

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-15-582

In the case of

Claim for

D.L.
(Appellant)

Supplementary Medical
Insurance Benefits (Part B)

D.L.
(Beneficiary)

(HIC Number)

National Government Services,
Inc.
(Contractor)

(ALJ Appeal Number)

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated January 6, 2015, because there is an error of law material to the outcome of the claim. See 42 C.F.R. § 405.1110. The ALJ issued a favorable decision, after conducting a hearing, concluding that Medicare covers the OmniPod insulin pods (billed as HCPCS Code A9274)¹, furnished to the appellant-beneficiary on December 10, 2013.

By memorandum dated March 5, 2015, the Centers for Medicare & Medicaid Services (CMS), acting through the Administrative Qualified Independent Contractor (AdQIC) (Q2Administrators, LLC), asked the Council to take own motion review of the ALJ's decision, pursuant to 42 C.F.R. § 405.1110(b). In deciding whether to accept own motion review, the Council limits its review of the ALJ's decision to those exceptions raised by CMS. 42 C.F.R. § 405.1110(c)(2). CMS's memorandum is admitted into the record as Exhibit (Exh.) MAC-1. The appellant filed exceptions to CMS's memorandum, received by the Council on March

¹ CPT (Current Procedure Terminology) codes were designed by the American Medical Association to describe medical and surgical services performed by providers. The CPT code system has been incorporated into the Healthcare Common Procedure Coding System (HCPCS) developed by CMS for processing, screening, identifying, and paying Medicare claims. See 42 C.F.R. §§ 414.2 and 414.40.

18, 2015, within the twenty-day deadline for responding. See 42 C.F.R. § 405.1110(b)(2). We admit the appellant's exceptions into the record as Exhibit MAC-2.

Having carefully considered the record, CMS's memorandum, the appellant's exceptions, and the applicable authorities, we accept own motion review because the ALJ has erred as a matter of law. Further, we agree with CMS that Medicare does not cover the OmniPod pods, billed as A9274, as durable medical equipment and, therefore, we reverse the ALJ's decision and hold the appellant liable for the non-covered charges.

FACTUAL AND PROCEDURAL BACKGROUND

The OmniPod system is a two-part insulin delivery system. Exh. 1 at 12. It consists of a disposable "pod," which attaches to the user's body with adhesive and delivers insulin through a small needle or cannula. See *id.* at 8; Hearing CD. According to the manufacturer, the pod integrates the insulin reservoir, cannula, infusion set, inserter, motor and power source of a conventional pump into one device that can be worn directly on the skin. Exh. MAC-1 at 7-8. The pod is worn for up to three days and then replaced. The second part is the Personal Diabetes Manager (PDM), which is portable and programmable, and sends dosing instructions to the pod, records data, and can be used to test blood glucose levels. Exh. 1 at 12; Hearing CD.

The appellant suffered severe, acute necrotizing pancreatitis in October 2004. Exh. 4 at 3. His physician has explained that he underwent pancreatic debridement and lost a portion of his pancreas due to the disease, resulting in brittle diabetes, which manifests as Type I Diabetes. *Id.* According to the physician, the appellant's blood glucose levels range from 35 to 323, and he suffers from "serious, severe, symptomatic hypoglycemia." *Id.* The appellant's endocrinologist recommended the OmniPod system for the appellant due to his brittle diabetes and active lifestyle. *Id.* at 2.

The appellant submitted a claim for 60 insulin delivery pods, as part of the OmniPod system, billed under the HCPCS Code A9274, external ambulatory insulin delivery system, disposable. See Exh. 1 at 31, 35. The Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) initially denied coverage and on redetermination explained that the OmniPod pods are considered to be a disposable drug delivery system and, as a disposable system, the pods do not qualify under the definition of DME.

