

August 11, 2021

<Provider Name>
<Provider Address 1>
<Provider Address 2>
<Provider City> <State> <zipcode5-zipcode4>

Dear Medicaid Provider:

RE: Recall of LeadCare® Blood Lead Tests Due to Risk of Falsely Low Results- Centers for Disease Control and Prevention (CDC) Health Alert Network (HAN) Health Advisory (Modified by MDHHS to Reflect Michigan's Recommendations)

Magellan Diagnostics, Inc. and the U.S. Food and Drug Administration (FDA) have issued a recall notice concerning the use of some LeadCare® Blood Lead Tests (certain LeadCare II, LeadCare Plus, and LeadCare Ultra test kit lots). These lots were distributed between October 27, 2020, and June 15, 2021. The use of these devices may cause serious injuries because they might underestimate blood lead levels. The FDA has identified this as a Class I recall, the most serious type of recall.

The purpose of this letter is to notify Medicaid providers about this recall notice and to recommend appropriate follow-up actions.

Background

Magellan Diagnostics, Inc. is recalling its LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests due to a significant risk of falsely low blood lead level results. The FDA has concerns that the falsely low results may contribute to health risks in special populations such as young children and pregnant individuals. A pregnant or lactating individual's exposure to lead is concerning because it may cause health problems for the parent and the developing baby. Obtaining falsely low blood lead level results may lead to inappropriate follow-up assessments, which may result in patient harm, including delayed puberty, reduced postnatal growth, decreased IQ, and inattention and behavior problems in children.

The FDA notified CDC on June 24, 2021, that some Magellan Diagnostics blood lead test kits were undergoing a voluntary recall by the manufacturer. The FDA is now recommending that Magellan Diagnostics customers discontinue the use of all affected test kit lots identified as part of the recall and quarantine remaining inventory.

Recommendations

- Discontinue use of all [affected test kit lots](#) identified as part of the recall.
- Retest children who were tested with the recalled LeadCare test kits whose results were less than 4.5 µg/dL. Retesting should be done with a venous blood sample analyzed with higher complexity testing.
- Retest children who were previously tested with a LeadCare test kit if the lot number of the initial test kit is unknown and the test was done between October 27, 2020, and June 15, 2021.
- Priority for retesting should be given to:
 - Children where there is clinical concern that symptoms or developmental problems may be related to lead exposure,
 - Populations at higher risk of elevated blood lead levels, such as children tested due to Medicaid-required screening or due to other state or local requirements, and
 - Individuals who are pregnant or breastfeeding.
- If retesting indicates blood lead levels in excess of the current CDC [Blood Level Reference Values \(BLRV\)](#) or state or local action level, the healthcare provider or public health official should refer to [CDC guidelines](#) or the [Michigan Department of Health and Human Services \(MDHHS\) Blood Lead Level Quick Reference for Primary Care Providers](#) for appropriate follow-up action.
- Discuss the recall and retesting recommendations with a parent and/or caregiver of children who meet the retesting criteria.

Per [MDHHS guidance](#), children with blood lead levels at or greater than 4.5 µg/dL should have had a subsequent test with a venous blood sample for confirmation. LeadCare instruments are currently approved for use only with capillary or finger/heel stick samples. Venous blood confirmation levels are performed with higher complexity testing such as inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectroscopy (GFAAS) and are generally considered more accurate.

EPSDT Requirements

Federal regulations require state Medicaid Programs to offer Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services, including blood lead level testing of Medicaid children:

- At 12 and 24 months of age, or
- Between 36 and 72 months of age if not previously tested for blood lead.

A blood lead risk assessment must also be performed during specific well child visits, with follow up blood lead level testing performed when indicated. **Blood lead retesting performed in response to the recall is covered as a Medicaid EPSDT service.**

Additional blood lead information from the CDC and MDHHS can be found by visiting:

- [CDC's Lead Poisoning Prevention Program](#)
- [CDC's Lead and Multi-element Proficiency Program](#)
- [MDHHS Environmental Health Education for Health Care Providers- Lead](#)

Additional recall information from Magellan can be found by visiting:

- [Magellan Diagnostics Recalls LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests Due to Risk of Falsely Low Results](#)

For additional support from the Michigan Department of Health and Human Services Childhood Lead Poisoning Prevention Program:

- Child Lead Poisoning Prevention Program: MDHHS-CLPPP@michigan.gov or 517-335-8885

A copy of the CDC Health Advisory can be found by visiting:

- <https://emergency.cdc.gov/han/2021/pdf/CDC-HAN-00445.pdf>

An electronic version of this document is available at www.michigan.gov/medicaidproviders
>> Policy, Letters & Forms.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Massey', followed by a horizontal line.

Kate Massey, Director
Medical Services Administration