DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-12-551

In the case of	**Claim for**
Network Health Insurance Corp. (NHIC) (Appellant)	Medicare Advantage (MA) (Part C)
**** (Enrollee)	**** (HIC Number)
Network Health Insurance Corp./Network Health Plan (MA Organization (MAO)/ MA Plan)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated November 3, 2011. The ALJ determined that the MA plan was required to authorize and pay for the home infusion pump therapy supplies which the enrollee requested from her MA plan (for treatments ordered by her physician) on June 13, 2011. The appellant has asked the Medicare Appeals Council to review this action.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c).

The request for Council review, submitted by the appellant Network Health Insurance Corp. (NHIC) and its MA plan and received by the Council on December 22, 2011, is admitted into the record as Exhibit (Exh.) MAC-1. The enrollee's response, submitted by her counsel in the form of a letter brief and received by the Council on February 17, 2012, is admitted into the record as Exh. MAC-2.

The regulation codified at 42 C.F.R. § 422.608 states that "[t]he regulations under part 405 of this chapter regarding MAC [Medicare Appeals Council] review apply to matters addressed by this subpart to the extent that they are appropriate." The regulations "under part 405" include the appeal procedures found at 42 C.F.R. part 405, subpart I. With respect to Medicare "fee-for-service" appeals, the subpart I procedures pertain primarily to claims subject to the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). 70 Fed. Reg. 11420, 11421-11426 (March 8, 2005). The Council has determined, until there is amendment of 42 C.F.R. part 422 or clarification by the Centers for Medicare & Medicaid Services (CMS), that it is "appropriate" to apply, with certain exceptions, the legal provisions and principles codified in 42 C.F.R. part 405, subpart I to this case.

The Council has carefully considered the administrative record, the request for review, and the enrollee's response. For the reasons set forth below, the Council adopts the ALJ's decision.

BACKGROUND

The ALJ's decision provides a detailed description of the factual and procedural background in this case, which the Council adopts, and summarizes here.

The enrollee has a condition of unknown origin that causes episodes of severe rigors, shaking, tremors, shortness of breath, and sometimes cyanosis. *See* Exh. 16; *see also, e.g.,* Exh. 16 at 228-31. These medical problems began in 2003, and the enrollee has been followed closely by her primary care physician (Dr. S.), undergone extensive testing, and been evaluated and treated at the University of Wisconsin's medical center, the Mayo Clinic, and the National Institute of Health's Undiagnosed Disorders Program. Testimony of Dr. S., CD Recording of ALJ Hearing, October 28, 2011 (ALJ Hearing) at 1:23 to 1:26 p.m. In March 2010, the enrollee had a tracheostomy tube inserted to enable her to breathe during these episodes. Exh. 16 at 256-62; *see also* additional medical records in Exh. 16.

Frequently, when the enrollee's episodes occur, she also has difficulty swallowing or is unable to swallow, and must rely on IV fluids (i.e. saline solution), via an infusion pump, to avoid dehydration. Exh. 16. When the enrollee requires IV fluids,

the fluids need to be administered over a number of hours (i.e., overnight) to avoid increasing her blood pressure to a dangerously high level. Testimony of Dr. S., ALJ Hearing at 1:39 to 1:41 p.m. The enrollee requires this treatment with IV fluids via infusion pump approximately three to six times per week. Testimony of Dr. S., ALJ Hearing at 1:29 to 1:30 p.m.; *also* Testimony of Enrollee, *id.* at 1:47 to 1:48 p.m.

The enrollee has been using the IV fluid infusion therapy at home since 2010. Testimony of Dr. S., ALJ Hearing at 1:37 to 1:39 p.m. The enrollee is a nurse, and she is competent to self-administer the infusion therapy. Testimony of Enrollee, *id.* at 1:47 to 1:52 p.m. The enrollee's primary care physician testified that as a result of the enrollee's use of this home infusion therapy to rehydrate, the number of emergency room treatments and hospitalizations that she has needed has dropped, in the most recent year (2011), to approximately five to ten percent of the number she needed two years previously. *Id.* at 1:37 to 1:39 p.m.