Id. at 27. On reconsideration, the Qualified Independent Contractor (QIC) also denied coverage, explaining that, pursuant to the Local Coverage Policy Article A47226, disposable drug delivery systems, including the one at issue, billed under HCPCS Code A9274, are not DME and, therefore, are not covered. *Id.* at 16. Both the DME MAC and the QIC held the beneficiary liable for the non-covered charges. See *id.* at 16, 27.

The appellant then requested ALJ review, and the ALJ conducted a telephonic hearing, at which only the appellant participated. See Exh. 1 at 1; Hearing CD. In his written decision, the ALJ cited to coverage criteria identified in National Coverage Determination (NCD) 280.14 for infusion pumps as well as the contractor's LCD L27215 and Policy Article A47226, both entitled, "External Infusion Pumps." See Dec. at 4-7. The ALJ reasoned that the fact that the pods themselves were disposable did not render the entire insulin pump disposable and the insulin pump did fall under the definition of DME. *Id.* at 7. The ALJ further determined that the appellant "substantially complied with the requirements of the relevant NCD, LCD, and applicable policy article." *Id.* Therefore, the ALJ concluded that the items billed as A9274 and furnished on December 10, 2013, were covered by Medicare. *Id.* at 8.

CMS's timely referral memorandum followed. Exh. MAC-1. In requesting own motion review, CMS asserts that the OmniPod pods for which the appellant sought coverage have been assigned HCPCS code A9274 and the ALJ lacks authority to redefine the HCPCS code or use a description different than the one assigned by CMS. *Id.* at 2. CMS further argues that the ALJ erred by not considering the LCD or Policy Article and, while finding that the appellant had substantially complied with their requirements, the ALJ did not discuss the express non-coverage provision in the Policy Article. *Id.*

In his response to the memorandum requesting own motion review, the appellant reiterates the arguments he made before the ALJ. See Exh. MAC-2. He explains that the OmniPod pod is not capable of delivering insulin without the PDM. *Id.* at 2. The appellant asserts that the PDM, not the pod, is the pump, and that PDM does not monitor anything. The appellant further asserts that the pod is just a high-tech syringe and supply for the PDM, but is not a pump because it is incapable of delivering insulin. *Id.* He continues to assert that CMS's classification of the pods is incorrect. *Id.*

DISCUSSION

This case is before the Council on own motion review pursuant to CMS's referral memorandum. CMS has the authority to refer a case to the Council for own motion review under certain circumstances. See 42 C.F.R. § 405.1110 ("CMS or any of its contractors may refer a case to the [Council] if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim"). As we have noted, CMS, acting through the AdQIC (Q2Administrators), has asserted in its referral memorandum that the ALJ committed an error of law material to the outcome of the claim by finding coverage for an item that does not qualify as DME. Exh. MAC-1 at 3. Therefore, the issue in this case is not whether the OmniPod system is medically reasonable and necessary for the appellant to help manage his diabetes. The issue is whether the OmniPod system, specifically the pod components of the system, are covered under Medicare's DME benefit category. After careful review of the record, we find that the pod is not covered under the DME benefit.

- I. The pod component of the OmniPod system is classified by CMS as HCPCS Code A9274.

In this case, the first step in analyzing Medicare coverage for the pods at issue is to ascertain whether they have been assigned a HCPCS code, and if so, what that code is. As noted above, HCPCS codes are part of a standardized, alpha-numeric coding system developed by CMS that is used primarily to identify products, supplies, and services and to submit claims for these items. 42 C.F.R. § 414.40. HCPCS is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, of itself, determine coverage or non-coverage for an item or service. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are independent of the process for making determinations regarding coverage and payment, such as in this case, through an LCD.

