MASSACHUSETTS

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Medical Policy
Chelation Therapy

Table of Contents

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**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.

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

HCPCS codes:	Code Description
J0470	Injection, dimercaprol, per 100 mg
J0600	Injection, edetate calcium disodium, up to 1,000 mg
J0895	Injection, deferoxamine mesylate, [Desferal] 500 mg
J3520	Edetate disodium, per 150 mg
S9355	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

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

ICD-10-CM Diagnosis codes:	Code Description
D56.0	Alpha thalassemia
D56.1	Beta thalassemia
D56.5	Hemoglobin E-beta thalassemia
E83.00	Disorder of copper metabolism, unspecified
E83.01	Wilson's disease
E83.09	Other disorders of copper metabolism
E83.111	Hemochromatosis due to repeated red blood cell transfusions
E83.52	Hypercalcemia
I44.0	Atrioventricular block, first degree
I44.1	Atrioventricular block, second degree
I44.2	Atrioventricular block, complete

I44.30	Unspecified atrioventricular block
I44.39	Other atrioventricular block
I44.4	Left anterior fascicular block
I44.5	Left posterior fascicular block
I44.60	Unspecified fascicular block
I44.69	Other fascicular block
I44.7	Left bundle-branch block, unspecified
I45.0	Right fascicular block
I45.10	Unspecified right bundle-branch block
I45.19	Other right bundle-branch block
I45.2	Bifascicular block
I45.3	Trifascicular block
I45.4	Nonspecific intraventricular block
I45.5	Other specified heart block
I49.8	Other specified cardiac arrhythmias
M1A.10x0	Lead-induced chronic gout, unspecified site, without tophus (tophi)
M1A.10x1	Lead-induced chronic gout, unspecified site, with tophus (tophi)
M1A.1110	Lead-induced chronic gout, right shoulder, without tophus (tophi)
M1A.1111	Lead-induced chronic gout, right shoulder, with tophus (tophi)
M1A.1120	Lead-induced chronic gout, left shoulder, without tophus (tophi)
M1A.1121	Lead-induced chronic gout, left shoulder, with tophus (tophi)
M1A.1190	Lead-induced chronic gout, unspecified shoulder, without tophus (tophi)
M1A.1191	Lead-induced chronic gout, unspecified shoulder, with tophus (tophi)
M1A.1210	Lead-induced chronic gout, right elbow, without tophus (tophi)
M1A.1211	Lead-induced chronic gout, right elbow, with tophus (tophi)
M1A.1220	Lead-induced chronic gout, left elbow, without tophus (tophi)
M1A.1221	Lead-induced chronic gout, left elbow, with tophus (tophi)
M1A.1290	Lead-induced chronic gout, unspecified elbow, without tophus (tophi)
M1A.1291	Lead-induced chronic gout, unspecified elbow, with tophus (tophi)
M1A.1310	Lead-induced chronic gout, right wrist, without tophus (tophi)
M1A.1311	Lead-induced chronic gout, right wrist, with tophus (tophi)
M1A.1320	Lead-induced chronic gout, left wrist, without tophus (tophi)
M1A.1321	Lead-induced chronic gout, left wrist, with tophus (tophi)
M1A.1390	Lead-induced chronic gout, unspecified wrist, without tophus (tophi)
M1A.1391	Lead-induced chronic gout, unspecified wrist, with tophus (tophi)
M1A.1410	Lead-induced chronic gout, right hand, without tophus (tophi)
M1A.1411	Lead-induced chronic gout, right hand, with tophus (tophi)
M1A.1420	Lead-induced chronic gout, left hand, without tophus (tophi)
M1A.1421	Lead-induced chronic gout, left hand, with tophus (tophi)
M1A.1490	Lead-induced chronic gout, unspecified hand, without tophus (tophi)
M1A.1491	Lead-induced chronic gout, unspecified hand, with tophus (tophi)
M1A.1510	Lead-induced chronic gout, right hip, without tophus (tophi)
M1A.1511	Lead-induced chronic gout, right hip, with tophus (tophi)
M1A.1520	Lead-induced chronic gout, left hip, without tophus (tophi)
M1A.1521	Lead-induced chronic gout, left hip, with tophus (tophi)
M1A.1590	Lead-induced chronic gout, unspecified hip, without tophus (tophi)
M1A.1591	Lead-induced chronic gout, unspecified hip, with tophus (tophi)
M1A.1610	Lead-induced chronic gout, right knee, without tophus (tophi)
M1A.1611	Lead-induced chronic gout, right knee, with tophus (tophi)
M1A.1620	Lead-induced chronic gout, left knee, without tophus (tophi)
M1A.1621	Lead-induced chronic gout, left knee, with tophus (tophi)

