<td>T56.5x3A</td>
<td>Toxic effect of zinc and its compounds, assault, initial encounter</td>
</tr>
<tr>
<td>T56.5x4A</td>
<td>Toxic effect of zinc and its compounds, undetermined, initial encounter</td>
</tr>
</tbody>
</table>
Chelation therapy is an established treatment for heavy metal toxicities and transfusional hemosiderosis, has been investigated for a variety of off-label applications, such as treatment of atherosclerosis, Alzheimer disease, and autism. This evidence review does not address indications for chelation therapy approved by the U.S. Food and Drug Administration. Instead, it addresses off-label indications, including Alzheimer disease, cardiovascular disease, autism spectrum disorder, diabetes, multiple sclerosis, and arthritis.

**Summary of Evidence**
For individuals who have Alzheimer disease, cardiovascular disease, or autism spectrum disorder, or diabetes, or multiple sclerosis, or arthritis who receive chelation therapy, the evidence includes a small number of randomized controlled trials (RCTs) and case series. Relevant outcomes are symptoms,
change in disease status, morbid events, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One RCT (the Trial to Assess Chelation Therapy) reported that chelation therapy reduced cardiovascular events in patients with previous myocardial infarction and that the benefit was greater in diabetic patients compared with nondiabetic patients. However, this trial had significant limitations (eg, high dropout rates) and, therefore, 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 inadequate to determine efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/2023</td>
<td>Annual policy review. Minor editorial refinements to policy statements; intent unchanged.</td>
</tr>
<tr>
<td>1/2023</td>
<td>Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.</td>
</tr>
<tr>
<td>3/2022</td>
<td>Annual policy review. Description, summary, and references updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>4/2021</td>
<td>Annual policy review. Description, summary, and references updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>3/2017</td>
<td>New references added from Annual policy review.</td>
</tr>
<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
</tbody>
</table>

**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines
References


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


