Letters of Support for Medicare Coverage of Omnipod from Key Diabetes-Related Patient Groups and Medical Societies

JDRF

American Diabetes Association

American Association of Clinical Endocrinologists

Endocrine Society

National Diabetes Volunteer Leadership Council

Joslin Diabetes Center

American Association of Diabetes Educators

May - June 2017
June 27, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
via email: Seema.verma@cms.hhs.gov

Dear Ms. Verma:

We wish to express our gratitude to CMS for the recent issuance of a local coverage determination for continuous glucose monitors, making it possible for Medicare beneficiaries with diabetes to more closely control their condition. All of us at JDRF appreciate how CMS staff worked constructively to ensure access to this critical technology.

We also wish to follow up on a letter we sent, dated April 20, 2017, regarding Medicare coverage of “patch pumps,” which are unique mechanisms for automated insulin delivery.

While Medicare covers other insulin pumps, it does not cover “patch pumps,” which provide an additional method of insulin delivery for people, like those with type 1 diabetes, who need multiple doses of insulin every day to stay alive. Individuals in private plans who are using these physician-prescribed devices to successfully manage their disease lose that coverage when they age into Medicare. These devices could provide Medicare beneficiaries with a valuable means of managing their diabetes, thus reducing Medicare expenditures on serious complications associated with poor glycemic control.

We understand that CMS has determined that patch pumps do not qualify for coverage under Part B as Durable Medical Equipment (DME) because they do not last the requisite three years. However, we believe very strongly that patch pumps do qualify for coverage under the Part D program. As part of the Medicare Modernization Act of 2003, Congress explicitly stated, in report language, that it was their intent to cover under Part D any insulin delivery device not covered under Part B as DME.¹ CMS’ own regulations at 42 CFR 423.100 define Part D Drugs to include “supplies that are directly associated with delivering insulin into the body,” which is

¹ "It is the intent of conferees that the definition of insulin, and medical supplies associated with the administration of insulin, as a covered prescription drug shall include medical supplies that the Secretary determines to be reasonable and necessary, such as insulin, insulin syringes, and insulin delivery devices that are not otherwise covered under the durable medical equipment benefit.”
precisely what patch pumps do. Moreover, CMS subsequently affirmed this position in the Medicare Prescription Drug Benefit Manual, which reiterates the principles of the congressional report and regulation.\textsuperscript{2}

As you may know, JDRF is the largest charitable funder of type 1 diabetes (T1D) research in the world, with a mission to accelerate the availability of life changing breakthroughs to cure, treat, and prevent T1D. All of us in the JDRF leadership hope that CMS will examine this issue and provide clear guidance establishing coverage for patch pumps.

If you have questions, please do not hesitate to contact me directly at drapp@jdrf.org, or Jesse Bushman, JDRF’s Senior Director of Health Policy at ibushman@jdrf.org.

Sincerely,

\[\text{Derek Rapp}
\text{President & CEO}
\text{JDRF}\]

cc: Demetrios Kouzoukas, Director, Center for Medicare
Carla DiBlasio, Senior Advisor
Liz Richter, Deputy Director, Center for Medicare
Amy Larrick, Director, CMS Medicare Drug Benefit and C and D Data Group
Chris Bauer, Director, Division of Part D Policy

\textsuperscript{2} Medicare Prescription Drug Benefit Manual. Chapter 6. Medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes, can satisfy the definition of a Part D drug.
June 1, 2017

Mr. Demetrios Kouzoukas  
Principal Deputy Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Blvd., Room C5-25-25  
Baltimore, MD 21244  
Demetrios.kouzoukas@cms.hhs.gov

Dear Mr. Kouzoukas,

On behalf of the American Diabetes Association, I write to urge the Centers for Medicare and Medicaid Services (CMS) to ensure Medicare beneficiaries with diabetes have access to all types of insulin pumps approved by the Food and Drug Administration (FDA).

Continuous subcutaneous insulin infusion (CSII), or insulin pumps, is the most effective disease management tool for some patients with diabetes with intensive insulin needs. Although Medicare covers insulin pumps for certain individuals with diabetes, not all types of FDA-approved insulin pumps are available to them. Certain pumps have advantages for some patients over others, depending on the individual’s needs. Diabetes affects people differently and patient-centered diabetes care is individualized to the patient.

