Policy Number: MP.019.MPC
Last Review Date: 02/15/2024
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MP.019.MPC Chelation Therapy

Maryland Physicians Care considers the **Administration of FDA-Approved Chelating Agents** medically necessary for *any* the following indications:

1. Secondary hemochromatosis due to chronic iron overload due to transfusion-dependent anemias (e.g., thalassemias, Cooley's anemia, sickle cell anemia, sideroblastic anemia).

2. Heavy metal toxicity, which includes the following:
   - Arsenic, mercury, iron, copper or gold poisoning when long-term exposure and toxicity has been confirmed through lab results (i.e., blood, plasma, and/or urine results) or clinical findings (i.e., symptoms consistent with metal toxicity).
   - Aluminum overload in chronic hemodialysis members
   - Copper overload in members with Wilson's Disease
   - Emergency treatment of hypercalcemia
   - Lead overload in cases of acute or long-term lead exposure

   Note: for metals not listed above, additional documentation must be maintained in the medical record.

3. Covered Place of Service: Chelation therapy is covered only in the following places of service that can provide the level of care and monitoring required for the procedure:
   - Hospital
   - Hospital-based ambulatory setting
   - Outpatient hospital
   - Emergency room
   - Renal dialysis facilities, and
   - Skilled nursing facilities

Limitations

1. Chelation therapy is considered **investigational and not medically necessary** for the treatment of any of the following:
   - Alzheimer's disease
   - Autism Spectrum Disorder
   - Atherosclerosis
   - Cadmium exposure

- Cancer
- Cardiovascular disease - prevention and treatment
- Chemical Endarterectomy with Edetate Disodium
- Parkinson's disease
- Peripheral vascular disease
- Rheumatoid arthritis

2. Non-Covered Locations: Chelation therapy requires close monitoring and is not covered in the following locations that cannot provide the level of care and monitoring required:
    - Office setting
    - Home setting, or
    - Certain ambulatory surgical centers

Note: Certain oral iron chelation agents may be taken in the home setting.

Background
Chelation therapy is the application of chelation techniques for the therapeutic or preventive effects of removing unwanted metal ions from the body. It involves the administration of drugs that bind heavy metal ions such as lead, arsenic, iron, and mercury in the blood stream preventing their interaction with vital organs, which include the nervous system and kidneys. Such drugs are known as chelating agents. The presence of heavy metals in the blood stream can be the result of several factors including environmental exposure. Additionally, many medical conditions may lead to excess iron in the blood stream causing health problems.

Chelation therapy has been proposed as a treatment for the removal of heavy metal ions to reduce cellular oxidative damage caused by the production of hydroxyl radicals. This therapy is being investigated for the treatment of numerous non-over-load conditions, including, cardiovascular disease, reperfusion injury during coronary angioplasty or cardiopulmonary bypass surgery, anthracycline-associated cardiac damage, Alzheimer's disease, autism spectrum disorder and rheumatoid arthritis. However, there is no or very limited scientific evidence that supports these uses of chelation therapy.

Specific chelation agents are used to treat certain kinds of poisonings. Common chelating agents include:

1. **Desfuroxamine Mesylate**: used for acute iron toxicity, and acute iron intoxication and chronic iron overload due to transfusion-dependent anemias. Intravenous preferred.
2. **Dimercaprol (BAL)**: indicated in the treatment of arsenic, gold and mercury (soluble inorganic compounds) poisoning, and as an adjunct in the treatment of lead toxicity, given intramuscularly.
3. **DMSA:** an analogue of Dimercaprol that can be given orally for lead and arsenic poisoning.
4. **D-penicillamine**: an oral chelating agent used for heavy metal toxicity - lead, arsenic or mercury.
5. **Calcium Disodium Versante (CaNa2-EDTA)**: a drug used in the treatment of lead toxicity. It reduces the blood concentrations of lead, and increases urinary excretion of zinc. It has also been found to chelate iron, copper, calcium, and manganese. This drug is used in conjunction with BAL in cases of lead toxicity. It should never be used alone in treating lead toxicity because it chelates only extracellular and not intracellular lead.
6. **Edetate Disodium**: a drug approved by the FDA for use in selected patients with high blood calcium levels (hypercalcemia) as well as for use among patients with heart rhythm problems due to intoxication with the drug, digitalis.

