

Policy: MP081

Section: Medical Benefit Policy

Subject: Chelation Therapy

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Chelation Therapy

II. Purpose/Objective:

To provide a policy of coverage regarding Chelation Therapy

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Chelation therapy is the administration of chelating agents to rid the body of toxic levels of heavy metal ions by forming complexes that render them physiologically inactive and enhancing their excretion in the urine.

INDICATIONS:

1. Heavy metal poisoning
2. Aluminum overload in persons with end stage renal disease
3. Control of ventricular arrhythmias or heart block associated with digitalis toxicity
4. Copper overload/toxicity secondary to Wilson's disease
5. Emergency treatment of hypercalcemia
6. Hemochromatosis
7. To decrease the risk of anthracycline cardiotoxicity in women with breast cancer treated with anthracycline agents (doxorubicin)
8. Acute iron intoxication or chronic iron overload caused by any of the following:
 - A. Ineffective erythropoiesis
 - B. Sideroblastic anemias – hereditary or acquired
 - C. Severe thalassemia
 - D. Porphyria cutanea tarda
 - E. Syndrome of liver iron overload
 - F. African iron loading
 - G. Parenteral iron administration by red cell transfusion for treatment of:
 - Severe beta thalassemia
 - Sickle cell anemia
 - Myelodysplastic syndromes
 - Refractory aplastic anemia

Note: Ophthalmologic use of topical edetate disodium in the treatment of band keratopathy is considered reasonable and necessary based on specialty provider input.

Guideline for utilization of chelation therapy

Chelation therapy will be considered medically necessary when the member's laboratory values meet or exceed the following levels: Variation from these standards will be considered on a per-case basis.

Arsenic:

24 hr urine greater than 50 mcg/L or greater than 100 mcg/24 hr. collection.

Lead

Whole blood greater than 45 mcg/dl (pediatric and adult)

Note: According to the current CDC guidance, there is limited data regarding the safety and effectiveness of chelation therapy in children with blood lead levels between 20 to 44 µg/dL and chelation therapy should be considered with caution. Requests for chelation treatment of symptomatic children in these ranges will be considered on a per-case basis in accordance with current CDC guidance.

Mercury

Urine greater than 25 mcg/L
Absolute indicator 150 mcg/L
Whole blood greater than 35 mcg/L

Thallium

Whole blood greater than 100 mcg/L
Urine greater than 200 mcg/L

Iron

Serum greater than 300 mcg/dl

Zinc

Serum greater than 150 mcg/dl
Plasma greater than 100 mcg/dl

Anthracycline cardiotoxicity

Limited to use in members with metastatic breast cancer who have received a cumulative dose of 300 mg/m² or greater of doxorubicin.

NOTE: The use of dexrazoxane HCl adjuvant to the initiation of doxorubicin-based chemotherapy is not recommended by the American Society of Clinical Oncology.

EXCLUSIONS:

There are insufficient blinded studies published in peer-reviewed medical literature to support the use of chelation therapy for the following indications. Therefore, the Plan does **NOT** provide coverage for Chelation Therapy as a treatment for any of the following conditions (may not be all-inclusive) because the utilization of this treatment modality is considered **experimental, investigational or unproven:**

Peripheral artery disease

Multiple sclerosis

Arteriosclerosis

Alzheimer's disease

Parkinson's disease

Porphyria

Atherosclerotic vascular disease

Diabetes

Autism

Arthritis

Rheumatoid arthritis

scleroderma

hypercholesterolemia

Other conditions not listed as indications

Chelation therapy for treatment of heavy metal (Arsenic, Cadmium, Lead and Mercury) toxicity typically requires multiple treatments administered over a period of several days, and requires continuous monitoring of the chelation therapy and its resultant sequelae as well as careful monitoring of heavy metal levels and the member's physical signs and symptoms. Places of service that can provide this level of care include inpatient and outpatient hospital, emergency department, dialysis centers and skilled nursing facilities. Chelation therapy for treatment of heavy metal toxicity provided in the office setting or home setting is **NOT COVERED**.

Chemical endarterectomy with intravenous administration of EDTA (Ethylenediamine –Tetraacetic Acid) is considered **experimental, investigational or Unproven** and is **NOT COVERED**.

Chelation therapy based on laboratory values derived from hair analysis is considered to be **Experimental, Investigational or Unproven** and is **NOT COVERED**. Lead in hair may be a reflection of external contamination rather than internal lead dose. Additionally, laboratory analysis is not standardized.

Chelation therapy for the treatment of toxicity from dental amalgam fillings is considered **experimental, investigational or Unproven** and is **NOT COVERED**. There is insufficient evidence to confirm an association between amalgam fillings and systemic symptoms and disorders.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Chelation Therapy

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

J1190 Injection, dexrazoxane HCl, per 250 mg

S9355 Home infusion therapy, chelation therapy; administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment, per

M0300 IV chelation therapy (chemical endarterectomy)

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

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LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/93 Chelation Therapy, 1/95 Chelation Therapy with EDTA

Revised: 5/97, 02/03, 3/04; 7/04 (guideline, coding, exclusion); 7/05 (coding, indication); 11/05 (exclusion clarification), 11/07 (added exclusions), 4/15 (added indication); 3/17 (add dental amalgam exclusion)

Reviewed: 11/06, 11/08, 12/09, 12/10, 12/11, 12/12, 4/14, 4/16, 3/18, 3/19, 3/20, 3/21, 3/22, 3/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.