

Chelation Therapy

Policy Number: **M120123202**
Effective Date: **4/1/2012**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: Internal External

Data Classification: Confidential Restricted Public

Applies to (Line of Business):

- Corporate (All)
- State Products, if yes which plan(s): MediSource; MediSource Connect; Child Health Plus Essential Plan
- Medicare, if yes, which plan(s): MAPD; PDP; ISNP; CSNP
- Commercial, if yes, which type: Large Group; Small Group; Individual
- Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes No

Purpose and Applicability:

To set forth the medical necessity criteria for **chelation therapy**.

Policy:

Commercial, Self-Funded and Medicare Advantage:

Independent Health provides coverage for chelation therapy when it is determined to be medically necessary. Chelation therapy may be considered medically necessary for the treatment of the following conditions:

- Control of ventricular arrhythmias or heart block associated with digitalis toxicity;
- Emergency treatment of hypercalcemia;
- Extreme conditions of metal toxicity;
- Treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis);
- Treatment of chronic iron overload due to non-transfusion-dependent thalassemia;
- Treatment of documented iron overload (hemochromatosis), lead poisoning, or other heavy metal toxicity;
- Acute iron poisoning (serum iron level greater than 50umol/L300ug/dL);
- Other heavy metals (arsenic, cadmium, gold, mercury, thallium poisoning based upon a positive urine screen for heavy metals in a symptomatic member supported by confirmatory positive serum levels); and
- Wilson's disease (hepatolenticular degeneration).

Non-Covered Conditions:

Other applications of chelation therapy are considered investigational and non-covered, including but not limited to:

- Atherosclerosis
- Coronary artery disease
- Multiple sclerosis
- Arthritis (includes rheumatoid arthritis)
- Hypoglycemia
- Autism
- Alzheimer's disease
- Diabetes

Note - Medicare Advantage:

There is currently National Coverage Determinations (NCD) for chelation therapy for treatment of atherosclerosis. Please refer to the links listed in the Reference section for Medicare Advantage members.

MediSource, MediSource Connect, Child Health Plus and Essential Plan:

MediSource, MediSource Connect, Child Health Plus and Essential Plan cover chelation therapy for lead poisoning.

Background:

Chelation therapy reduces the accumulation of essential heavy metals, such as iron and copper, or nonessential metals, such as lead and aluminum, in overloaded patients. Chelators bind with heavy metal ions to form a water-soluble complex, which is excreted in the urine or feces.

Overload conditions treated by chelation include acute or long-term lead exposure, sickle cell anemia or thalassemia, and Wilson's disease. With appropriate heavy metal toxicity diagnosis, several studies published in the peer-reviewed medical literature have established that chelation therapy can be useful in binding toxic metal ions and facilitating their excretion through the liver or kidneys, and mitigating the morbidity associated with heavy metal toxicity such as end organ damage and impaired neurologic functioning.

There is a lack of peer-reviewed clinical trial data to support the use of chelation for indications such as multiple sclerosis, and Alzheimer's disease.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes No

Pre-authorization is not required. Criteria above will be utilized upon retro-review.

Definitions

Chelation: The process by which a molecule encircles and binds to a metal and removes it from tissue.

Chelation therapy: The use of chelating agents, such as edetate calcium disodium (EDTA), dimercaprol, deferoxamine, penicillamine, and succimer to rid the body of toxic levels of iron, lead, or other heavy metals.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Bacon BR, Adams PC, Kowdley KV, et al.; American Association for the Study of Liver Diseases. Diagnosis and management of hemochromatosis: 2011 practice guideline by the American Association for the Study of Liver Diseases. *Hepatology*. 2011 Jul;54(1):328-43.

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<http://www.cdc.gov/nceh/lead/casemanagement/managingEBLLs.pdf> Accessed November 21, 2023

DeBaun MR, Chou ST. Red blood cell transfusion in sickle cell disease: Indications and transfusion techniques. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on November 21, 2023)

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National Center for Complementary and Integrative Health (NCCIH) [web site]. Chelation for Coronary Heart Disease January 2, 2020. Available at: <https://nccih.nih.gov/health/chelation> Accessed November 21, 2023.

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Vinchinsky EP. Iron chelators: Choice of agent, dosing, and adverse effects. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on November 29, 2022)

Wax PM. Current use of chelation in American health care. J Med Toxicol. 2013 Dec;9(4):303-7. doi: 10.1007/s13181-013-0347-2.

Regulatory References

Centers for Medicare and Medicaid (CMS) [web site]. National Coverage Determination (NCD) for Chelation Therapy for Treatment of Atherosclerosis (20.21). Available at: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=86&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&Keyword=chelation&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAA AAAA%3d%3d&> Accessed November 21, 2023

Centers for Medicare and Medicaid (CMS) [web site]. National Coverage Determination (NCD) for Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis (20.22). Available at: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=146&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&Keyword=chelation&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAA AAAA%3d%3d&> Accessed November 21, 2023

New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes. Section 2 – Medicine, Drugs, and Drug Administration. Version April 2023. Available at: https://www.emedny.org/providermanuals/physician/PDFS/Physician_Procedure_Codes_Sect2.pdf Accessed November 21, 2023

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest) MA - 00566. April 12, 2013.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member’s contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes No

Revision Date	Owner	Notes
2/1/2024	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised
2/1/2023	Health Care Services	Reviewed
3/1/2022	Health Care Services	Reviewed
4/1/2021	Health Care Services	Reviewed
4/1/2020	Medical Management	Revised
5/1/2019	Medical Management	Revised
5/1/2018	Medical Management	Revised
5/1/2017	Medical Management	Revised
6/1/2016	Medical Management	Revised
6/1/2015	Medical Management	Revised
4/1/2014	Medical Management	Revised
4/1/2013	Medical Management	Revised