Most insulin pumps have tubes which connect the pump to the infusion site, however, an FDA-approved tubeless patch pump technology exists and serves the same essential insulin delivery function as other FDA-approved insulin pumps. This tubeless technology may be easier for some patients with dexterity issues, neuropathy or retinopathy to use as it does not require handling of tubing sets. Unfortunately, CMS has determined this pump is not covered under Medicare Part B, as other insulin pumps are, because its design differences do not meet Medicare’s definition of Durable Medical Equipment (DME). We note the Medicare Part D statute and accompanying Congressional report language provide an opportunity for CMS to provide Part D coverage for insulin delivery devices that are not otherwise covered under the DME benefit. Beneficiaries should have access to the FDA-approved insulin pump that can most effectively manage their disease, whether under Part B or Part D.

Patients with diabetes aging into the Medicare program who have been using a particular insulin pump with great success should be able to continuing using the technology that has allowed them to effectively manage their diabetes and avoid horrific and costly long term complications. This is in the best interest of the patient and of the Medicare program. Unfortunately, beneficiaries aging into the Medicare program using tubeless insulin pumps are abruptly forced to stop using the insulin delivery system that has kept them healthy.

Day-to-day management of diabetes – which requires a constant process of self-assessment and self-treatment for individuals who depend on insulin – rests squarely with the individual
living with the disease. It is critical that these individuals have the opportunity to work with their health care providers to choose the therapeutic approaches that best meet their needs.

We urge you to ensure high quality care for people with diabetes who are becoming Medicare beneficiaries, as well as those already in Medicare program, and appreciate your consideration of our comments.

Sincerely,

Dr. LaShawn McIver, MD, MPH
Senior Vice President, Government Affairs & Advocacy
American Diabetes Association
May 25, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Room C5-25-25
Baltimore, MD 21244
Seema.Verma@ems.hhs.gov

Dear Administrator Verma,

On behalf of the American Association of Clinical Endocrinologists (AACE), I write to commend the recent decision by the Centers for Medicare and Medicaid Services (CMS) to recognize therapeutic continuous glucose monitors (CGMs) as durable medical equipment under the Medicare statute. We thank you for your efforts to facilitate this very important decision. The CMS decision on CGMs represents a critical step forward in securing Medicare coverage for millions of people with diabetes who successfully use this technology to manage their disease. In addition to CGMs, we respectfully request that CMS use its administrative authority to provide coverage for the FDA-approved OmniPod, a highly effective insulin delivery system that is used by patients with Type 1 diabetes. We reiterate our position on this issue, made in our letter of July 13, 2016, which is attached for your reference.

A robust market for insulin delivery systems that generates innovation and competition benefits patients with diabetes. It is critically important for CMS to ensure Medicare patients have access to the full range of FDA approved and effective insulin delivery systems, including the OmniPod.

On behalf of AACE, I urge your swift and favorable decision on this issue. Access to the OmniPod system is crucial for patients, who rely on this device, in order to best manage their diabetes and prevent significant complications of their disease.

Thank you for your consideration of this request.

Sincerely,

Jonathan D. Leffert, MD, FACP, FACE, ECNU
President

Attachment
From: Dyer, Meredith
Sent: Tuesday, May 23, 2017 12:49:00 PM
To: Demetrios.kouzoukas@cms.hhs.gov; Patrick.conway@cms.hhs.gov
Cc: Seema.Verma@cms.hhs.gov; Secretary@HHS.gov
Subject: Follow-up: Coverage Issue Related to Insulin Pumps

Good afternoon,

On behalf of the Endocrine Society, I am writing to follow up on an access issue regarding wireless insulin pumps. Attached please find a letter the Society submitted last August that outlines a number of problems stemming from the failure to provide coverage. If you have a moment to let me know where this stands, and if there's any additional information that we can send to you, I would very much appreciate it.

Thank you again,

Meredith
August 10, 2016

Dr. Patrick Conway, MD, MSc
Acting Principal Deputy Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Room C5-25-25
Baltimore, MD 21244

Dear Dr. Conway,

On behalf of the Endocrine Society, I am writing you regarding the need to provide Medicare coverage for OmniPod wireless continuous insulin pumps, an issue of great concern to our members and the patients that they treat. With more than 18,000 members, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research and treatment of the full range of endocrine disorders, including diabetes.

Currently, Medicare does not cover the tubing-free, wireless continuous insulin pump although this insulin delivery system was approved by the FDA over ten years ago. For years, the Endocrine Society has joined with many in the diabetes community to advocate for DME coverage for OmniPod. CMS continuously has rejected these requests without justification. Recently, however, we became aware of legislative history and congressional intent concerning the creation of the Part D Drug Benefit that speaks to providing coverage through this mechanism. In anticipating new technologies and the possibility of new ways to deliver insulin, Congress stated that it was its intention for Part D to cover any insulin delivery device not covered under Part B as durable medical equipment (DME). In addition, CMS has even published policies stating that all products directly associated with the delivery of insulin into the body, including future potential delivery mechanisms, are to be covered under the Part D Drug Benefit, if not covered as DME under Part B.

