NO. 91077-R6

CHELATION THERAPY

Effective date: 03/01/2026 **Last reviewed**: 02/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy establishes the coverage criteria for Chelation Therapy, including the applicable diagnoses and documentation requirements necessary to determine medical necessity.

Related policies:

- None

SUMMARY OF CHANGES – R6

Additions:

- New Policy Scope section
- New FDA/Regulatory section
- New Medical/Professional Society Guidelines section
- New Government Regulations section listing applicable CMS NCDs or LCDs
- Added additional non-covered conditions for chelation therapy

Clarifications:

- Policy was restructured to specify not medically necessary conditions into one section, removing "1 B" and "1 C" on prior R5 version
- Updated references

I. MEDICAL NECESSITY CRITERIA

A. Chelation Therapy

1. Chelation therapy for the following diagnoses is medically necessary:
   a. Biliary cirrhosis

b. Cooley's anemia
c. Cystinuria
d. Heavy metal poisoning (e.g., arsenic, copper, gold, iron, lead, mercury)
e. Wilson's disease
f. Patients who have iron overload secondary to multiple blood transfusions (e.g., sickle cell anemia)

B. Chelation therapy as a treatment for *all* other conditions has not been proven to be effective and is considered not medically necessary. These conditions include, but are not limited to:
    1. Autism Spectrum Disorders
    2. Cardiovascular disease (including atherosclerosis, coronary artery disease)
    3. Neurodegenerative disorders (Alzheimer's disease or other dementias)
    4. Stroke

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
NCD: 20.21- NCD - Chelation Therapy for Treatment of Atherosclerosis (20.21) NCD: 20.22- NCD - Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis (20.22)	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

Chelation is a process of administering a substance such as ethylene diamine tetra-acetic acid (EDTA), 2,3-dimercaptosuccinic acid (DMSA), or 2,3-dimercaptopropane-1-sulfonate (DMPS), to remove heavy metals such as iron or mercury from the body. Chelation therapy involves repeated intravenous administration of the chelating agent, drugs that are heavy metal antagonists that binds certain metals and render them physiologically inactive so they can be excreted in the urine. A typical protocol might consist of 30 intravenously administered solutions of 3 grams of disodium EDTA with concomitant administration of varying levels of ascorbic acid, B-vitamins, heparin, and the minerals magnesium, copper, zinc, selenium and manganese delivered over 1.5 to 3 hours in 500 ml to 1000 ml of normal saline. Therapy is often delivered on a weekly or biweekly basis and may be followed up with a less frequent maintenance schedule (Seely, 2005). Chelation therapy has been proven to be an effective treatment for specific medical diagnoses. In series of Choosing Wisely guidelines, the American College of Medical Toxicology and American Academy of Clinical Toxicology do not recommend chelation except for documented metal intoxication, which has been diagnosed using validated tests in appropriate biological samples. Chelation does not improve objective outcomes in autism, cardiovascular disease, or neurodegenerative conditions like Alzheimer's disease.

A phase 2, double-blind, placebo-controlled RCT (n=81; Ayton et al., 2025) evaluated deferiprone (15 mg/kg twice daily for 12 months) in patients with amyloid-confirmed mild cognitive impairment or early Alzheimer's disease. Results showed that reducing brain iron with deferiprone did not slow neurodegeneration and was linked to worse cognitive outcomes (Ayton, Barton, Brew, et al., 2025).

The American Academy of Family Physicians states that the use of chelation therapy for conditions other than heavy metal intoxication—such as atherosclerotic vascular disease or neurodegenerative disorders—remains investigational and is not recommended. A Cochrane review of two RCTs (333 participants) found no demonstrated benefit of iron-chelating drugs for spontaneous intracerebral hemorrhage. The potential role of iron chelators in ischemic stroke or subarachnoid hemorrhage remains uncertain (Van der Loo et al., 2020).

A systematic review of chelation therapy for atherosclerotic cardiovascular disease examined five studies with a total of 1993 randomized participants did not find any clear differences between people treated with chelation and people given the control, for the outcomes evaluated. None of the outcomes included more than two studies, therefore further high-quality trials that focus on clinical outcomes are necessary (Villarruz-Sulit, 2020). Due to insufficient evidence to determine the effectiveness of chelation therapy in improving clinical outcomes of people with atherosclerotic cardiovascular disease. More high-quality, randomized controlled trials are needed that assess the effects of chelation therapy on longevity and quality of life among people with atherosclerotic cardiovascular disease or neurodegenerative disease remains investigational.