The enrollee's home infusion pump was covered by private insurance before she enrolled in the appellant's MA plan, and coverage of the pump is not an issue on appeal. The enrollee seeks coverage of the supplies necessary to use the pump for rehydration, including the IV fluids (i.e., sterile saline solution), tubing, a needle that connects with the catheter, a syringe, a heparin flush and sodium chloride flush, and an IV dressing change tray, and alcohol swabs and other supplies to ensure sterile technique, *inter alia.* Testimony of Dr. S., ALJ Hearing at 1:33 to 1:35 p.m.; *see also* Exh. 15 at 160-61.

The enrollee sent her first written request for these supplies to the MA plan on June 13, 2011, after enrolling in the plan. Exh. 1 at 40. The MA plan denied coverage for the home infusion therapy supplies (initially and on redetermination), as did the Independent Review Entity (IRE) on reconsideration. Exh. 4, Exh. 5 at 90, Exh. 7 at 115-16.

Upon the enrollee's request, the ALJ held a hearing and heard testimony from the enrollee and her primary care physician (Dr. S.). ALJ Hearing at 1:05 to 2:15 p.m. MA plan representatives were present at the hearing and made brief arguments but did not offer testimony. *Id.* at 1:51 to 1:56 p.m.

In her hearing decision, issued November 3, 2011, the ALJ concluded that the MA plan must authorize and pay for the

enrollee's home infusion therapy supplies because the evidence shows that the supplies are reasonable and necessary in accordance with Medicare coverage criteria, including National Coverage Determination 280.14 (Infusion Pumps). Dec. at 1-2, 4-8; *see* Pub. 100-3, Medicare National Coverage Determinations (NCD) Manual (MNCDM), Chapter 1, Part 4, § 280.14 (NCD 280.14).[1] The ALJ noted that legally an MA plan must provide enrollees with coverage of all Part A and Part B Medicare-covered services (except hospice services). Dec. at 3-8; *see* 42 C.F.R. § 422.100(a), (c). The Medicare National Coverage Determination for infusion pumps, after enumerating five particular covered uses for external infusion pumps, states that other uses of the pumps are covered if the contractor's medical staff verifies the appropriateness of the therapy and the prescribed pump for the individual patient. NCD 280.14.B.1.f. The testimony of the enrollee and her primary care physician made clear that the MA plan's medical staff could verify the appropriateness of the therapy and the prescribed pump for the individual patient in this case. ALJ Hearing at 1:23 to 1:51 p.m.

The ALJ's decision also addressed the fact that the Local Coverage Determination (LCD L27215) (stating coverage and payment rules), unlike the applicable NCD, does not have a provision for the coverage of "other [i.e., unlisted] uses" of an external infusion pump. Dec. at 7. Because an LCD cannot render any part of an NCD meaningless, the enrollee's use of the home infusion pump therapy is still covered under the NCD's "other uses" provision. *Id.* The ALJ further explained that the evidence established that the enrollee needs infusion of the IV fluids on a gradual, overnight basis, and is competent to self-administer them with the external infusion pump. *Id.* Therefore, the supplies for the external infusion pump therapy shall be covered by the appellant's MA plan, because they are reasonable and necessary for treatment of her severe medical condition and are medically appropriate under NCD 280.14. *Id.* at 7-8.

In its request for Council review, the MA plan contends that:

- NHIC "has not received a claim for [the enrollee's] home [infusion] therapy services or supplies;"

[1] Manuals issued by the Centers for Medicare and Medicaid Services (CMS) can be found at http://www.cms.hhs.gov/manuals.

- NHIC correctly denied coverage because the supplies are not considered reasonable and necessary, according to the standards of Original Medicare;

- NCD 280.14 is applicable to the external infusion pump, but not to the supplies required;

- The "Other Uses" provision in the NCD does not *require* coverage of the home external infusion pump supplies, but simply *allows for* coverage;

- The IRE reconsideration stated that home infusion therapy supplies are not covered by Medicare; and

- In the enrollee's case, home infusion therapy is not medically necessary because alternative options for treatment exist.

Exh. MAC-1.

