**Medical Coverage Policy |** Chelation Therapy for Off-Label Uses

**EFFECTIVE DATE:** 01|01|2017
**POLICY LAST UPDATED:** 12|06|2016

## OVERVIEW

Chelation therapy, an established treatment for heavy metal toxicities and transfusional hemosiderosis, has been investigated for a variety of off-label applications, such as treatment of atherosclerosis, Alzheimer disease, and autism. This policy addresses the following off-label uses of chelation therapy:

- Alzheimer disease
- Atherosclerotic cardiovascular disease
- Arthritis, including rheumatoid arthritis
- Autism
- Diabetes
- Multiple sclerosis

This policy does not address the following U.S Food and Drug Administration (FDA)-approved indications for which chelation therapy is considered standard of care treatment:

- Extreme conditions of metal toxicity
- Treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) and due to non-transfusion-dependent thalassemia (NTDT)
- Wilson disease (hepatolenticular degeneration)
- Lead poisoning
- Control of ventricular arrhythmias or heart block associated with digitalis toxicity
- Emergency treatment of hypercalcemia

**This policy is applicable to Commercial Products only. For Blue CHiP for Medicare, see related policy section.**

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

**Commercial Products**

Off-label applications of chelation therapy (non-FDA-approved uses) are considered not medically necessary due to insufficient peer reviewed literature demonstrating efficacy of the therapy, including, but not limited to:

- Alzheimer disease
- Arthritis (includes rheumatoid arthritis)
- Atherosclerosis (eg, coronary artery disease, secondary prevention in patients with myocardial infarction, or peripheral vascular disease)
- Autism
- Diabetes

- Multiple sclerosis

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

## BACKGROUND

Chelation therapy is an established treatment for the removal of metal toxins by converting them to a chemically inert form that can be excreted in the urine. Chelation therapy comprises intravenous or oral administration of chelating agents that remove metal ions such as lead, aluminum, mercury, arsenic, zinc, iron, copper, and calcium from the body. Specific chelating agents are used for particular heavy metal toxicities. For example, desferrioxamine (not FDA-approved) is used for patients with iron toxicity, and calcium-ethylenediaminetetraacetic acid (EDTA) is used for patients with lead poisoning. (Disodium-EDTA is not recommended for acute lead poisoning due to the increased risk of death from hypocalcemia.)

Another class of chelating agents, called metal protein attenuating compounds (MPACs), is under investigation for the treatment of Alzheimer disease, which is associated with the disequilibrium of cerebral metals. Unlike traditional systemic chelators that bind and remove metals from tissues systemically, MPACs have subtle effects on metal homeostasis and abnormal metal interactions. In animal models of Alzheimer disease, they promote the solubilization and clearance of beta amyloid by binding its metal-ion complex, and also inhibit redox reactions that generate neurotoxic free radicals. MPACs therefore interrupt 2 putative pathogenic processes of Alzheimer disease. However, no MPACs have received FDA approval for the treatment of Alzheimer disease.

Chelation therapy also has been discussed as a treatment for other indications including atherosclerosis and autism. For example, EDTA chelation therapy has been proposed in patients with atherosclerosis as a method of decreasing obstruction in the arteries.

There is insufficient evidence that chelation therapy improves health outcomes for patients with conditions that are off-label for FDA-approved chelating agents, including, but not limited to, atherosclerosis, autism, Alzheimer disease, and diabetes. Thus, chelation therapy for these off-label applications is considered not medically necessary.

## CODING

**Commercial Products**

The following code represents the infusion service only and is not separately reimbursed:
**S9355**

**Chemical Endarterectomy**

The following code and any of the medications utilized as part of the service are not medically necessary when filed with the ICD-10 diagnosis codes below:
**M0300**

E08.00-E13.9 Diabetes mellitus code range
F84.0 Autism disorder
G30.0-G30.9 Alzheimer's disease code range
G35 Multiple sclerosis
I25.10-I25.9 Atherosclerosis code range
M05.00-M06.09 Rheumatoid arthritis code range
M15.0-M19.93 Osteoarthritis code range

Failure of participating providers to report Chemical Endarterectomy using M0300 will be considered improper coding by BCBSRI.

## RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations Policy

## PUBLISHED

Provider Update, January 2017
Provider Update, August 2015
Provider Update, October 2014
Provider Update, July 2013
Provider Update, May 2012
Provider Update, July 2011
Provider Update, October 2009

## REFERENCES


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3. Very high blood lead levels among adults - United States, 2002-2011. MMWR Morb Mortal Wkly Rep. Nov 29 2013;62(47):967-971. PMID 24280917

4. Centers for Disease Control and Prevention (CDC). Toxicological profile for mercury, chapter 2- health effects, March 1999. http://www.atsdr.cdc.gov/ToxProfiles/TP.asp?id=115&tid=24. Accessed April, 2015.

5. Centers for Disease Control and Prevention (CDC). Emergency preparedness and response: case definition - thallium (last updated 04/25/2013). http://emergency.cdc.gov/agent/thallium/casedef.asp. Accessed April, 2015.

6. Kempson IM, Lombi E. Hair analysis as a biomonitor for toxicology, disease and health status. Chemical Society Reviews. 2011;40(7):3915-3940.

7. Centers for Disease Control and Prevention. Deaths associated with hypocalcemia from chelation therapy--Texas, Pennsylvania, and Oregon, 2003-2005. MMWR Morb Mortal Wkly Rep. 2006;55(8):204-207.

8. Food and Drug Adminstration. Hospira, Inc., et al.; Withdrawal of Approval of One New Drug Application and Two Abbreviated New Drug Application. http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-13273.htm. Accessed April, 2015.

9. U.S Food and Drug Administration. FDA warns consumers about potential health risks from using Thorne Research's Captomer products, 06/12/2014.

http://www.fda.gov/Drugs/DrugSafety/ucm400977.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery. Accessed May 22, 2015.

10. Sampson E, Jenagaratnam L, McShane R. Metal protein attenuating compounds for the treatment of Alzheimer's disease. Cochrane Database Syst Rev. 2008(1):CD005380.

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