Further, it should be noted that the lack of Medicare access to OmniPod is not in the best health interest of its beneficiaries. The Society believes that it is critical for patients to be able to manage their diabetes easily and that patient-centered approaches should be used when determining treatments for patients with diabetes. The OmniPod offers some distinct advantages to elderly diabetes patients who experience dexterity issues, neuropathy, retinopathy and other diabetes-related complications. Many of these patients have found it easier to manage pumps that do not require handling of insertion needles, insulin reservoirs, and tubing sets. In addition, many patients have successfully managed their diabetes with the Omnipod for many years. However, these beneficiaries are forced to discontinue the use of these devices as they age into Medicare and are forced to revert to shots or use other delivery systems that are more difficult for them to use.

The Society urges you to reconsider your previous decision and provide coverage of the OmniPod through the Part D Drug Benefit. We would like to meet with you to discuss further or, should you have any questions or need additional information on this important issue, please contact Meredith Dyer, Associate Director, Health Policy at mdyer@endocrine.org or (202) 971-3637.

Sincerely,

Henry Kronenberg, MD
President, Endocrine Society
June 28, 2017

Seema Verma
Administrator,
Centers for Medicare and Medicaid Services

Dear Administrator Verma,

We are writing on behalf of the National Diabetes Volunteer Leadership Council (NDVLC) to alert you to a significant access obstacle that exists for Medicare beneficiaries with diabetes. Although approved by the FDA and established as medically necessary by the majority of private commercial insurance plans, the Omnipod Insulin Management Systems is not covered by Medicare.

Unlike the tubed/tethered insulin infusion pumps, the Omnipod system is comprised of a tubeless, disposable pod that directly delivers insulin into the body at the direction of a wireless, hand-held Personal Diabetes Manager. The tubeless, water-proof nature of the Pods provide patients with 72-hour uninterrupted insulin delivery, and there is no need to disconnect when getting dressed or bathing. This unique form and function enhances patient health outcomes by its continuous insulin delivery system.

As you know, individuals with diabetes often struggle for years to achieve and maintain optimal glucose levels to prevent the acute and long-term complications of this disease. By the time they age into the Medicare program, most of these patients have found a method of insulin delivery that has met their needs and maintained their health. Forcing patients to switch to an alternative delivery method that they are unfamiliar with, or worse, one that does not optimally meet the their individual needs, both jeopardizes patient safety and places additional financial burden on our healthcare system.

At the annual meeting of the American Diabetes Association this past week, several researchers presented data demonstrating how the existing Omnipod system enhances patient safety and long-term health outcomes. Very compelling data were also presented indicating the significant potential expected from several new innovations coming from the Omnipod system.

Because most Medicaid programs typically follow Medicare decisions, we are concerned that the benefits of the current Omnipod system and its future innovations will remain solely accessible to patients whose healthcare is funded through private commercial insurance carriers. It is our position that the innovative approach to insulin delivery provided by the OmniPod system should be accessible to patients whose healthcare is funded by the Medicare and Medicaid programs just as it is for members of private insurance plans.

We understand that the Centers for Medicare and Medicaid Services has the authority to establish coverage for the Omnipod system under the Part D Drug program as a medical supply that is directly associated with the delivery of insulin into the body. We are hopeful CMS will establish coverage for the
Omnipod system. Please feel free to contact us if you would like further clarity regarding our position on this and the impact the current lack of access has on patients with diabetes.

Sincerely,

Larry Ellingson,  
Vice President, NDVLC  
Chair of the Board 2004-2005  
American Diabetes Association

Stewart Perry  
Treasurer, NDVLC  
Chair of the Board 2008  
American Diabetes Association

Larry Smith  
President, NDVLC  
Chair of the Board 2006  
American Diabetes Association  
229 Tahoma Dr  
Lexington KY 40503

www.NDVLC.org

cc:  
Demetrios Kouzoukas, Principal Deputy Administrator  
Carla DiBlasio, Senior Advisor  
Senator Jeanne Shaheen  
Senator Susan Collins  
Congresswoman Diana DeGette  
Congressman Tom Reed
May 26, 2015

The Honorable Andy Slavitt
Acting Administrator
Center for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Via E-mail: Andy_Slavitt@cms.hhs.gov

Dear Acting Administrator Slavitt:

As you might know, the Joslin Diabetes Center, affiliated with Harvard Medical School, is recognized worldwide for driving innovative solutions in diabetes prevention, research, education, and care. Including our Boston headquarters, Joslin runs 26 Diabetes Centers in 14 States. Nowhere in the world is there a more concentrated effort to finding a cure and ensuring that people with diabetes live long, healthy lives. I am writing to you today on an important access issue affecting Medicare beneficiaries living with diabetes.

