CRITERIA FOR TREATMENT:

This protocol is appropriate for children with confirmed venous blood lead levels (VPb) 45-69 ug/dL if the following conditions are met:

1) The patient is asymptomatic. If the patient has signs of acute encephalopathy treatment guideline #4 is recommended. A careful history should be taken for possible signs or symptoms of acute toxicity. Symptoms of lead poisoning include the following:
   - GI: Anorexia, constipation, abdominal pain, vomiting
   - CNS: Irritability (may be subtle), lethargy, change in sleep or behavior patterns, headache, decreased play, ataxia, decreased coordination, vomiting
   - Severe involvement: Seizures, coma, hypertension, papilledema, cranial nerve paralysis

2) Absence of a history of allergy to Chemet

3) Absence of pre-existing renal or hepatic disease

4) No treatment with other chelating agents within the past 2 weeks. It is best to wait 2-4 weeks between consecutive courses of Chemet.

5) An absolute neutrophil count > 1200 prior to the initiation of treatment

6) The family is able to comply with the treatment plan. The family must be able to administer the medication and comply with laboratory monitoring as outlined.

7) The child must reside in a documented lead-safe environment during outpatient chelation; otherwise, inpatient treatment is indicated. The lead status of the home will be determined for Maine patients by the Maine Childhood Lead Poisoning Prevention Program (MCLPPP), (207) 287-4311, or for New Hampshire patients by the Health Homes and Lead Poisoning Prevention Program (HHLPPP), (603) 271-4507 and (800) 897-5323.

ADVERSE EFFECTS OF CHEMET (SUCCIMER):

The most common adverse effects are gastrointestinal, including nausea, vomiting, diarrhea, appetite loss, and loose stools. Rashes, some necessitating discontinuation of therapy, have been reported in about 4% of patients, primarily in adults. Mild, transient elevations of serum transaminases (ALT, AST) have been observed in 6-10% of patients, primarily in adults. Rarely, proteinuria has been described. Mild to moderate neutropenia has been noted, requiring close monitoring of the ANC (absolute neutrophil count) during treatment and the need for medical evaluation if signs or symptoms of infection develop.
PRIOR TO TREATMENT:

1) A careful history and physical exam should be conducted to verify that the patient is asymptomatic.

2) Exposure history, including occupational history of parents, should be obtained and documented.

3) Obtain BP. Confirm height and weight (for dosing).

4) Contact must be made, with the Maine Childhood Lead Poisoning Prevention Program (MCLPPP), at (207) 287-4311 for Maine patients and with the Health Homes and Lead Poisoning Prevention Program (HHLPPP), (603) 271-4507 and (800) 897-5323 for New Hampshire patients, to verify that the child is in a documented lead-safe environment.

5) Laboratory: The following baseline laboratory data should be obtained:
   - Repeat VPb – (Venous Lead): 1 ml in lavender micro
   - ZPP – (Zinc Protoporphyrin): 0.2 ml in lavender micro
   - CMP: 0.6 ml in mint green micro
   - CBC with differential (calculate ANC): 0.5 ml in lavender micro
   - Urinalysis (for protein)
   - Iron studies – Iron, Ferritin, TIBC: 3 ml in gold

6) Radiologic Evaluation:
   Obtain an abdominal x-ray on any child with newly diagnosed lead poisoning or any child with known lead poisoning with an increase in lead level not consistent with a post-chelation rebound. X-ray evidence of lead in the gastrointestinal tract, particularly in the stomach and small intestine, indicates the need for gut decontamination. Lead has no appreciable absorption in the colon or rectum.

7) All families should be referred for a social work assessment (for housing assistance)

TREATMENT:

1) If there is x-ray evidence of lead in the gastrointestinal tract, GI decontamination should be carried out. (This should be done on an inpatient basis). Polyethylene glycol solution (GoLytely) can be used for lead densities in the stomach and/or small intestine. Lead has no appreciable absorption in the colon or rectum. The dose of GoLytely is 20-40 ml/kg/hr up to a maximum of 1000 ml per hour via nasogastric tube for a minimum of 4 hours and/or until the patient has a bowel movement.

2) Begin Chemet at 10 mg/kg (rounded to the nearest 100 mg) PO TID (see dosing schedule below) for 5 days, then BID for 14 days. The drug comes in 100 mg capsules that may be opened and sprinkled on food or in beverages; ice cream works well.

DOSING (TID x 5 days; then, BID x 14 days)

<table>
<thead>
<tr>
<th>LBS</th>
<th>KG</th>
<th>DOSE (MG)</th>
<th>NUMBER OF CAPSULES/DOSE</th>
</tr>
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<tbody>
<tr>
<td>18-35</td>
<td>8-15</td>
<td>100</td>
<td>1</td>
</tr>
<tr>
<td>36-55</td>
<td>16-23</td>
<td>200</td>
<td>2</td>
</tr>
<tr>
<td>56-75</td>
<td>24-34</td>
<td>300</td>
<td>3</td>
</tr>
<tr>
<td>76-100</td>
<td>35-44</td>
<td>400</td>
<td>4</td>
</tr>
<tr>
<td>&gt; 100</td>
<td>≥ 45</td>
<td>500</td>
<td>5</td>
</tr>
</tbody>
</table>

3) Iron should not be administered simultaneously with Chemet. If indicated for iron deficiency anemia, it may be given 2-3 hours after the dose.
TREATMENT, Continued:

4) Instructions to parents must include that they:
   - Assure that the child receives adequate hydration
   - If a rash develops, discontinue the medication and contact the prescriber
   - Seek medical evaluation for signs/symptom of infection

5) Observe for any side effects of treatment as listed above. If fever or signs of infection are noted, check CBC with differential; consider withholding treatment for ANC < 1200.

6) On DAYS 6 and 20 of therapy, the following labs should be repeated.
   - VPb: 1 ml in lavender micro
   - ZPP: 0.2 ml in lavender micro
   - CMP: 0.6 ml in green micro
   - CBC with differential: 0.5 ml in lavender micro. Calculate ANC and consider withholding treatment for ANC < 1200.
   - Urinalysis (for protein)

FOLLOW-UP:

1) The first follow-up visit should be one week after chelation has been completed, and, then, again at two weeks after chelation has been completed. Follow-up should continue at monthly intervals until the VPb is < 15 ug/dL, then, every two to three months.

2) The following labs should be obtained at each follow-up visit
   - VPb: 1 ml in lavender micro
   - ZPP: 0.2 ml in lavender micro

   Rechelation is indicated if at any time after 2 weeks, the VPb is > 45 ug/dL, or > 40 ug/dL in the face of a large lead burden (elevated ZPP). Many children will require more than one round of chelation therapy.

3) Continue monitoring until VPb is < 15 ug/dl on two occasions, three months apart

4) All children with significant lead exposure, and, especially, those who have undergone chelation, require a neurodevelopmental assessment. This should be obtained within 2 months of completion of the initial course of chelation, and, then, yearly until the age of 6.

Important Contact Numbers

Maine State Lab (for lead testing results): (207) 287-2727
Maine Childhood Lead Poisoning Prevention Program: (207) 287-4311

New Hampshire Healthy Homes and Lead Poisoning Prevention Program: (603) 271-4507 and (800) 897-5323