Option Care, a durable medical equipment prosthetics and orthotics supplier (Supplier) furnished the Medicare beneficiary (Appellant) with the antibiotic Ceftriaxone and supplies to be administered intravenously at home. National Government Services, Inc. (NGS), the Medicare administrative contractor, denied the claim initially and on appeal because Medicare does not pay for antibiotic drugs and related supplies when used in the home according to local coverage determination (LCD) L27215.¹

In reversing the denial, the Administrative Law Judge (ALJ) found, “LCD L27215 does not provide coverage criteria specifically on-point in this case. However, ... based upon the facts highlighted above, the drug and related items are medically necessary, reasonable and necessary under Section 1862 of the Act, and are covered by Medicare.” ALJ decision at 9.

The ALJ erred in determining that the antibiotic and supplies furnished for intravenous administration in the home are covered. The Medicare statute provides limited coverage of drugs and biologicals under Part B. Section 1861(s)(2) of the Social Security Act (the Act) covers certain oral drugs used as part of an anticancer chemotherapeutic regimen, prescription drugs used in immunosuppressive therapy furnished in connection with a covered organ transplant, and drugs that are “furnished as incident to a physician’s professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills.” See also 42 C.F.R. Section 410.26; Medicare Benefit Policy Manual (MBPM) (CMS Pub

¹ LCDs are available online at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.
Medicare also covers drugs used with a covered external infusion pumps under the durable medical equipment (DME) benefit in certain circumstances pursuant to national coverage determination (NCD) 280.14. NCDs are located in the Medicare National Coverage Determinations Manual (MNCDM) (CMS Pub 100-3). However, the antibiotic drugs and disposable supplies furnished for home use do not fall under any of the above benefit categories.

**Background:**

The Supplier furnished a Medicare beneficiary the antibiotic drug Ceftriaxone and administration supplies between July 11, 2011 and July 31, 2011 to treat E-Coli Bacteremia with Osteomyelitis. Exh 3 at 8. According to a letter from the beneficiary’s physician, the Ceftriaxone was administered intravenously through a percutaneous central (PICC) line over a one and a half hour period for seven weeks. Exh 3 at 2. The Supplier billed Medicare with the following Healthcare Common Procedure Coding System (HCPCS) codes:

- A4223 – infusion supplies not used with external infusion pump, per cassette or bag
- A4221 – supplies for maintenance of drug infusion catheter, per week
- J0696 – injection, Ceftriaxone sodium, per 250 mg

Exh 1 at 2. The Supplier billed codes J0696 and A4223 with a “-GY” modifier, which is used to bill for services a supplier knows are statutorily excluded or do not meet the definition of a Medicare benefit. See Medicare Claims Processing Manual (MCPM) (CMS Pub 100-4), Chapter 1, Section 60.1.2. The Supplier billed code A4221 with the “-GA” modifier, indicating Medicare will likely deny the services as not reasonable and necessary and the Supplier has a signed Advanced Beneficiary Notice on file.

NGS denied the claim for the services. Exh 1. In its December 9, 2011 redetermination decision, NGS affirmed the denial essentially because Medicare does not pay for prescription drugs in these circumstances unless necessary for use with a covered external infusion pump. Exh 3 at 5. The contractor cited LCD L27215, *External Infusion Pumps* as authority for non-coverage. *Id.*

In his request for reconsideration, the Appellant explained that after being hospitalized for 20 days for E-coli Bacteremia and Sepsis with Osteomyelitis of his lumbar spine, he was sent home to receive the antibiotic through a PICC line at home. Exh 3 at 1. On March 22, 2012, the qualified independent contractor (QIC) explained that drugs could only be covered when used with an external infusion pump. However, the QIC stated:

> The documentation submitted indicates an infusion pump was not required to administer the ceftriaxone. Therefore, the ceftriaxone and infusion supplies are not covered. The LCD L27215 states that other drugs are covered if an infusion pump is necessary to safely

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administer the drug. Supplies for the maintenance of a parenteral drug infusion catheter (A4221) are covered during the period of covered use of an infusion pump.

In conclusion, the decision of the QIC is unfavorable because the documentation submitted indicates an infusion pump was not required to administer the ceftriaxone, as outlined in the LCD L27215.

Exh 5 at 3.

