

June 20, 2018

Peter J. Gurk, MD
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Letter via email: peter.gurk@noridian.com

Wilfred Mamuya, MD PhD
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Jurisdiction A
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Letter via email: Wilfred.mamuya@noridian.com

Dear Drs. Gurk and Mamuya:

We are writing to share our concerns about recent changes that appear to be inappropriately limiting access to external insulin infusion pump rentals for certain people with diabetes. We represent the nation's largest diabetes patient and clinician organizations, including:

- JDRE, the largest charitable funder of type 1 diabetes (T1D) research in the world, whose mission is to accelerate the availability of life-changing breakthroughs to cure, prevent, and treat T1D,
- The American Diabetes Association (ADA), the nation's leading voluntary health organization whose mission is to prevent and cure diabetes, and to improve the lives of all people affected by diabetes,
- The American Association of Clinical Endocrinologists (AACE), which represents more than 7,500 endocrinologists in the United States and abroad and is the largest association of clinical endocrinologists in the world, and
- The Endocrine Society, the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions. The Society has more than 18,000 members, including scientists, physicians, educators, nurses and students in 122 countries.

We understand that in July 2017, Noridian instituted an edit on claims made for external insulin infusion pump rentals in its role as the Jurisdiction D Durable Medical Equipment Medicare Administrative Contractor (DME MAC). This edit checked each claim for an insulin pump rental (E0784) for a corresponding Part B claim for pump insulin (J1817), and denied the rental claim if such an insulin claim did not exist.

While we believe that this edit was intended to prevent Medicare fraud, we wanted to bring to your attention a number of reasons why a Part B insulin claim may not exist at the time of the pump rental claim filing:

1. The pharmacy hasn't yet filed the claim with Part B;

2. The beneficiary had leftover insulin from a 90 day supply and hasn't filled their first J1817 claim yet;
3. The beneficiary receives their insulin from another program to which they are entitled; (VA, employer insurance, other military benefit); OR
4. The pharmacy does not know that the claim is for pump insulin, and instead files the claim under Part D

While we understand that the fourth situation, related to Part D billing, is an improper claim, this impropriety is on the part of the pharmacy filling the insulin prescription, and not the supplier or patient. If this is the concern, it can likely be avoided by better pharmacist education and appropriate Part D audits, rather than by denying insulin pumps to beneficiaries who need them to manage their diabetes.

The first three circumstances seem to be permissible according to the Medicare statute and regulations. Pharmacies have a year to file a Part B claim, beneficiaries should not fill unnecessary insulin prescriptions while they have remaining unused insulin, and beneficiaries, such as veterans, entitled to lower-priced drugs under alternative insurance plans may utilize these plans.

Despite this, we have heard anecdotally that Noridian has denied hundreds of claims for insulin pump rentals, and is no longer allowing suppliers to appeal these claims unless they have proof of a valid Part B insulin claim. Prior to the prohibition of appeals without a valid Part B insulin claim, we were informed that Noridian was overturning a majority of initial denials, indicating that the number of improper payments discovered by this edit is quite low. Multiple suppliers have shared concerns with us that they will no longer be able to provide insulin pumps to beneficiaries in Jurisdictions A and D.

Diabetes is a complex disease which requires individualized, patient-centered care. Ongoing patient self-management is critical to preventing acute complications and reducing the risk of devastating long-term complications. Insulin pumps are the most effective disease management tool for some people with diabetes with intensive insulin needs. It is critical that these individuals have the opportunity to work with their healthcare providers to choose the therapeutic approaches that best meet their needs.

We urge Noridian to reverse this recent change that is incorrectly denying insulin pump coverage to some beneficiaries, and instead pursue alternative, more targeted compliance measures so that our constituents may continue to receive the care they need. We greatly appreciate your time and consideration.

Please direct your response to Jesse Bushman, Senior Director of Health Policy at JDRF, at jbushman@jdrf.org or by phone at 202-465-4128.

Signed,



Cc: George Mills, Centers for Medicare & Medicaid Services, Deputy Center Director, Center for Program Integrity, George.mills@cms.hhs.gov

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