The enrollee responded, through counsel, in a letter brief citing and discussing legal sources in support of the ALJ's decision. The enrollee's brief emphasized that the Centers for Medicare and Medicaid Services (CMS) has issued a transmittal for NCD 280.14 stating that contractors *shall apply* the discretionary exceptions (such as 280.14.B.1.f. ("Other Uses")) based upon supported documentation on a case-by-case basis. Exh. MAC-2. Therefore, the enrollee asserts, the MA plan is required to assess whether the infusion pump supplies are medically reasonable and necessary in her case, and the plan's assessment can be reviewed and corrected on appeal, if necessary, as with other Medicare determinations based on reasonableness and necessity. *Id.* The enrollee also contends that section 110.3 of Chapter 15 of the Medicare Benefit Policy Manual (MBPM), states that payment may be made for supplies (such as oxygen) that are necessary for the effective use of durable medical equipment. According to the MBPM, those supplies include drugs and biologicals which must be put directly into the equipment in order to achieve the therapeutic benefit. *Id.*

DISCUSSION

As noted above, after careful consideration, the Council adopts the ALJ's decision in this case in its entirety. Therefore, the

following discussion addresses the issues raised in the MA plan's request for review, and the points raised in the enrollee's response.

First, despite the MA plan's contention that it did not receive a claim for the enrollee's infusion therapy supplies, the record reflects that the MA plan did receive a written request on June 13, 2011 (Exh. 1). In fact, in its request for Council review, the MA plan states that it "denied" the enrollee's "*request for home infusion therapy supplies*, including: IV pump, tubing, syringes, Heparin and normal saline for flushes of port, dressing, and Huber needles," on June 22, 2011. Exh. MAC-1 at 1 (emphasis added); *see also* Exh. 2 at 1; Exh. 5 at 90 (additional denials).

Second, the MA plan also errs in asserting that it is not required to cover the home infusion therapy supplies in this case because they are not covered by "Original Medicare," and because they are not necessary and reasonable. As the ALJ stated, the Medicare regulations confirm that an MA plan must include, as part of its basic benefits, all Part A and Part B Medicare-covered services (except hospice services). 42 C.F.R. § 422.100(a), (c). Again, as the ALJ correctly determined, the home infusion pump supplies at issue in this case are Medicare-covered supplies under Part B, because NCD 280.14 provides for the coverage of the pump under 280.14.B.1.f. ("Other Uses"), and for the coverage of the supplies necessary to use the pump under NCD 280.14.B.1.f.; Pub. 100-2, MBPM, Chapter 15, § 110.3;[2] and the applicable parts of LCD L27215.[3]

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[2] This section of the Medicare Benefit Policy Manual provides, *inter alia,* that payment may be made for supplies, e.g., oxygen, which are necessary for the effective use of durable medical equipment. Such supplies include those drugs and biologicals which must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment. It is indisputable that in this case the necessary biologicals include the sterile saline solution the enrollee must infuse gradually by pump to rehydrate during and after an episode, and the necessary supplies include those needed to establish a link to her catheter and maintain a sterile environment and process. Testimony of Dr. S. and of Enrollee, ALJ Hearing, October 28, 2011.

[3] *See* LCD L27215 at 7 ("[w]hen an infusion pump is covered the . . . necessary supplies are also covered. When a pump has been purchased by the Medicare program, other insurer, or the patient . . . the supplies are covered as long as the coverage criteria for the pump are met").

Third, the MA plan is incorrect in its contention that the "Other Uses" provision in the NCD does not *require* coverage of the home external infusion pump supplies, but simply *allows for* coverage. The language of the "Other Uses" provision states that "Other uses of external infusion pumps *are* covered *if the contractor's medical staff verifies the appropriateness of the therapy and the prescribed pump for the individual patient."* NCD 280.B.1.f. (emphasis added). A CMS transmittal dated October 27, 2006 instructs that contractors *shall* apply the NCD section 280.B.1.f. "Other uses" provision based upon supported documentation on a case-by-case basis. Pub. 100-20, One Time Notification, CMS Manual System, Transmittal 242, Change Request 5537, dated October 27, 2006, at first page of Attachment.[4] The same transmittal states that "shall" denotes a mandatory requirement. The meaning is clear. As part of Part B Medicare coverage for infusion pumps and necessary supplies, coverage for other uses not specified in the NCD (such as the use involved in this case) shall be determined by the Medicare contractor or Part C plan based upon supported documentation. Provisions of this type are widely employed in determining Medicare coverage under Part B. However, if the MA plan errs in its assessment of the medical appropriateness of the therapy and prescribed pump and/or supplies for an individual enrollee, that error can be challenged in the appeal process, as has occurred here. For these reasons, the MA plan is required to cover infusion pumps and supplies, based on their coverage in Medicare Part B, in cases when they are medically appropriate, reasonable, and necessary.[5]

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[4] This transmittal can be found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads//R242OTN.pdf.

