Health Plans

Manual: IU Health Plans
Department: Utilization Management
Policy # MP011
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Medicare Advantage **X Commercial**

Chelation Therapy Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for Chelation Therapy.

II. Scope

This policy applies to all Utilization Management staff having decision-making responsibilities where authorization is required for Fully insured commercial plan.

III. Exceptions

1. Chelation therapy is considered investigational and not medically necessary for the treatment of **any of the following**:
    1. Alzheimer's disease
    2. Autism Spectrum Disorder
    3. Atherosclerosis
    4. Cadmium exposure
    5. Cancer
    6. Cardiovascular disease - prevention and treatment
    7. Chemical Endarterectomy with Edetate Disodium
    8. Parkinson's disease
    9. Peripheral vascular disease
    10. Rheumatoid arthritis
    11. Home infusion therapy
    12. 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 (M0300)
2. ***Non-Covered Locations*:** Chelation therapy requires close monitoring and is not covered in **any of the following** locations that cannot provide the level of care and monitoring required:
    1. Office setting
    2. Home setting
    3. Certain ambulatory surgical centers

IV. Definitions

Chelation therapy is the chemical process in which a synthetic solution (usually Calcium EDTA-calcium ethylenediaminetetraacetic acid) is injected into the bloodstream to remove heavy metals or minerals from the body. It is used as a treatment for lead poisoning. Any other use of chelation therapy is controversial. It can be performed in an outpatient setting with advanced support capabilities due to the high incidence of adverse reactions which have lessened with the use of Calcium EDTA. The U.S. Food and Drug Administration has approved chelation therapy for the treatment of lead poisoning. Calcium EDTA binds with the lead and is then excreted by the kidneys. Other drugs that can be used include but are not limited to:

1. **Deferoxamine 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 Versenate (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.

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V. Policy Statements

IU Health Plans considers **Chelation Therapy** medically necessary for **ALL of the following**:

1. Administration of FDA-approved chelating agents is considered medically necessary for the treatment of **ONE of the following** conditions:
    1. Secondary hemochromatosis due to chronic iron overload due to transfusion-dependent anemias (examples include but are not limited to thalassemia's, Cooley's anemia, sickle cell anemia, sideroblastic anemia).
    2. Heavy metal toxicity, which includes **ONE of the following**:
        a. 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).
        b. Aluminum overload in chronic hemodialysis members
        c. Copper overload in members with Wilson's Disease
        d. Lead overload in cases of acute or long-term lead exposure (Blood level greater than 44 mcg/dl and less than 70 mcg/dl)
        e. For metals not listed above, additional documentation must be maintained in the medical record.

2. Covered Place of Service: Chelation therapy is covered only in **ONE of the following** places of service that can provide the level of care and monitoring required for the procedure:

1. Hospital
2. Hospital-based ambulatory setting
3. Outpatient hospital
4. Emergency room
5. Renal dialysis facilities, and
6. Skilled nursing facilities

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
J3520	Edetate disodium, per 150 mg-NON-COVERED CODE
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-NON-COVERED CODES
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

VI. Procedures

None

VII. References/Citations

1. Centers for Medicare and Medicaid Services CMS). National Coverage Determination (NCD) Chelation Therapy for the Treatment of Atherosclerosis (20.21) Effective Date-Longstanding. National Coverage Determination (NCD) for Chelation Therapy forTreatment of Atherosclerosis (20.21) (cms.gov)
2. Centers for Medicare and Medicaid Services CMS). National Coverage Determination(NCD) for Ethylenediamine-Tetra-acetic (EDTA) Chelation Therapy for the Treatment of Atherosclerosis (20.22). Effective Date-Longstanding. National Coverage Determination (NCD) for Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis (20.22) (cms.gov)
3. Fulgenzi, A., & Ferrero, M. E. (2019). EDTA Chelation Therapy for the Treatment of Neurotoxicity. *International journal of molecular sciences*, *20*(5), 1019. https://doi.org/10.3390/ijms20051019

4. Isidori, A., Loscocco, F., Visani, G., Chiarucci, M., Musto, P., Kubasch, A. S.,Platzbecker, U., & Vinchi, F. (2021). Iron Toxicity and Chelation Therapy in Hematopoietic Stem Cell Transplant. *Transplantation and cellular therapy*, *27*(5), 371–379. https://doi.org/10.1016/j.jtct.2020.11.007
5. Millstine, D. (2021, October; Modified September 2022). *Chelation Therapy*. Merck Manual Profession Edition. Chelation Therapy - Special Subjects - Merck Manuals Consumer Version
6. Seetharaman, J., & Sarma, M. S. (November 7,2021). Chelation therapy in liver diseases of childhood: Current status and response. *World journal of hepatology*, *13*(11), 1552– 1567. https://doi.org/10.4254/wjh.v13.i11.1552

VIII. Forms/Appendices

None

IX. Responsibility

Medical Director