Protocol

Chelation Therapy

(80102)

Medical Benefit		**Effective Date**: 10/01/13	**Next Review Date**: 05/15
Preauthorization	No	**Review Dates**: 02/07, 01/08, 11/08, 09/09, 05/10, 05/11, 05/12, 05/13, 07/13, 05/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Chelation therapy, an established treatment for treating heavy metal toxicities, has been investigated for a variety of other applications including treatment of atherosclerosis, Alzheimer's disease, and autism.

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 consists of the 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, deferoxamine is used for patients with iron toxicity, and calcium-ethylenediaminetetraacetic acid (-EDTA) is used for patients with lead poisoning. Note that disodium-EDTA is not recommended for acute lead poisoning due to the increased risk of death from hypocalcemia. (1) Another class of chelating agents, called metal protein attenuating compounds (MPACs), is under investigation for the treatment of Alzheimer's 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's disease, they promote the solubilization and clearance of Aβ-amyloid protein by binding its metal-ion complex and also inhibit redox reactions that generate neurotoxic free radicals. MPACs therefore interrupt two putative pathogenic processes of Alzheimer's disease. However, no MPACs have received U.S. Food and Drug Administration (FDA) approval for the treatment of Alzheimer's disease. Chelation therapy has also 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.

Regulatory Status

Calcium-EDTA was approved by the FDA for lowering blood lead levels among patients with lead poisoning. Disodium-EDTA was approved by the FDA for use in selected patients with hypercalcemia and for use in patients with heart rhythm problems due to intoxication with the drug, digitalis. In 2008, the FDA withdrew approval of disodium-EDTA due to safety concerns and recommended that other forms of chelation therapy be used. (2)

Several iron chelating agents have received FDA approval. Deferoxamine for subcutaneous, intramuscular, or intravenous injections was approved for treating acute iron intoxication and chronic iron overload due to transfusion-dependent anemia. Deferasirox, approved in 2005, is available as a tablet for oral suspension and is

indicated for the treatment of chronic iron overload due to blood transfusions in patients age two years and older. Under the accelerated approval program, the FDA expanded approval of deferasirox in 2013 to include the treatment of patients age 10 and older with chronic iron overload due to nontransfusion-dependent thalassemia (NTDT). In 2011, the FDA approved the iron chelator deferiprone for the treatment of patients with transfusional overload due to thalassemia syndromes when other chelation therapy is inadequate. Deferiprone is available in tablet form for oral use.

Policy (Formerly Corporate Medical Guideline)

Chelation therapy may be considered **medically necessary** in the treatment of each of the following conditions:

- control of ventricular arrhythmias or heart block associated with digitalis toxicity;
- emergency treatment of hypercalcemia;
- extreme conditions of metal toxicity;
- treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) and due to nontransfusion-dependent thalassemia (NDTD);
- Wilson's disease (hepatolenticular degeneration); and
- lead poisoning.

Other applications of chelation therapy are considered **investigational** including, but not limited to:

- atherosclerosis (e.g., coronary artery disease, secondary prevention in patients with myocardial infarction, or peripheral vascular disease);
- multiple sclerosis;
- arthritis (includes rheumatoid arthritis);
- hypoglycemia;
- autism;
- Alzheimer's disease; and
- diabetes.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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25. CMS NCD for Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis (20.22), Effective Date of this Version, this is a longstanding national coverage determination. The effective date of this version has not been posted.