In systematic review of chelation therapy in patients with cardiovascular disease, the authors found that overall, 17 studies suggested improved outcomes, 5 reported no statistically significant effect of treatment, and 2 reported no qualitative benefit. Repeated EDTA for CVD treatment may provide more benefit to patients with diabetes and severe peripheral arterial disease. Differences across infusion regimens, including

dosage, solution components, and number of infusions, limit comparisons across studies. Additional research is necessary to confirm these findings and to evaluate the potential mediating role of metals (Ravalli, 2022). The review included 4 clinical trials, 15 prospective before/after studies, and 5 retrospective case series assessing mortality, disease severity, plasma biomarkers of disease chronicity, and/or quality of life.

To definitively determine the effectiveness and safety of chelation therapy, the National Center for Complementary and Alternative Medicine and the National Heart, Lung, and Blood Institute released a request for applications in 2001 for a definitive study of edetate disodium treatment in subjects with coronary artery disease (CAD), and the aptly named TACT (Trial to Assess Chelation Therapy). A total of 1708 post-MI patients who were 50 years or older with a creatinine of 2.0 or less were enrolled and received 55,222 infusions of disodium EDTA or placebo with a median follow-up of 55 months. TACT didn't provide enough evidence to support routine use of this treatment for heart disease. But it did find that chelation therapy offered moderate protection against future cardiovascular events, such as stroke and heart attack, in those with diabetes (Lamas, 2016). In a follow-up study, Trial to Assess Chelation Therapy 2 (TACT2) was a multicenter, double-masked trial comparing the effect of 40 infusions of an EDTA-based solution with placebo infusions administered approximately weekly and comparing the effect of high doses of oral multivitamins and minerals with oral placebo. TACT2 was designed to replicate TACT, its predecessor study, but involved diabetic patients with prior MI to assess the relationship between the expected prognostic benefits and the depletion of body stores of lead and cadmium with repeated EDTA infusions. Results TACT2 concluded that despite effectively reducing blood lead levels, EDTA chelation was not effective in reducing cardiovascular events in stable patients with coronary artery disease who have diabetes and a history of MI.

Chelation therapy has been proposed for the treatment of Autism Spectrum Disorder (ASD). However, the safety and efficacy of chelation therapy for ASD has not been well studied in controlled trials (Adams, 2009). Use of chelation is based on the hypothesis that the behaviors observed in children with ASD are secondary to toxicity from mercury or other heavy metals and that children with ASD do not excrete heavy metals effectively. However, there is little evidence to support this hypothesis. American Academy of Pediatrics Council on Environmental Health recommend against routinely testing urine for metals and minerals in children with autistic behaviors. Toxicologic exposures have not been conclusively associated with the development of autistic behaviors in children. Testing for metals and minerals may be harmful if treatment is guided on the basis of these results (Choosing Wisely Recommendation 487).

The Association for Science in Autism Treatment states that there is no evidence supporting the use of chelation for autism. Existing studies are of poor quality and lack validity, and the theoretical basis for chelation as an autism intervention is fundamentally flawed. The organization strongly advises against its use, citing inadequate evidence, absence of clinical rationale, and the potential for severe adverse effects (Tereshko & Mauk, 2024).

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Academy of Pediatrics (AAP)	Treatment of Lead Poisoning

American Academy of Family Physicians (AAFP)	Chelation Therapy | AAFP
American Heart Association	Chelation Therapy | Circulation or 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines
National Comprehensive Cancer Network (NCCN)	mds.pdf
Association for Science in Autism Treatment	Chelation Treatment Summary for Autism

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

VI. CODING

See also Priority Health Billing Policy No. 159 Chelation Therapy

ICD-10 Codes that may support medical necessity

D56.0 – D56.9	Thalassemia
D57.00 – D57.819	Sickle-cell disorders
E72.00 – E72.09	Disorders of amino-acid transport
E83.00 – E83.09	Disorders of copper metabolism
E83.10 – E83.19	Disorders of iron metabolism
E83.52	Hypercalcemia
K74.3	Primary biliary cirrhosis
K74.4	Secondary biliary cirrhosis
K74.5	Biliary cirrhosis, unspecified
T56.0x1A - T56.0x4S	Toxic effects of lead and its compounds
T56.1x1A - T56.1x4S	Toxic effect of mercury and its compounds
T56.3x1A - T56.3x4S	Toxic effect of cadmium and its compounds
T56.4x1A - T56.4x4S	Toxic effect of copper and its compounds
T56.5x1A - T56.5x4S	Toxic effect of zinc and its compounds
T56.811A - T56.814S	Toxic effect of thallium
T56.891A - T56.894.S	Toxic effect of other metals
T56.91xA - T56.94xS	Toxic effect of unspecified metal
T57.0x1A - T57.0X4S	Toxic effect of arsenic and its compounds
T80.92xA - T80.92xS	Unspecified transfusion reaction

CPT/HCPCS Codes

J0470	Injection, dimercaprol, per 100 mg
J0600	Injection, edetate calcium disodium, up to 1000 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J3520	Edetate disodium, per 150 mg (not covered for Medicaid)

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 – *requires prior auth*

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

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