

<b>Policy Title:</b>	<b>BAL in Oil (dimercaprol) (intravenous) Calcium EDTA/Calcium Disodium Versenate (edetate calcium disodium) (intravenous or intramuscular)</b>		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	01/01/2022		
<b>Review Date:</b>	12/9/2021, 9/8/2022, 3/2/2023, 12/14/2023, 01/04/2024		

**Purpose:** To support safe, effective, and appropriate use of BAL in Oil (dimercaprol) and Calcium EDTA (edetate calcium disodium).

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**

Bal in Oil (dimercaprol) and Calcium EDTA (edetate calcium disodium) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**

Coverage of will be reviewed prospectively via the prior authorization process based on criteria below.

**Summary of Evidence:**

Clinical studies support the efficacy of BAL in Oil and Calcium EDTA in the treatment of heavy metal poisoning. Key findings from these studies indicate significant reductions in blood levels of toxic metals following administration of BAL in Oil and Calcium EDTA. This therapy has demonstrated effectiveness in chelating heavy metals and facilitating their excretion from the body. BAL in Oil and Calcium EDTA has shown favorable safety profiles, with adverse effects typically limited to transient symptoms such as nausea, vomiting, and injection site reactions.

**Coverage Criteria:**

- Patient has documented diagnosis of lead poisoning with blood lead levels greater than 44 mcg/dL; AND
- If request is for BAL in Oil:
  - a. Medication is being used for acute lead poisoning ONLY
  - b. Medication is prescribed concomitantly with Calcium EDTA
  - c. Medication is not used in patients with hepatic insufficiency; AND
- If request is for Calcium EDTA:
  - a. Medication is being used for acute or chronic lead poisoning

- b. Medication is prescribed concomitantly with BAL in Oil when blood lead levels exceed 70 mcg/dL
- c. Member’s laboratory values (renal and hepatic function, urinalysis and urine sediment and serum electrolyte levels) are routinely monitored before each course of therapy and daily during therapy in severe cases
- d. Medication is not used in patients with active renal disease or hepatitis; AND
- Medication is prescribed by or in consultation with a provider who specializes in chelation therapy (e.g., a medical toxicologist or poison control specialist); AND
- Medications are dosed according to the US Food and Drug Administration labeled dosing for lead poisoning

**Coverage duration:**

- 1 month

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

**Policy Rationale:**

Bal in Oil and Calcium EDTA were reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Bal in Oil and Calcium EDTA according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

**Dosage/Administration:**

<b>Drug</b>	<b>Indication</b>	<b>Dose</b>
BAL in Oil	Acute lead poisoning	4 mg/kg every 4 hours for 2-7 days
Calcium EDTA	Acute lead poisoning Chronic lead poisoning	1000 mg/m <sup>2</sup> /day for 5 days (alone) 1500 mg/m <sup>2</sup> /day for 5 days given with the second BAL in oil dose (with BAL in Oil)

**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0470	Injection, dimercaprol, per 100 mg
J0600	Injection, edetate calcium disodium, up to 1,000 mg

References:

1. BAL in Oil [prescribing information]. Decatur, IL: Taylor Pharmaceuticals; June 2022. Accessed November 2023.
2. Calcium Disodium Versenate [prescribing information]. Bristol, TN: Graceway Pharmaceuticals, LLC; July 2013. Accessed November 2023.