Patients with heavy metal toxicity usually require chelation therapy 2-6 times a day, for 2-5 days (depending on the level, agent, and condition of the patient). In addition, they require close monitoring of their physical signs and symptoms and heavy metal levels. Additionally chelation therapy and its resultant sequelae must be continuously monitored.

The American Heart Association (AHA), the US Food and Drug Administration (FDA), the National Institutes of Health (NIH) and the American College of Cardiology (ACC) have stated that there is inadequate scientific evidence to justify the application of Chelation Therapy for atherosclerosis on a clinical basis.

> *"We have found no scientific evidence to demonstrate any benefit from chelation therapy with ethylenediamine tetraacetic acid (E.D.T.A.), to treat arteriosclerotic heart disease. Up to now, there have been no adequate, controlled, published scientific studies using currently approved scientific methodology to support this therapy for cardiovascular disease".*

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The American Medical Association (AMA) indicates that there is no scientific documentation that Chelation Therapy is effective in the treatment of cardiovascular disease, atherosclerosis, rheumatoid arthritis and cancer.

> *"There is no scientific documentation that the use of chelation therapy is effective in the treatment of cardiovascular disease, atherosclerosis, rheumatoid arthritis, and cancer. If chelation therapy is to be considered a useful medical treatment for anything other than heavy metal poisoning, hypercalcemia or digitalis toxicity, it is the responsibility of its proponents to conduct properly controlled scientific studies, to adhere to FDA guidelines for drug investigation, and to disseminate study results in the usually accepted channels".*

Codes

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
J0470	Injection, Dimercaprol, per 100 mg
J0600	Injection, Edetate Calcium Disodium up to 1000 mg
J0895	Injection, Deferoxamine Mesylate, 500 mg
Non-Covered Codes	
J3520	Edetate disodium, per 150 mg
M0300	Chemical endarterectomy by use of Ethylenediamine-Tetra-Acetic (EDTA) in the treatment of atherosclerosis, arteriosclerosis, calcinosis or similar generalized conditions, or in the treatment of heavy metal poisoning
S9355	Home infusion therapy, chelation therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment
ICD-10 codes covered if selection criteria are met:	
E83.10	Disorder of iron metabolism, unspecified
E83.110	Hereditary Hemochromatosis
E83.111	Hemochromatosis due to repeated red blood cell transfusions
E83.118	Other Hemochromatosis
E83.119	Hemochromatosis unspecified
E83.00	Disorder of copper metabolism, unspecified
E83.01	Wilson's disease

E83.09	Other disordered of copper metabolism
E83.52	Hypercalcemia
D56.1	Beta thalassemia
D56.2	Delta-beta thalassemia
D56.3	Thalassemia minor
D56.4	Hereditary persistence of fetal hemoglobin [HPFH]
D56.5	Hemoglobin E-beta thalassemia
D56.8	Other thalassemias
D56.9	Thalassemia, unspecified
D57.41	Sickle-cell thalassemia with crisis
D57.411	Sickle-cell thalassemia with acute chest syndrome
D57.412	Sickle-cell thalassemia with splenic sequestration
D57.419	Sickle-cell thalassemia unspecified
D57.00	Sickle-cell unspecified
D57.01	Hb-SS disease with acute chest syndrome
D57.02	Hb-SS disease with splenic sequestration
D57.1	Sickle-cell disease without crisis
D57.20	Sickle-cell/ Hb-C disease without crisis
D57.211	Sickle-cell/Hb-C disease with acute chest syndrome
D57.212	Sickle-cell/Hb-C disease with splenic sequestration
D57.219	Sickle-cell/Hb-C unspecified
D57.3	Sickle-cell trait
D57.80	Other sickle-cell without crisis
D57.811	Other sickle-cell disorders with acute chest syndrome
D57.812	Other sickle-cell disorders with splenic sequestration
D57.819	Other sickle-cell unspecified
D64.0	Hereditary sideroblastic anemia
D64.1	Secondary sideroblastic anemia due to disease
D64.2	Secondary sideroblastic anemia due to drugs and toxins
D64.3	Other sideroblastic anemias