[5] In its request for Council review, the MA plan also contends that the infusion supplies should not be covered because the IRE denied coverage. Exh. MAC-1, *citing* Exh. 7. However, the IRE's reasoning and conclusion were not correct. For example, the IRE does not cite or discuss any of the relevant legal authorities (i.e., NCD 280.14; LCD L27215; MBPM, Chapter 15, § 110.3). Moreover, the Medicare appeals regulations provide for *de novo* review by the ALJ and *de novo* review by the Council. *See, e.g.,* 42 C.F.R. § 405.1100(c).

During this appeal process the MA plan also erred in referring to sources and documents that have little or no probative value in determining the legal issues in the appeal. For example, the MA plan has stated that it based its coverage denials on, *inter alia,* a June 2010 GAO Home Infusion Therapy Report to Congressional Requestors, a page from a commercial web-based service that provides information about medical coding, a copy of the Milliman Care Guidelines to Inpatient and Surgical Care, and a 2006 CMS Memorandum stating that *Part D* of Medicare does not cover supplies needed for home infusion therapy. None of these sources provides legal authority addressing the

Finally, despite the detailed, uncontroverted testimony presented at the ALJ hearing by the enrollee and her primary care physician, the MA plan contends that home infusion therapy is not medically necessary for the enrollee because alternative options for her treatment exist. There is no support in the record for this contention. Moreover, there is substantial evidence demonstrating that home infusion therapy is medically reasonable and necessary for the enrollee to rehydrate during and after these episodes, essential to her regaining health following the episodes, and highly cost-effective when compared with the repeated emergency room treatments and hospitalizations she required before adopting this form of treatment upon her doctors' recommendations. *See, e.g.,* Testimony of Enrollee and of Dr. S., ALJ Hearing, October 28, 2011; and medical records in Exh. 16.

To summarize the ALJ's relevant factual findings, fully supported by the record:

- When the enrollee has an episode, she suffers severe rigors, shaking, tremors, shortness of breath, inability to swallow, dehydration, and hypotension (with dangerously low levels of blood pressure).

- The enrollee's difficulty swallowing prevents her from getting adequate fluid and food intake. It is especially important for her to rehydrate to preserve her kidney function, because one of her kidneys has been atrophying for a number of years.

- The appellant's primary care physician has instructed her to infuse 250 mL of fluids initially, and an additional 750 mL gradually, overnight. If the enrollee infuses fluids too quickly, her blood pressure will shoot up to a dangerously high level.

- The enrollee needs to infuse fluids in this manner three to six days a week in order to support her pressure and hydration status.

Medicare Part B (and related Medicare Part C) coverage of infusion pumps and supplies for home use in this case. Rather, as explained above, the relevant legal authorities are NCD 280.14, the applicable parts of LCD L27215, and § 110.3 of Chapter 15 of the MBPM.

- If the enrollee cannot self-administer infusion therapy with fluids at home when an episode occurs, she must go to an emergency room, ambulatory surgery center, or hospital, which is set up for long period IV administration. Doctors' offices and clinics do not have staff members with the necessary training, equipment, and longer hours necessary for long period IV administration.

- The enrollee, who is a nurse by training, has demonstrated that she is competent to self-administer these fluids with a home infusion pump.

Dec. at 1-2, 7-8; *see also* Testimony of Enrollee and Dr. S., ALJ Hearing at 1:23 to 1:55 p.m.; and medical records in Exh. 16. The enrollee's primary care physician concluded his medical testimony by saying, "The home infusion therapy she is receiving is appropriate for her, given the unique nature of her case. Without this, I don't know how we could manage this in any other fashion." ALJ Hearing at 1:43 p.m. Therefore, as the ALJ determined, the supplies that the enrollee requires for this use of the external infusion pump are reasonable and necessary for treatment of her severe medical condition and are medically appropriate under NCD 280.14.

The Council concludes that there is no basis for changing the ALJ's decision. The Council therefore adopts the ALJ's decision.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

Date: April 11, 2012