The Appellant’s counsel requested an ALJ hearing, arguing:

Medicare Part B coverage exists if the treatment was reasonable and necessary and payable under Durable Medical Equipment, Prosthetics, Orthotics, and Supplies if the treatment serves a medical purpose, is ordered by a physician and is appropriate for use in the home. The beneficiary was prescribed ceftriaxone sodium injections to be injected and administered at home by the claimant’s daughter-in-law and a home care nurse as furnished by the beneficiary’s physicians.

The Medicare programs also covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA)...Absent evidence to the contrary, presume that drugs delivered intravenously are not usually self-administered by the patient.” Ibid. Under Medicare Benefits Policy Manual, 60.4, given that the injections were given under the supervision and inspection by the nurse to the homebound patient, the injections should be covered.

Exh 10 at 1-2.

After an October 24, 2012 telephone hearing, the ALJ reversed the denial, determining:

The ALJ notes that LCD L27215 does not outline specific criteria applicable to coverage of J0696 (Ceftriaxone). However, the ALJ stresses that the drug was indeed and [sic] administered and infused to the Beneficiary as ordered.

In summary, the ALJ finds that LCD L27215 does not provide coverage criteria specifically on-point in this case. However, the ALJ finds that based upon the facts highlighted above, the drug and related items are medically necessary, reasonable and necessary under Section 1862 of the Act, and are covered by Medicare.

ALJ decision at 9.

Applicable Law, Regulation, and Medicare Policy:

Generally, Part B Medicare provides limited benefits for drugs and biological. See MBPM, Chapter 2, Section 50. Section 1861(s)(2) of the Social Security Act allows Medicare Part B coverage of drugs and biologicals in the following situations:

A signed Appointment of Representative form is located at Exh 8 at 7.
(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills …;

(B) hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this title;

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;

(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)—

Emphasis added. 42 C.F.R. Section 410.26(b) states that Medicare covers services and supplies, including drugs and biological, furnished “incident to the service of a physician” under the following conditions:

(1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

(2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

(3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

(4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

(5) Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

Emphasis added. In addition, certain drugs are covered under the DME benefit for external infusion pumps in specific circumstances. NCD 280.14. DME is defined as equipment that:

Can withstand repeated use; i.e., could normally be rented and used by successive patients;

Is primarily and customarily used to serve a medical purpose;
Generally is not useful to a person in the absence of illness or injury; and,
Is appropriate for use in a patient’s home.

NCD 280.1; 42 C.F.R. Section 414.202. Equipment is covered if it meets the definition of DME, it is reasonable and necessary for treating the beneficiary, and is used in the patient’s home. MBPM, Chapter 15, Section 110.

NCD 280.14 defines infusion pumps as “medical devices used to deliver solutions containing parenteral drugs under pressure at a regulated flow rate.” Infusion pumps are covered only for certain indicated drugs and only when other methods of intravenous administration (e.g., disposable elastomeric pump or intravenous gravity drip line) are contraindicated. Id. External infusion pumps are billed using HCPCS codes E0779 – E0791. These codes generally describe electric, battery powered or mechanical devices that constitute reusable DME. Supplies used for intravenous administration of a drug, including disposable bags, catheters, washes and irrigating kits used for intravenous infusion, are disposable and thus do not meet the definition of DME. NCD 280.1 specifies that nonreusable supplies are not DME and therefore noncovered. See also NGS’ Local Coverage Article for External Infusion Pumps – A47226 ("Disposable 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”).

Under the DME benefit, it must be reasonable and necessary for a particular drug to be administered through an infusion pump as opposed to other methods of intravenous administration such as an intravenous gravity drip line. NCD 280.14 lists specific indications for which Medicare covers infusion pumps. These include iron poisoning, thromboembolic disease, chemotherapy for liver cancer, morphine for intractable cancer pain, and subcutaneous insulin infusion. As indicated above, NGS has issued an LCD for External Infusion Pumps (L27215). In addition to the indications listed in the NCD, the LCD lists several additional covered indications for external infusion pumps if certain criteria are met. However, none of the covered indications include Ceftriaxone or any other antibiotic drug.

42 C.F.R. Section 410.36(a) specifies medical supplies, appliances and devices that covered under Medicare Part B:

(1) Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

(2) Prosthetic devices, other than dental, that replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, including—

(i) Replacement of prosthetic devices; and

(ii) One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery during which an intraocular lens is inserted.

(3) Leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the individual's physical condition.

Medicare Claims Processing Manual (CMS Pub 100-4), Chapter 1, Section 60.1.2 instructs suppliers to use the modifier “GY” when submitting claims for items or services that are noncovered by statute or that do not meet the definition of a Medicare benefit.