T37.8X1A	Poisoning by other specified systemic anti-infectives and antiparasitics, accidental (unintentional), initial encounter
T37.8X1D	Poisoning by other specified systemic anti-infectives and antiparasitics, accidental (unintentional), subsequent encounter
T37.8X1S	Poisoning by other specified systemic anti-infectives and antiparasitics, accidental (unintentional), sequela
T37.8X2A	Poisoning by other specified systemic anti-infectives and antiparasitics, intentional self-harm initial encounter
T37.8X2D	Poisoning by other specified systemic anti-infectives and antiparasitics, intentional self-harm subsequent encounter
T37.8X2S	Poisoning by other specified systemic anti-infectives and antiparasitics, intentional self-harm sequela
T37.8X3A	Poisoning by other specified systemic anti-infectives and antiparasitics, assault initial encounter
T37.8X3D	Poisoning by other specified systemic anti-infectives and antiparasitics, assault subsequent encounter
T37.8X3S	Poisoning by other specified systemic anti-infectives and antiparasitics, assault sequela
T37.8X4A	Poisoning by other specified systemic anti-infectives and antiparasitics, undetermined initial encounter
T37.8X4D	Poisoning by other specified systemic anti-infectives and antiparasitics, undetermined subsequent encounter
T37.8X4S	Poisoning by other specified systemic anti-infectives and antiparasitics, undetermined sequela
T37.8X5A	Adverse effect of other specified systemic anti-infectives and antiparasitics initial encounter
T37.8X5D	Adverse effect of other specified systemic anti-infectives and antiparasitics subsequent encounter
T37.8X5S	Adverse effect of other specified systemic anti-infectives and antiparasitics sequela
T45.4X1A	Poisoning by iron and its compounds, accidental (unintentional) initial encounter
T45.4X1D	Poisoning by iron and its compounds, accidental (unintentional)

	subsequent encounter
T45.4X1S	Poisoning by iron and its compounds, accidental (unintentional) sequela
T45.4X2A	Poisoning by iron and its compounds, intentional self-harm initial encounter
T45.4X2D	Poisoning by iron and its compounds, intentional self-harm subsequent encounter
T45.4X2S	Poisoning by iron and its compounds, intentional self-harm sequel
T45.4X3A	Poisoning by iron and its compounds, assault initial encounter
T45.4X3D	Poisoning by iron and its compounds, assault subsequent encounter
T45.4X3S	Poisoning by iron and its compounds, assault sequela
T45.4X4A	Poisoning by iron and its compounds, undetermined initial encounter
T45.4X4D	Poisoning by iron and its compounds, undetermined subsequent encounter
T45.4X4S	Poisoning by iron and its compounds, undetermined sequela
T45.4X5A	Adverse effect of iron and its compounds initial encounter
T45.4X5D	Adverse effect of iron and its compounds subsequent encounter
T45.4X5S	Adverse effect of iron and its compounds sequela
T56.0X1A	Toxic effect of lead and its compounds, accidental (unintentional) initial encounter
T56.0X1D	Toxic effect of lead and its compounds, accidental (unintentional) subsequent encounter
T56.0X1S	Toxic effect of lead and its compounds, accidental (unintentional) sequela
T56.0X2A	Toxic effect of lead and its compounds, intentional self-harm initial encounter
T56.0X2D	Toxic effect of lead and its compounds, intentional self-harm subsequent encounter
T56.0X2S	Toxic effect of lead and its compounds, intentional self-harm Sequel
T56.0X3A	Toxic effect of lead and its compounds, intentional assault initial encounter

