

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Chelation Therapy

DRUG.00003

Override	Approval Duration
Prior Authorization	1 year

Medications
BAL in Oil (dimercaprol)
Calcium Disodium Versenate (edetate calcium disodium)
Chemet (succimer, DMSA)
Desferal (deferoxamine mesylate)

APPROVAL CRITERIA

Requests for the administration of U.S. Food and Drug Administration (FDA)-approved chelating agents may be approved for the treatment of individuals with relevant clinical findings suggestive of heavy metal toxicity and probably exposure history in **any** of the following conditions when confirmed by laboratory testing*:

- I. Individuals with disorders of iron metabolism (for example, primary or secondary hemochromatosis); **OR**
- II. Lead overload in cases of acute or long-term lead exposure; **OR**
- III. Individuals with disorders of copper metabolism (for example Wilson's disease); **OR**
- IV. Arsenic, mercury, iron, copper or gold poisoning when long-term exposure and toxicity has been confirmed; **OR**
- V. Aluminum overload in individuals on chronic hemodialysis.

***Note:** Laboratory testing to confirm heavy metal toxicity should include blood or plasma specimens. In the case of suspected arsenic or mercury toxicity, it may be more appropriate to confirm diagnosis through a non-challenged urinalysis.

Chelation therapy may **not** be approved for the treatment of all other conditions, including but not limited to:

- I. Heavy metal toxicity diagnosis via provoked urine testing; **OR**
- II. Alzheimer's disease; **OR**

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- III. Autism Spectrum Disorders (ASD); **OR**
- IV. Cadmium exposure; **OR**
- V. Cardiovascular disease (prevention and treatment); **OR**
- VI. Chronic fatigue syndrome; **OR**
- VII. Symptoms thought to be secondary to dental amalgam therapy; **OR**
- VIII. Parkinson's disease; **OR**
- IX. Peripheral vascular disease; **OR**
- X. Rheumatoid arthritis.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. American Academy of Pediatrics. Policy Statement. Lead exposure in children: prevention, detection, and management. Pediatrics. 2005; 116(4):1036-1046.
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 - National Coverage Determination: Chelation Therapy for Treatment of Atherosclerosis. NCD #20.21. Effective date not posted
 - National Coverage Determination: Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis. NCD #20.22. Effective date not posted
6. Dans AL, Tan FN, Villarruz-Sulit EC. Chelation therapy for atherosclerotic cardiovascular disease. Cochrane Database Syst Rev. 2002;(4):CD002785.
7. Fisher S, Brunskil S, Doree C, et al. Desferrioxamine mesylate for managing transfusional iron overload in people with transfusion-dependent thalassaemia. Cochrane Database Syst Rev. 2013a;(3):CD004450.
8. Fisher S, Brunskil S, Doree C, et al. Oral deferiprone for iron chelation in people with thalassaemia. Cochrane Database Syst Rev. 2013b;(3):CD004839.
9. James S, Stevenson SW, Silove N, Williams K. Chelation for autism spectrum disorder (ASD). Cochrane Database Syst Rev. 2015;(5):CD010766.
10. Meerphol J, Antes G, Rucker G, et al. Deferasirox for managing iron overload in people with thalassaemia. Cochrane Database Syst Rev. 2012;(2):CD007476.
11. Meerphol J, Schell L, Rucker G, et al. Deferasirox for managing iron overload in people with myelodysplastic syndrome. Cochrane Database Syst Rev. 2014a;(10):CD007461.

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12. Meerphol J, Schell L, Rucker G, et al. Deferasirox for managing transfusional iron overload in people with sickle cell disease. Cochrane Database Syst Rev. 2014b;(3):CD007477.
13. Sampson EL, Jenagaratnam L, McShane R. Metal protein attenuating compounds for the treatment of Alzheimer's disease. Cochrane Database Syst Rev. 2014;(5):CD005380.

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