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Clinical Coverage Guideline



Chelation Therapy

Guideline Number: HS-092

Original Effective Date: 3/16/2009

Revision Date: n/a

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Chelation therapy is considered medically necessary for the following conditions, given that therapy is conducted with chelating agents approved for treatment of the specific conditions:

- Iron overload due to transfusion-dependent anemias (e.g. thalassemias, sickle cell anemia, Cooley's anemia) of secondary hemochromatosis; **OR,**
- Aluminum overload due to hemodialysis; **OR,**
- Prophylaxis against doxorubicin-induced cardiomyopathy; **OR,**
Heavy metal overload or toxicity (e.g., lead, arsenic, mercury, iron, copper, or gold) confirmed by appropriate laboratory results and clinical findings consistent with metal toxicity; **OR,**
- Emergency treatment of hypercalcemia; **OR,**
- Control of ventricular arrhythmias associated with cardiac glycoside toxicity; **OR,**
- Copper overload/toxicity secondary to Wilson's disease; **OR,**
- Internal plutonium, americium, or curium contamination; **OR,**
- Cystinuria

Chelation therapy is considered experimental and investigational for the treatment of the following indications:

- Atherosclerotic vascular diseases; **OR,**
- Coronary artery disease; **OR,**
- Reperfusion injury during coronary angioplasty or cardiopulmonary bypass surgery; **OR,**
- Progressive renal insufficiency in Type II diabetic nephropathy; **OR,**
- Alzheimer's Disease; **OR,**
- Parkinson's Disease; **OR,**
- Primary biliary cirrhosis; **OR,**
- Ankylosing spondylitis; **OR,**
- Autism; **OR,**
- Glioblastoma; **OR,**

- Scleroderma; **OR**,
- Porphyria; **OR**,
- Hypercholesterolemia; **OR**,
- Chronic fatigue syndrome secondary to dental amalgam therapy; **OR**,
- Rheumatoid arthritis; **OR**,
- Any indication not listed in the medically necessary section above.

BACKGROUND

Chelation therapy is an established treatment for heavy metal poisoning. Heavy metals, which cannot be metabolized, persist in the body and exert their toxic effects by combining with one or more reactive groups (ligands) essential for normal physiological functions. Chelating agents, also known as heavy metal antagonists, form complexes with toxic heavy metals rendering them physiologically inactive and enhancing their excretion in the urine.

Although chelation therapy has been investigated as a treatment for a wide variety of diseases and conditions, including Alzheimer's disease, Parkinson's, and rheumatoid arthritis, there has not been adequate scientific evidence to prove the effectiveness and safety of such methods. Further study is needed to ascertain the level of efficacy chelation therapy has for these applications. The medical necessity of chelation therapy for the treatment of chronic fatigue syndrome following dental amalgam restorative therapy cannot be established due to the lack of scientific studies.

Chelating Agents

Common chelating agents include but are not limited to:

Deferoxamine mesylate (desferrioxamine, Desferal[®]): used for acute iron intoxication or chronic iron overload due to transfusion-dependent anemias. Intramuscular (IM) preferred route of administration for patients not in shock. Additionally, may be given subcutaneously (SQ) or intravenously (IV).

Deferasirox (ExJade[®]): an oral chelating agent used for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older.

Dimercaprol (BAL): lead toxicity in conjunction with calcium EDTA. Also used for arsenic, gold, and mercury toxicity. Administered intramuscularly (IM).

DMSA (dimercaptosuccinic acid, Succimer, Chemet[®]): an analogue of Dimercaprol that can be given orally for blood lead levels above 45 µ/dL.

D-penicillamine (Cuprimine[®], Depen[®]): an oral chelating agent used for copper poisoning or Wilson's disease. May be used in lead poisoning but not as effective as DMSA.

Edetate calcium disodium (calcium disodium Versenate[®], calcium EDTA, sodium calcium EDTA, edathamil calcium disodium, CaNa₂-EDTA): can be used in conjunction with BAL in lead toxicity. IV infusion preferred, but may be used IM.