“All laws and regulations pertaining to the Medicare and Medicaid programs … and applicable implementing regulations, are binding on ALJs and the MAC.” 42 C.F.R. Section 405.1063(a).

Discussion:

Medicare is a defined benefit program. For Medicare coverage, an item or service first must fall within a benefit category, it must not be excluded by law, and it must be reasonable and necessary for the diagnosis or treatment of illness or injury.

According to the Medicare and You handbook:

[Part B] Medicare covers a limited number of drugs like injections you get in a doctor's office, certain oral cancer drugs, drugs used with some types of durable medical equipment (like a nebulizer or external infusion pump), and under very limited circumstances, certain drugs you get in a hospital outpatient setting. … Other than the examples above, you pay 100% for most prescription drugs, unless you have Part D or other drug coverage.

Medicare and You 2011 at 40.5 Section 1861(s) of the Act identifies five circumstances in which Part B covers drugs. Two of these involve oral drugs used as part of an anticancer chemotherapeutic regimen, one involves a covered organ transplant, and one is specific to hospital services. Section 1861(s)(2)(B), (J), (Q) and (T). Section 1861(s)(2)(A) of the Act provides Medicare coverage for drugs that are “furnished as incident to a physician's professional service, of kinds which are commonly furnished in physicians’ offices and are commonly either rendered without charge or included in the physicians' bills.” Medicare also covers prescription drugs and supplies necessary for the effective use of a covered infusion pump under the durable medical equipment benefit. NCD 280.14; MBPM, Chapter 15, Section 110.3.

In this case, the drug administered was not used in an anticancer regimen or in immunosuppressive therapy following an organ transplant. The drugs also were not administered with a covered infusion pump, and thus not covered under the DME benefit for external infusion pumps.6 See NCD 280.14. Even if the beneficiary did have

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5 The current Medicare and You handbook includes identical language and is available online at http://www.medicare.gov/Publications/.

6 Even if the beneficiary did have a covered infusion pump, the use of Ceftriaxone to treat osteomyelitis or a perineal fistula is not a covered indication for infusion pumps according to NCD and LCD policies.
a covered infusion pump, the use of Ceftriaxone to treat osteomyelitis or a perineal fistula is not a covered indication for infusion pumps according to NCD and LCD policies. Id.; L27215.

In its request for ALJ hearing, the Appellant argued first that “Part B coverage exists if the treatment was reasonable and necessary and payable under Durable Medical Equipment, Prosthetics, Orthotics, and Supplies if the treatment serves a medical purpose, is ordered by a physician and is appropriate for use in the home.” Exh 10 at 1. However, drugs and biological are an entirely distinct benefit category from DME. Drugs and disposable supplies neither meet the definition of DME (they cannot withstand repeated use) nor do they constitute covered prosthetics, orthotics or supplies. See 42 C.F.R. Section 410.36(a).

The Appellant next urged that the drugs should be covered as “incident to” a physician’s service, “given that the injections were given under the supervision and inspection by the nurse to the homebound patient.” Exh 10 at 2. However, drugs covered as incident to a physician’s services would be furnished by the physician or the physician’s staff while under the physician’s direct supervision, either in the physician’s office or a hospital outpatient setting. Section 1861(s)(2)(A) – (B) of the Act; 42 C.F.R. Section 410.26(b). In such cases, the physician would bill for the drugs and supplies. See MBPM, Chapter 15, Section 50.3; 60.1 (“The charge, if any, for the drug or biological must be included in the physician’s bill, and the cost of the drug or biological must represent an expense to the physician”); MCPM, Chapter 23, Section 30.

As noted above, the Supplier billed codes J0696 and A4223 with a “-GY” modifier, indicating the Supplier was aware the drug and supplies are statutorily excluded or do not meet the definition of a Medicare benefit. See MCPM, Chapter 1, Section 60.1.2.

We do not dispute the beneficiary’s assertion, or the ALJ’s finding, that the intravenous drug was reasonable and necessary to treat the beneficiary’s condition. However, the antibiotic drugs are not covered under Part B Medicare, nor were they used with an infusion pump covered under Part B. Because they do not fall under a covered Part B benefit, the beneficiary is liable for the noncovered services.

Conclusion:

Because the ALJ erred in finding the at-home intravenous drug and infusion supplies billed with HCPCS codes J0696, A4223 and A4221 are covered by Medicare, we refer this we refer this case to the Medicare Appeals Council for review on its own motion.