

May 31, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Dear Administrator Verma,

The Diabetes Technology Coalition (DTC) writes to request written clarification on the specific waiver for clinical indications for infusion pumps contained in CMS-1744-IFC issued on March 31st and on the enforcement discretion related to clinical indications for therapeutic continuous glucose monitors contained in CMS-5531-IFC issued on April 30th.

The DTC is a group of organizations representing people with diabetes and the provider society advocacy community with a common interest in addressing issues impacting short and long-term coverage and access to current and future diabetes technologies and devices.

The DTC commends you for taking swift action in response to the current COVID-19 public health emergency to ease Medicare requirements and ensure beneficiaries receive the health care services they need without risking exposure to the COVID-19 virus. There is some confusion, however, among stakeholders in the diabetes community about the waivers issued related to insulin pumps and continuous glucose monitors.

The waiver of clinical indications related to respiratory related devices, oxygen and oxygen equipment, home infusion pumps and home anticoagulation therapy (II.U. of the March 31st COVID-19 IFC) states that “we are finalizing on an interim basis that we will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles) allowing for maximum flexibility for practitioners to care for their patients. This enforcement discretion will only apply during the PHE for the COVID-19 pandemic. These policies include but are not limited to: “... NCD 280.14 Infusion Pumps and LCD L33794 External Infusion Pumps.”

As NCD 280.14 and LCD L333794 also include insulin pumps, we are seeking clarification on whether this waiver applies to all claims for insulin pumps with a diabetes diagnosis code, even in the absence of a respiratory diagnosis code, or does the waiver only apply to claims that have both a diabetes diagnosis code and a respiratory diagnosis code?

Similarly, the CMS enforcement discretion of clinical indications for additional LCDs (II.S. 2 of the April 30th COVID-19 IFC) states that CMS “will not enforce the clinical indications for therapeutic continuous glucose monitors in LCDs. For example, we will not enforce the current clinical indications restricting the type of diabetes that a beneficiary must have or relating to the demonstrated need for frequent blood glucose testing in order to permit COVID-19 infected patients with diabetes to receive a Medicare covered therapeutic continuous glucose monitor.”

Does this enforcement discretion of the clinical indications for therapeutic continuous glucose monitors apply to all claims for therapeutic continuous glucose monitors with a diabetes diagnosis code, even in the absence of a respiratory diagnosis code, or does the waiver only apply to claims that have both a diabetes diagnosis code and a respiratory diagnosis code?

The DTC requests a written response to these two questions as soon as possible so we can provide the correct interpretation of these policies changes during the public health emergency for our constituent members who prescribe and/or use insulin pumps and continuous glucose monitors.

These waivers and enforcement flexibilities are prudent to protect people with diabetes who are at high-risk for the COVID-19 virus and to ensure they have the diabetes devices they need to manage their disease during this public health crisis. We believe -- and hope that you agree -- that these waivers should apply to all people with diabetes, regardless of respiratory disease status, as part of the mitigation efforts to prevent virus exposure and to preserve capacity and resources within the healthcare system during this pandemic.

We also urge you to consider permanently waiving the clinical indications contained in the NCD "Infusion Pumps" (280.14) and LCD Glucose Monitors (L33822) following the public health emergency because they do not reflect current scientific knowledge and evidence-based clinical practice guidelines. The clinical indications are outdated, and as coverage criteria they prevent people with diabetes who could benefit from these devices from being able to obtain them. The DTC would be happy to discuss permanent waiver of this coverage criteria with you at your convenience.

We look forward to your expeditious written response to our two questions about the public health emergency waivers and to working with you in the future to make sure that patients with diabetes have access to technological innovations that will provide optimal disease management and patient outcomes. If you have any questions, please contact Jill Rathbun at jill_rathbun@galileogrp.com or 703-214-7224.

Sincerely,

American Association of Clinical Endocrinologists
Association of Diabetes Care & Education Specialists
Beyond Type 1
Children with Diabetes
College Diabetes Network
DiabetesSisters
Endocrine Society
JDRF
Pediatric Endocrine Society

CC: Brady Brookes, Deputy Administrator and Chief of Staff
Demetrios Kouzoukas, Principal Deputy Administrator for Medicare and Director, Center for Medicare
Jean Moody-Williams, Acting Director, Center for Clinical Standards and Quality