Although the appellant's primary argument throughout the appeals process has been that the OmniPods are improperly coded, CMS is *exclusively* responsible for assigning uniform national definitions of services and codes to represent services, including items of DME. See 42 C.F.R. § 414.40. CMS assigns codes through the Medicare DME Pricing, Data Analysis and Coding contractor (PDAC contractor). The PDAC contractor receives,

evaluates and processes coding verification applications for DME, prosthetics, orthotics, and supplies (DMEPOS); establishes, maintains and updates all coding verification decisions on the product classification list (which includes the OmniPod system); provides coding guidance for suppliers on the proper use of HCPCS and conducts DMEPOS data analysis, among other duties. See <https://www.dmepdac.com> (last visited May 1, 2015).

CMS has assigned the following codes to represent the two parts of the OmniPod system:

A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories; and
E0607	Home glucose monitor.

See <https://www.dmepdac.com/dmecsapp> (DME Coding System search function, search "OmniPod" under "Product Name") (last visited May 5, 2015). That is, the pod component of the OmniPod system at issue in this case, which holds and delivers the insulin and integrates the function of a pump, is coded as A9274. The programmable PDM, which sends dosing instructions to the pump, records data, and can be used to test blood glucose levels, is coded E0607.

As the AdQIC explained in its memorandum, the PDAC contractor created these codes for the OmniPod system upon request from the manufacturer, which provided information regarding how the system functions. See Exh. MAC-1 at 7; http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/downloads/SO_0501_Agenda.pdf (last visited May 5, 2015). According to the manufacturer, the pod integrates the insulin reservoir, cannula, infusion set, inserter, motor and power source of a conventional pump into one device that can be worn directly on the skin. Exh. MAC-1 at 7-8. Subsequently, in 2010, the PDAC denied the manufacturer's request to change the code for the PDM because the PDAC determined that the existing code adequately described the equipment. See, <http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.html> (2010 Public Meeting Summaries, June 8 Summary-DME-final) (last visited May 5, 2015). Therefore, although the appellant has argued that neither CMS nor its contractors have considered how the system functions, that is not accurate. CMS, through the PDAC contractor, has assigned the HCPCS codes to the OmniPod system components on

request from the manufacturer and after receiving information from the manufacturer.

In order to determine whether Medicare covers the pod component of the OmniPod system, one must refer to the assigned HCPCS code, both for the pods and for the PDM. As we have indicated, the Council, and likewise ALJs, are bound by CMS's assignment of codes to the OmniPod system. The ALJ erred, in this regard, by disregarding the relevance of the HCPCS code assigned to the pods. In other words, the ALJ declared that the pods were simply the disposable supply of an insulin delivery system and were, therefore, covered, despite the fact that the PDAC contractor has determined that the pods alone are an "[e]xternal ambulatory insulin delivery system, disposable" and that the PDM is a "[h]ome glucose monitor." See Dec. at 7-8.

II. The coverage criteria for Continuous Infusion Pumps, identified in NCD 280.14, are not applicable.

The second step in analyzing Medicare coverage in this case is to determine whether any NCD applies. ALJs and the Council are bound by applicable Medicare statutes, regulations, CMS rulings, and NCDs. 42 C.F.R. § 405.1060(a)(4). The ALJ cited the coverage requirements for DME identified in NCD 280.14, entitled "Infusion Pumps." See Medicare National Coverage Determination Manual (NCDM), Pub. 100-3, Ch. 1, § 280.14 (NCD 280.14). He then concluded that the appellant met the NCD's requirements but did not analyze how the NCD applied and how the appellant satisfied its requirements. See Dec. at 4-5, 7.

Medicare is a defined benefit program. The regulations at 42 C.F.R. § 414.40 in effect on the date of service define DME as equipment which:

- Can withstand repeated use;
- Has an expected life of at least three years
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be DME. An item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented. Medical supplies of an expendable nature

are not considered "durable" within the meaning of the definition. Medicare Benefit Policy Manual, IOM Pub. 100-02, ch. 15, §110.1.