T56.0X3D	Toxic effect of lead and its compounds, intentional assault subsequent encounter
T56.0X3S	Toxic effect of lead and its compounds, intentional assault sequela
T56.0X4A	Toxic effect of lead and its compounds, undetermined initial encounter
T56.0X4D	Toxic effect of lead and its compounds, undetermined subsequent
T56.0X4S	Toxic effect of lead and its compounds, undetermined sequela
T56.1X1A	Toxic effect of mercury and its compound, accidental initial encounter
T56.1X1D	Toxic effect of mercury and its compound, accidental subsequent encounter
T56.1X1S	Toxic effect of mercury and its compound, accidental sequela
T56.1X2A	Toxic effect of mercury and its compounds, intentional self-harm initial encounter
T56.1X2D	Toxic effect of mercury and its compounds, intentional self-harm subsequent encounter
T56.1X2S	Toxic effect of mercury and its compounds, intentional self-harm sequela
T56.1X3A	Toxic effect of mercury and its compounds, assault initial encounter
T56.1X3D	Toxic effect of mercury and its compounds, assault subsequent encounter
T56.1X3S	Toxic effect of mercury and its compounds, assault sequela
T56.1X4A	Toxic effect of mercury and its compounds, undetermined initial encounter
T56.1X4D	Toxic effect of mercury and its compounds, undetermined subsequent encounter
T56.1X4S	Toxic effect of mercury and its compounds, undetermined sequel
T56.4X1A	Toxic effect of copper and its compounds, accidental initial encounter
T56.4X1D	Toxic effect of copper and its compounds, accidental initial subsequent encounter
T56.4X1S	Toxic effect of copper and its compounds, accidental initial sequela
T56.4X2A	Toxic effect of copper and its compounds, intentional self-harm initial encounter
T56.4X2D	Toxic effect of copper and its compounds, intentional self-harm subsequent encounter
T56.4X2S	Toxic effect of copper and its compounds, intentional self-harm sequela
T56.4X3A	Toxic effect of copper and its compounds, assault initial encounter

T56.4X3D	Toxic effect of copper and its compounds, assault subsequent encounter
T56.4X3S	Toxic effect of copper and its compounds, assault sequela
T56.4X4A	Toxic effect of copper and its compounds, undetermined initial encounter
T56.4X4D	Toxic effect of copper and its compounds, undetermined subsequent encounter
T56.4X4S	Toxic effect of copper and its compounds, undetermined sequel
T56.891A	Toxic effect of other metals, accidental (unintentional) initial encounter
T56.891D	Toxic effect of other metals, accidental (unintentional) subsequent encounter
T56.891S	Toxic effect of other metals, accidental (unintentional) sequela
T56.892A	Toxic effect of other metals, intentional self-harm initial encounter
T56.892D	Toxic effect of other metals, intentional self-harm subsequent encounter
T56.892S	Toxic effect of other metals, intentional self-harm sequela
T56.893A	Toxic effect of other metals, assault initial encounter
T56.893D	Toxic effect of other metals, assault subsequent encounter
T56.893S	Toxic effect of other metals, assault sequela
T56.894A	Toxic effect of other metals, undetermined initial encounter
T56.894D	Toxic effect of other metals, undetermined subsequent encounter
T56.894S	Toxic effect of other metals, undetermined sequela
T56.91XA	Toxic effect of unspecified metal, accidental (unintentional) initial encounter
T56.91XD	Toxic effect of unspecified metal, accidental (unintentional) subsequent encounter
T56.91XS	Toxic effect of unspecified metal, accidental (unintentional) sequela
T56.92XA	Toxic effect of unspecified metal, intentional self-harm initial encounter
T56.92XD	Toxic effect of unspecified metal, intentional self-harm subsequent encounter
T56.92XS	Toxic effect of unspecified metal, intentional self-harm sequela
T56.93XA	Toxic effect of unspecified metal, assault initial encounter
T56.93XD	Toxic effect of unspecified metal, assault subsequent encounter
T56.93XS	Toxic effect of unspecified metal, assault sequela

T56.94XA	Toxic effect of unspecified metal, undetermined initial encounter
T56.94XD	Toxic effect of unspecified metal, undetermined subsequent encounter
T56.94XS	Toxic effect of unspecified metal, undetermined sequela