Edetate disodium (disodium EDTA, edathamil disodium, sodium edetate): IV infusion for emergency treatment of acute hypercalcemia in selected patients.

CODING

Chelation therapy is considered medically necessary for treatment when the above criteria have been met.

CPT® Codes

No applicable codes.

ICD-9-CM Procedure Codes

No applicable codes.

Covered HCPCS Codes

J0470 Injection, dimercaprol, per 100 mg
*Use this code for BAL

J0600 Injection, edentate calcium disodium, up to 1,000 mg
*Use this code for Calcium Disodium Versenate and Calcium EDTA

J0895 Injection, deferoxamine mesylate, 500 mg
*Use this code for Desferal

J3520* Injection Edetate disodium, per 150 mg
*Use this code for Endrate, Disotate, Meritate, Chealmadie, EDTA.
*Medically necessary if used for Emergency IV infusion treatment of Acute Hypercalcemia in select patients.
*Not covered when used in chelation therapy for treatment for atherosclerosis.

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.

Covered ICD-9-CM Diagnosis Codes

270.0 Disturbance of amino-acid transport, i.e. Cystinuria

275.0 Disorders of iron metabolism

275.1 Disorders of copper metabolism;, i.e. Wilson's Disease

282.41 Sickle-cell thalassemia without crisis

282.42 Sickle-cell thalassemia with crisis

282.49 Other thalassemia

282.60 - 282.64 Sickle-cell anemia

282.68 Other sickle-cell disease without crisis

282.69 Other sickle-cell disease with crisis

961.1 Poisoning by Arsenical anti-infectives

961.2 Poisoning by Heavy metal anti-infectives; lead and mercury

964.0 Poisoning by agents primarily affecting blood constituents; iron and its compounds

984.0 - 984.9 Toxic effect of lead and its compounds (including fumes); inorganic, organic, other and unspecified

985.0 Toxic effect of mercury and its compounds

985.1 Toxic effect of arsenic and its compounds

985.5 Toxic effect of cadmium and its compounds

985.8 Toxic effect of other specified metals

985.9 Toxic effect of other metals

Experimental / Investigational / Unproven / Not Covered

CPT Codes

No applicable codes

ICD-9-CM Procedure Codes

No applicable codes

Non-Covered HCPCS Codes

J3520* Injection Edetate disodium, per 150 mg (Use this code for Endrate, Disotate, Meritate, Chealmadie, EDTA.

*Not covered when used in chelation therapy for treatment for atherosclerosis.

J8499* Oral Prescription Drug, Non-chemotherapeutic, NOS

*Use this code for Deferasirox, ExJade, DMSA, Dimercaptosuccinic Acid, Succimer, Chemet and D-penicillamine, Cuprimine, Depen

M0300 IV chelation therapy (chemical endarterectomy)

Non-covered ICD-9-CM Diagnosis Codes – This list of non-covered diagnosis may not be all inclusive.

191.9	Glioblastoma
272.0	Hypercholesterolemia
277.1	Disorders of prophyrin metabolism; Porphyria
299.00 - 299.01	Autistic disorder
331.0	Alzheimer's Disease
332.0	Parkinson's Disease; Paralysis agitans
414.00 - 414.05	Coronary atherosclerosis
440.20 - 440.29	Atherosclerosis of the extremities
440.30 - 440.32	Atherosclerosis of Bypass Graft of Extremities
440.4	Chronic Total Occlusion of Artery of the extremities
440.8 - 440.9	Atherosclerosis of other specified arteries; generalized and unspecified
443.9	Peripheral vascular disease, unspecified
571.6	Biliary cirrhosis, primary
710.11 – 710.18	Systemic Scleroderma (Codes to specific site)
714.0	Rheumatoid arthritis
720.0	Ankylosing Spondylitis
780.71	Chronic Fatigue Syndrome
V45.82	Percutaneous transluminal coronary angioplasty status

*Current Procedural Terminology (CPT) 2009 American Medical Association: Chicago, IL.®©

REFERENCES

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