M1A.1690	Lead-induced chronic gout, unspecified knee, without tophus (tophi)
M1A.1691	Lead-induced chronic gout, unspecified knee, with tophus (tophi)
M1A.1710	Lead-induced chronic gout, right ankle and foot, without tophus (tophi)
M1A.1711	Lead-induced chronic gout, right ankle and foot, with tophus (tophi)
M1A.1720	Lead-induced chronic gout, left ankle and foot, without tophus (tophi)
M1A.1721	Lead-induced chronic gout, left ankle and foot, with tophus (tophi)
M1A.1790	Lead-induced chronic gout, unspecified ankle and foot, without tophus (tophi)
M1A.1791	Lead-induced chronic gout, unspecified ankle and foot, with tophus (tophi)
M1A.18x0	Lead-induced chronic gout, vertebrae, without tophus (tophi)
M1A.18x1	Lead-induced chronic gout, vertebrae, with tophus (tophi)
M1A.19x0	Lead-induced chronic gout, multiple sites, without tophus (tophi)
M1A.19x1	Lead-induced chronic gout, multiple sites, with tophus (tophi)
Q24.6	Congenital heart block
R00.1	Bradycardia, unspecified
T46.0x1A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, accidental (unintentional), initial encounter
T46.0x1D	Poisoning by cardiac-stimulant glycosides and drugs of similar action, accidental (unintentional), subsequent encounter
T46.0x2A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm, initial encounter
T46.0x2D	Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm, subsequent encounter
T46.0x2S	Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm, sequela
T46.0x3A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, assault, initial encounter
T46.0x3D	Poisoning by cardiac-stimulant glycosides and drugs of similar action, assault, subsequent encounter
T46.0x3S	Poisoning by cardiac-stimulant glycosides and drugs of similar action, assault, sequela
T46.0x4A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, undetermined, initial encounter
T46.0x4D	Poisoning by cardiac-stimulant glycosides and drugs of similar action, undetermined, subsequent encounter
T46.0x4S	Poisoning by cardiac-stimulant glycosides and drugs of similar action, undetermined, sequela
T46.0x5A	Adverse effect of cardiac-stimulant glycosides and drugs of similar action, initial encounter
T46.0x5D	Adverse effect of cardiac-stimulant glycosides and drugs of similar action, subsequent encounter
T46.0x5S	Adverse effect of cardiac-stimulant glycosides and drugs of similar action, sequela
T56.0x1A	Toxic effect of lead and its compounds, accidental (unintentional), initial encounter
T56.0x2A	Toxic effect of lead and its compounds, intentional self-harm, initial encounter
T56.0x3A	Toxic effect of lead and its compounds, assault, initial encounter
T56.0x4A	Toxic effect of lead and its compounds, undetermined, initial encounter
T56.4x1A	Toxic effect of copper and its compounds, accidental (unintentional), initial encounter
T56.4x2A	Toxic effect of copper and its compounds, intentional self-harm, initial encounter
T56.4x3A	Toxic effect of copper and its compounds, assault, initial encounter
T56.4x4A	Toxic effect of copper and its compounds, undetermined, initial encounter
T56.5x1A	Toxic effect of zinc and its compounds, accidental (unintentional), initial encounter
T56.5x2A	Toxic effect of zinc and its compounds, intentional self-harm, initial encounter
T56.5x3A	Toxic effect of zinc and its compounds, assault, initial encounter
T56.5x4A	Toxic effect of zinc and its compounds, undetermined, initial encounter

T56.891A	Toxic effect of other metals, accidental (unintentional), initial encounter
T56.892A	Toxic effect of other metals, intentional self-harm, initial encounter
T56.893A	Toxic effect of other metals, assault, initial encounter
T56.894A	Toxic effect of other metals, undetermined, initial encounter

The following HCPCS code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

HCPCS Codes

HCPCS codes:	Code Description
M0300	IV chelation therapy (chemical endarterectomy)

Description

Chelation Therapy

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 (see Appendix Table 1). Specific chelating agents are used for particular heavy metal toxicities. For example, deferoxamine is used for patients with iron toxicity, and calcium-ethylenediaminetetraacetic acid (EDTA) is used for patients with lead poisoning. Disodium-EDTA is not recommended for acute lead poisoning due to the increased risk of death from hypocalcemia.[1,]

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, MPACs promote the solubilization and clearance of β-amyloid by binding its metal-ion complex and also inhibit redox reactions that generate neurotoxic free radicals. Therefore, MPACs interrupt 2 putative pathogenic processes of Alzheimer disease. However, no MPACs have received FDA approval for treating Alzheimer disease.

Chelation therapy also has been considered 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.

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Summary

Description

Chelation therapy, 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, or 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

Date	Action
4/2024	Annual policy review. References updated. Policy statements unchanged.
4/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
1/2023	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
3/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2018	Annual policy review. Policy criteria clarified. 6/1/2018.
3/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2017	New references added from Annual policy review.
11/2015	Annual policy review. Hypoglycemia deleted from the policy statement. Clarified coding language. Effective 11/1/2015.
11/2014	Annual policy review. Investigational indications clarified. Coding information clarified. Effective 11/1/2014.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
12/2013	Annual policy review. New medically necessary and investigational indications described. Effective 12/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
2/2011	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
4/2010	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
9/2009	Medical Policy122 describing covered and non-covered indications.

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

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