References

1. Allain P, Mauras Y, Premel-Cabic A, et al. Effects of an EDTA infusion on the urinary elimination of several elements in health subjects. Br J Clin Pharmacol. 1991; 31(3):347-349. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1368364/
2. American Heart Association (AHA), Chelation Therapy, AHA Recommendation. 2015. https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.114.010774
3. American College of Cardiology. Position Statement on Chelation Therapy. 02/26/2016. https://www.acc.org/latest-in-cardiology/articles/2016/02/26/09/34/chelation-therapy-for-cad
4. Barrett S, Baratz RS. Chelation Therapy and Insurance Fraud. Quackwatch. Revised: August 15, 2019. http://www.quackwatch.org/01QuackeryRelatedTopics/chelationfraud.html
5. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 20.21 - Chelation Therapy for Treatment of Atherosclerosis. Effective date not posted- longstanding NCD. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=86&ncdver=1&bc=AgAAgAAAAAAAAA%3d%3d&
6. Centers for Medicare and Medicaid Services (CMS): Medicare Claims Processing Manual, Ch. 8-outpatient ESRD hospital, independent facility, and physician/supplier claims. Revised 08/06/2021. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf
7. Centers for Medicare and Medicaid Services (CMS): Medicare National Coverage Determinations Manual, Ch. 1, Part 1 (Sections 10-80.12), Revised 09/08/2021. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf
8. Centers for Medicare and Medicaid Services CMS). National Coverage Determination (NCD) No. 20.22 - Ethlenediamine-Tetra-Acetic (EDTA) chelation

therapy for treatment of atherosclerosis. Effective date not posted- longstanding NCD. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=146&ncdver=1&DocID=20.22&kq=true&bc=gAAAAAgAAAAAAA%3D%3D&

9. Department of Health and Human Services. Agency for Healthcare Research and Quality. (AHRQ). National Guideline Clearinghouse (NGC). Diagnosis and management of hemochromatosis: 2011 practice guideline by the American Association for the Study of Liver Diseases. NGC No. 8787. Last updated: Jan. 6, 2012. https://www.ncbi.nlm.nih.gov/pubmed/21452290
10. Ernst E.: Chelation therapy for coronary heart disease: an overview of all clinical investigations, Am Heart J. 2000; 140(1):139-141. http://www.ncbi.nlm.nih.gov/pubmed/10874275
11. Flora SJ, Pachauri V. Chelation in Metal Intoxication. Int J Environ Res Public Health. 2010 Jul; 7(7): 2745-2788. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2922724
12. Guldager B, Jelnes R, Jorgensen SJ, et al. EDTA Treatment of intermittent claudication -- a double-blind placebo-controlled study. J Intern Med; 1992; 231: 261-267. https://pubmed.ncbi.nlm.nih.gov/1556523/
13. Johnson LE. Overview of Minerals. In: The Merck Manual of Diagnosis and Therapy. Robert S. Porter, eds. Whitehouse Station, NJ; Merck & Co. Last Review/Revision July, 2023. http://www.merckmanuals.com/professional/nutritional_disorders/mineral_deficiency_and_toxicity/overview_of_minerals.html
14. Knudtson ML, Wyse DG, Galbraith PD, et al.: Chelation therapy for ischemic heart disease: a randomized, controlled trial. JAMA. 2002 Jan; 287(4):481-486. http://jama.jamanetwork.com/article.aspx?articleid=321724
15. Ley TJ, Griffith P, Nienhuis AW. Transfusion haemosiderosis and chelation therapy, Clin Haematol. 1982. 11: 437-445. http://www.ncbi.nlm.nih.gov/pubmed/7042160
16. National Heart, Lung and Blood Institute: Disease and Conditions Index, What are Thalassemias? Updated: May 31, 2022. http://www.nhlbi.nih.gov/health/health-topics/topics/thalassemia/
17. Neukirchen J. Iron chelation in MDS: Still a controversial issue. Leuk Res. 2014 Feb;38(2):145-6. doi: 10.1016/j.leukres.2013.12.004. Epub 2013 Dec 11. http://www.ncbi.nlm.nih.gov/pubmed/24373456

18. Olivieri NF, Freedman MH, Koren G., et al. Comparison of oral iron chelator L1 and desferrioxamine in iron-loaded patients. Lancet. 1990; 336(8726):1275-1279. http://www.ncbi.nlm.nih.gov/pubmed/1978115
19. Taher AT, Viprakasit V, Musallam KM, et al. Treating iron overload in patients with non-transfusion-dependent thalassemia. Am J Hematol. 2013 May;88(5):409-415. doi: 10.1002/ajh.23405. Epub 2013 Mar 8. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3652024/pdf/ajh0088-0409.pdf

Archived References

1. Hayes Medical Technology Report. Chelation Therapy, Overload Conditions. Annual review March 27, 2008. Archived: November 12, 2008.

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