



Easy Choice Health Plan

Harmony Health Plan of Illinois

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

Chelation Therapy

Policy Number: HS-092

Original Effective Date: 3/16/2009

**Revised Date(s): 3/31/2010; 3/31/2011;
3/1/2012; 3/7/2013; 3/6/2014; 3/5/2015;
3/3/2016; 3/2/2017; 2/1/2018**

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.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). 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 CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

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 studies.

POSITION STATEMENT

Applicable To:

- Medicaid
- Medicare

Exclusions

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.

Coverage

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

CODING

CPT® 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. This drug is used in chelation therapy, a treatment for atherosclerosis that is not covered by Medicare. *Medically necessary if used for Emergency IV infusion treatment of Acute Hypercalcemia in select patients.

- M0300** IV chelation therapy (chemical Endarterectomy) (not covered by Medicare)
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. *S- Codes are **NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes**

Non-Covered HCPCS Codes

- J3520*** Injection Edetate disodium, per 150 mg. Use this code for Endrate, Disotate, Meritate, Chealmadie, EDTA. This drug is used in chelation therapy, a treatment for atherosclerosis that is not covered by Medicare.
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)

Covered ICD-10-CM Diagnosis Codes

- D56.0-D56.9** Thalassemia
D57.0 - D57.819 Sickle-cell disorders
D58.2 Other hemoglobinopathies
D61-01-D61.9 Other aplastic anemias and other bone marrow failure syndromes
D64.0-D64.4 Other Anemias
E72.00 - E72.09 Disorders of amino-acid transport
E83.110 Hereditary hemochromatosis
E83.111 Hemochromatosis due to repeated red blood cell transfusions
E83.118 Other hemochromatosis
E83.119 Hemochromatosis, unspecified
E79.0 Hyperuricemia without signs of inflammatory arthritis and tophaceous disease
E83.00 - E83.09 Disorders of copper metabolism
E83.10 - E83.19 Disorders of iron metabolism
E83.52 Hypercalcemia
R78.71 Abnormal lead level in blood
R78.79 Finding of abnormal level of heavy metals in blood
R78.89 Finding of other specified substances, not normally found in blood
R79.0 Abnormal level of blood mineral
R79.89 Other specified abnormal findings of blood chemistry
R79.9 Abnormal finding of blood chemistry, unspecified
R82.5 Elevated urine levels of drugs, medicaments and biological substances
R82.6 Abnormal urine levels of substances chiefly nonmedicinal as to source
R82.7 Abnormal findings on microbiological examination of urine
R82.8 Abnormal findings on cytological and histological examination of urine
R82.90 Unspecified abnormal findings in urine
R82.91 Other chromoabnormalities of urine
R82.99 Other abnormal findings in urine
R89.2 Abnormal level of other drugs, medicaments and biological substances in specimens from other organs, systems and tissues
R89.3 Abnormal level of substances chiefly nonmedicinal as to source in specimens from other organs, systems and tissues
M1A.10X0-M1A.19X1 Lead-induced chronic gout
T56 Toxic effects of lead compound
R82.5,R82.6,R89.2,R89.3 Nonspecific abnormal toxicological findings
T37.8X1A - T38.8X6S Poisoning by, adverse effect of and underdosing of glucocorticoids and synthetic analogues
T45.4X1A - T45.4X6S Poisoning by, adverse effect of and underdosing of iron and its compounds
T49.0X1A - T49.0X6S Poisoning by, adverse effect of and underdosing of local antifungal, anti-infective and anti-inflammatory drugs
T56.0X1A - T56.94XS Toxic effects of metals
T57.0X1A - T57.0X4S Toxic effect of arsenic and its compounds

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. National coverage determination for chelation therapy for treatment of atherosclerosis (20.21). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Accessed January 19, 2018.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
2/1/2018	
3/2/2017	
3/3/2016, 3/5/2015, 3/6/2014, 3/7/2013, 3/1/2012	<ul style="list-style-type: none">• Approved by MPC. No changes.• Approved by MPC. Coding changes only.• Approved by MPC. No changes.
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
3/31/2011	<ul style="list-style-type: none">• Approved by MPC.