Since the founding of the Joslin Center over a century ago, Joslin has been at the forefront of diabetes research efforts and the introduction of new technologies to treat diabetes. One of these innovative technologies that is used by many of our patients and throughout the country to successfully control their diabetes is the FDA-approved, tubing-free, wireless insulin pump (OmniPod). Today OmniPod enjoys broad private insurance coverage and enables patients to live a much more normal life and avoid the serious complications associated with diabetes.

Patients who have relied on this pump to keep them healthy and vibrant and who have had reimbursement and coverage under private plans lose coverage and access when they transition to Medicare. This is despite the fact that OmniPod provides the same insulin delivery function as all the other traditional insulin pumps approved by the FDA and available to Medicare beneficiaries. Unfortunately, this lack of adequate Medicare coverage and access also has a harmful ripple effect on Medicaid diabetes patients -- including a large number of children.

Joslin urges CMS to take whatever steps are necessary to cover and reimburse this pump in the same manner as all of the other covered pumps. This is the right thing to do so that doctors and patients together could continue to choose the best diabetes treatment for them. Diabetes patients should not lose access to treatment options once they transition to Medicare.
Thank you for your consideration of this Medicare access issue that has a direct effect on patient health.

Sincerely,

John L. Brooks III

cc: The Honorable Sylvia M. Burwell, Secretary, Department of Health and Human Services

Patrick Conway, MD, Acting Principal Deputy Administrator, Deputy Administrator for Innovation and Quality, and Chief Medical Officer, Centers for Medicare & Medicaid Services
July 11, 2016

Dr. Patrick Conway, MD, MSc
Acting Principal Deputy Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Room C5-25-25
Baltimore, MD 21244

Dear Dr. Conway,

I’m writing on behalf of the 14,000 members of the American Association of Diabetes Educators (AADE), who are healthcare providers from various disciplines who provide care and education to people with diabetes and their caregivers. Many of our members provide training on diabetes devices including those used for insulin pump therapy. I write to ask that you consider using the authority Congress has already granted to Medicare to reverse the current Medicare policy that denies coverage for the OmniPod, an FDA approved highly effective insulin delivery system that is used by people with diabetes.

As you know, durable, tubed-insulin pumps are covered and adequately reimbursed by Medicare. Yet the OmniPod, a 72-hour disposable pod that provides 3 days of continuous insulin delivery, is not reimbursed in a similar manner, despite the fact that it performs the same insulin delivery function as the durable pumps.

The vast majority of private insurance companies provide coverage and reimbursement for the wearable OmniPod in the same manner as they cover the durable, tubed insulin pumps. The lack of any meaningful Medicare coverage for this insulin pump despite being FDA approved presents a particular problem for people with diabetes who have had private insurance coverage and suddenly realize they will be forced to stop using this delivery system or Medicare beneficiaries who are new to an insulin pump whose preference is to use a tubeless pump management system.

This lack of Medicare access creates two standards of care for pump therapy -- one for those with private insurance and a more restricted standard for Medicare, and correspondingly, Medicaid beneficiaries. All people living with diabetes -- regardless of their age, race, or income level -- deserve access to the full range of FDA-approved medical devices necessary to effectively manage their disease.

While we understand that CMS has determined that OmniPod does not qualify for coverage under Part B as Durable Medical Equipment (DME), we do not understand why CMS continues to refuse to allow for coverage of this device under Part D. The Congress explicitly stated that it was their intent to cover under Part D any insulin delivery device not covered under Part B as DME (Social Security Act (SSA) §1860D-2(e)(1)(b)). The report language specifically that accompanied this stated the intent of Congress “to include medical supplies that the Secretary determines to be reasonable and necessary, such as insulin, insulin syringes and insulin delivery devices that are not otherwise covered under the Part B
DME benefit.” With this clearly expressed Congressional intent and CMS’s subsequent own published policy reiteration of the same principle, it is unexplainable as to why CMS has not used the clear authority it has to cover the OmniPod system, as a Part D benefit.

A change in the current policy would also open the door to Medicaid coverage and access for children for whom this tubeless insulin delivery device is now not an option. Medicare’s current coverage policy also results in denying children and adults who receive their healthcare through Medicaid access to OmniPod or other such pumps.

On behalf of AADE, I respectfully request that CMS use the legislative and regulatory authority it has had for years to find an immediate administrative solution to the current shortsighted Medicare policy that denies coverage for the FDA-approved OmniPod.

Sincerely,

Hope Warshaw, MMSc, RD, CDE, BC-ADM, FAADE
2016 President
American Association of Diabetes Educators