CHELATION THERAPY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms “experimental” and “investigational” are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.
CHELATION THERAPY (cont.)

Description:

Chelation therapy is the administration of a “chelating agent” to remove toxic levels of unwanted metals (e.g., iron, lead, calcium and copper). The chelating agent binds the metals into new, stable compounds that can be excreted in the urine. Routes of administration are intravenous, subcutaneous, intramuscular or oral.

Chelating agents include, *include but are not limited to*:

- Calcium disodium versenate (edetate calcium disodium) (calcium EDTA)
- Chemet® (succimer)
- Cuprimine® (penicillamine)
- Deferoxamine mesylate (Desferal)
- Deferasirox (deferbesirox)
- Depen® (penicillamine)
- Exjade® (deferbesirox)
- Ferriprox® (deferferrone)
- Digoxin immune fab (Digibind, DigiFab)
- Dimercaprol (BAL in oil)
- dimercapto-propane sulfonate (DMPS)
- dimercapto-succinic acid (DMSA)
- Edetate disodium (disodium EDTA, endrate) (FDA withdrew approval in 2008 due to safety concerns.)
- Jadenu™ (deferbesirox)
- Syprine® (trientine hydrochloride)
- Thiamine tetrahydrofurfuryl disulfide (TTFD)
CHELATION THERAPY (cont.)

Criteria:

- Chelation therapy for elevated blood levels is considered *medically necessary* with documentation of ANY of the following toxicities:
  1. Aluminum
  2. Arsenic poisoning, acute
  3. Cadmium
  4. Chromium
  5. Copper overload as the result of Wilson’s disease in an individual who is not tolerant of penicillamine
  6. Gold poisoning
  7. Hypercalcemia, emergency treatment
  8. Iron intoxication, acute
  9. Iron overload, chronic
     - Result of blood transfusions (transfusional hemosiderosis), or
     - Result of nontransfusion-dependent thalassemia (NTDT)
  10. Lead poisoning, acute and chronic
  11. Magnesium
  12. Manganese
  13. Mercury poisoning, acute
  14. Nickel
  15. Vanadium
  16. Ventricular arrhythmias associated with digitalis toxicity
  17. Zinc

- Chelation therapy for elevated urine levels is considered *medically necessary* with documentation of ANY of the following toxicities:
  1. Arsenic poisoning, chronic
  2. Cystinuria
  3. Magnesium
CHELATION THERAPY (cont.)

Criteria: (cont.)

- Chelation therapy for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon insufficient scientific evidence to permit conclusions concerning the effect on health outcomes.

These indications include, but are not limited to:

1. Alzheimer’s disease
2. Arthritis (includes rheumatoid arthritis)
3. Atherosclerosis (coronary artery disease, peripheral vascular disease, secondary prevention in individuals with myocardial infarction)
4. Autism
5. Cancer
6. Chronic fatigue syndrome secondary to dental amalgam therapy
7. Diabetes
8. Fibromyalgia
9. Hypertension
10. Impotence
11. Multiple sclerosis
12. Porphyria
13. Psychiatric disorders
14. Scleroderma
15. Elevated urine levels of any metal not previously listed

Resources:

Literature reviewed 03/02/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


CHELATION THERAPY (cont.)

Resources: (cont.)


10. LabCorp Laboratory Corporation of America. February 2006.


