Original Effective Date: 11/01/2016
Current Effective Date: 06/27/2024
Last P&T Approval/Version: 04/24/2024
Next Review Due By: 04/2025
Policy Number: C9816-A

Chemet (succimer)

PRODUCTS AFFECTED

Chemet (succimer)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Lead toxicity

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. LEAD TOXICITY:
1. Documentation of lead toxicity with blood lead levels >45mcg/dL
   AND
2. FOR ADULTS ONLY (>18): Documentation of signs/symptoms of mild, moderate, or severe toxicity (e.g., abdominal pain, constipation, arthralgia, headache, lethargy, irritability, drowsiness,

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ataxia, convulsions, coma, lead encephalopathy, etc. see Appendix)

CONTINUATION OF THERAPY:

A. LEAD TOXICITY:

1. Documentation of blood lead levels above 45mcg/dL
   AND
2. Documented clinical rationale for continuation from prescriber

DURATION OF APPROVAL:

Initial authorization: 19 days, Continuation of Therapy: for up to 19 days (A minimum of two weeks between courses is recommended unless blood lead levels indicate the need for more prompt treatment)

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a Toxicologist or other medical practitioner with experience and expertise in the management of lead poisoning [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

12 months of age and older

QUANTITY:

10 mg/kg or 350 mg/m2 three times daily for 5 days, followed by 10 mg/kg or 350 mg/m2 twice daily for 14 days (see Appendix)
Maximum single dose 500mg

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Antidotes - Chelating Agents

FDA-APPROVED USES:

Indicated for the treatment of lead poisoning in pediatric patients with blood lead levels above 45 mcg/dl. *CHEMET is not indicated for prophylaxis of lead poisoning in a lead containing environment; the use of CHEMET should always be accompanied by identification and removal of the source of the lead exposure.*

COMPENDIAL APPROVED OFF-LABELED USES:

Treatment of lead toxicity in adults

APPENDIX

APPENDIX:

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POUNDS (LB)	KILOGRAMS (KG)	DOSE (MG)	NUMBER OF CAPSULES
18-35	8-15	100	1
36-55	16-23	200	2
56-75	24-34	300	3
76-100	35-44	400	4
>100	>45	500	5

To be administered every 8 hours for 5 days, followed by dosing every 12 hours for 14 days The clinical presentation varies widely, depending upon the age at exposure, the amount of exposure, and the duration of exposure. Younger patients tend to be affected more than older children and adults, because lead is absorbed from the gastrointestinal tract of children more effectively than from that of adults. The neurological system is most vulnerable to lead toxicity. Children are more likely to develop central nervous system toxicity while the peripheral nervous system is more often affected in adults. The manifestations in children include temperamental lability, irritability, behavioral changes, hyperactivity or decreased activity, loss of developmental milestones and language delay. Patients may develop lead colic, nausea, vomiting and anorexia. Occasionally, some patients with acute poisoning can develop severe diarrhea and dehydration. Other symptoms include:

- Abdominal pain, loss of appetite, vomiting, constipation
- Headache, ataxia, somnolence
- Lethargy, seizures, stupor, coma

In adults, similar symptoms may develop, although cognitive changes may be discerned more easily, especially since exposures are more typically acute. In addition, adults with chronic exposure may develop other symptoms, such as the following:

- Weakness of extensor muscles (e.g., foot drop, wrist drop)
- Delirium, hallucinations

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Chemet (succimer) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Chemet (succimer) include: patients with a history of allergy to the drug.

OTHER SPECIAL CONSIDERATIONS:
Monitor CBC with differential, LFT's, platelet count and serum creatinine/BUN

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

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AVAILABLE DOSAGE FORMS:
Chemet CAPS 100MG

REFERENCES

1. Chemet (succimer) package insert. Seymour, IN: Kremers Urban Pharmaceuticals Inc; October 2018.
2. Shannon MW, Best D, Binns, HJ, et al. Lead exposure in children: prevention, detection, and management. Pediatrics. 2005;116:1036-1045
3. WHO guideline for the clinical management of exposure to lead. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q2 2024
REVISION-Notable revisions: Diagnosis Required Medical Information Prescriber Requirements Quantity FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q2 2023
REVISION-Notable revisions: Prescriber Requirements Quantity	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file

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