The ALJ erred in this case because the pod cannot withstand repeated use. It is instead an expendable item designed to be disposed after no more than three days. Thus, the pod does not qualify as DME. Under the HCPCS codes that the PDAC contractor assigned to the OmniPod system, and specifically the pod components, the system does not qualify under the DME benefit as an external infusion pump, but rather as a disposable external ambulatory insulin delivery system. In addition, the pods are for use with the PDM, which is also not coded as an external infusion pump, but rather a home glucose monitor. The pump function does not reside in the PDM, notwithstanding appellant's arguments to the contrary. Therefore, NCD 280.14 is not applicable in this case. Moreover, there is no NCD for disposable external insulin delivery systems.

III. Local Coverage Determination L27215 and related Policy Article A47226 specify that Medicare does not cover items coded as A9274 because they do not qualify as DME.

The next step in analyzing Medicare coverage in this case is to determine whether there is a relevant LCD and/or related Policy Article, in effect on the date of service. In this case, the DME MAC that considered the appellant's claim published LCD L27215 and related Policy Article, A47226, both titled "External Infusion Pumps," in effect on the date of service at issue. While neither an ALJ nor the Council is bound by LCDs, we "will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). If an ALJ or the Council declines to follow an LCD, the ALJ's or the Council's decision must explain the basis for not doing so. 42 C.F.R. § 405.1062(b). Although we are not required to give a Policy Article substantial deference, historically we have done so.

While the ALJ recognized these authorities generally, he did not address the DME MAC's specific pertinent determinations or indicate why he did not follow them. Specifically, the DME MAC has determined, as stated in the Policy Article, that "[d]isposable drug delivery systems, including elastomeric infusion pumps (A4305, A4306, A9274) are *non-covered devices because they do not meet the Medicare definition of durable medical equipment*. Drugs and supplies used with disposable drug

delivery systems are also non-covered items." A47226 (emphasis added). The article further explains that "[a] disposable drug delivery system (A4305, A4306, A9274) is a device used to deliver solutions containing injectable drugs that is not reusable, i.e., it is used by a single patient for a limited time and then discarded." *Id.* The pods at issue are coded as A9274, which represents a disposable, *not durable*, drug delivery system. Therefore, as expressly indicated in the Policy Article, the pods are not covered by Medicare under the DME benefit category.

The appellant has argued that the OmniPod PDM and the pods work together as an insulin pump. See Exh. MAC-2. However, as described above, the OmniPod PDM is coded as E0607, a "home glucose monitor," not as a pump. The pump function resides in the disposable pod. CMS, through the PDAC contractor, has determined that the PDM (coded as E0607) is not an infusion pump. The appellant's assertion (as well as the ALJ's conclusion) that the pods are merely a supply for a covered infusion pump, contrary to the contractors' determinations, is unpersuasive. The appellant's disagreement with the contractor's classification of the OmniPod system components, which was based on information supplied by the manufacturer, does not present a basis not to follow the LCD and Policy Article.

IV. Section 1879 of the Act does not apply to limit liability when the denial is statutory.

Stated generally, if items or services are denied coverage on the basis that they are not reasonable and necessary, then section 1879 of the Act may afford financial protection to providers, suppliers, and beneficiaries who neither knew, nor could be expected to have known, that the items or services would be denied coverage. However, here, as we have explained, the analysis does not concern whether the pods are reasonable and necessary but rather whether they meet the definition of DME and, thus, whether they fall under that statutory benefit category. Therefore, the liability protections of section 1879 of the Act do not apply. See Medicare Claims Processing Manual (MCPM) (IOM Pub. 100-04), Ch. 30, § 20.2.2.

(Continued on next page.)

DECISION

In accordance with the above discussion, we conclude that the OmniPod insulin pods (HCPCS code A9274) furnished to the appellant on December 10, 2013, are not durable medical equipment and are not covered by Medicare. The appellant-beneficiary is liable for the non-covered charges. We reverse the ALJ's decision.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

/s/ Constance B. Tobias, Chair
Departmental Appeals Board

Date: May 11, 2015