### CMS Referral for Own Motion Review by DAB/MAC

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<tr>
<th>Appellant at ALJ Level</th>
<th>ALJ Appeal Number</th>
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<td>1-1097802958</td>
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<th>Beneficiary (if not the Appellant)</th>
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<tr>
<th>Health Insurance Claim Number (HICN)*</th>
<th>Specific Item(s) OR Service(s)</th>
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<td></td>
<td>E2300 (power seat elevation system)</td>
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<th>Provider, Practitioner OR Supplier</th>
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<td>Travis Medical Sales Corp.</td>
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<th>Basis for referral</th>
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<td>Any Case</td>
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<td>° Error of law material to the outcome of the claim</td>
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<td>° Broad policy or procedural issue of public interest</td>
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<td>CMS as a Participant</td>
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<td>° Decision not supported by the preponderance of evidence</td>
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<td>° Decision not supported by substantial evidence</td>
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**Rationale for Referral:**

Travis Medical Sales Corp., a durable medical equipment (DME) supplier, furnished a wheelchair with multiple accessories to a Medicare beneficiary (Appellant). Medicare paid for the wheelchair and most accessories except the power seat elevation system billed with Healthcare Common Procedure Coding System (HCPCS) code E2300. The E2300 was denied initially and at the first two levels of appeal because it does not meet the definition of DME. On further appeal, the Administrative Law Judge (ALJ) reasoned that “Medicare policy should consider the medical condition of a beneficiary and whether he or she benefits therapeutically from an item before outright denying it because it can dually be considered a convenience item.” ALJ decision at 5. He determined “the power seat elevation (E2300) and power standing feature (E2301)\(^1\) accessories” are covered because “they allow the Beneficiary to perform ADLs necessary to his health and safe well-being. With these accessories, the Beneficiary can perform crucial activities without relying on a home health aide or other routine, and likely more costly, assistance.” ALJ decision at 5.

The ALJ erred in finding the power seat elevation system covered on the basis that the individual beneficiary benefitted therapeutically from the equipment. DME is defined as equipment furnished by a supplier or home health agency that (1) can withstand repeated use; (2) is primarily and customarily used to serve a medical purpose; (3) generally is not useful to an individual in the absence of an illness or injury; and (4) is appropriate for use in the home. 42 C.F.R. § 414.202. According to the contractor’s Local Coverage Article for Wheelchair Options/Accessories (A20284) a power seat elevation system (E2300) is noncovered because it is does not primarily and

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\(^1\) The ALJ decision letter indicates that a claim for E2301 (power standing feature) is also at issue. Although the contractor’s policy article addresses both E2300 and E2301, only E2300 is at issue here. Neither the Medicare Summary Notice in the record nor the Appellant’s requests for review mentions E2301.
customarily serve a medical purpose and thus does not meet the definition of DME. See also Local Coverage Determination (LCD) for Wheelchair Options/Accessories (L11451). In Chapter 30, § 20.2.2 of the Medicare Claims Processing Manual (MCPM) (CMS Pub 100-4), CMS explains, “items that do not meet the definition of durable medical equipment … can never be covered even though in an individual case they may seem medically necessary because of the patient’s condition.”

Thus, since power seat elevation systems are presumptively nonmedical in nature, Medicare does not pay regardless of whether they may provide a medically therapeutic benefit in a particular instance. The ALJ fails to consider the contractor’s LCD L11451 and Policy Article A20284. All laws and regulations pertaining to the Medicare program, including, the Act and applicable implementing regulations, are binding on ALJs and the MAC. 42 C.F.R. § 405.1063(a). “ALJs and the [Medicare Appeals Council] are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable in a particular case.” 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy, the decision must explain the reasons why the policy was not followed. 42 C.F.R. § 405.1062(b). The ALJ erred in allowing coverage for the power seat elevation system without considering whether E2300 meets the regulatory definition of DME and without affording deference to well-established CMS and contractor policies.

Background:

The DME supplier furnished a power wheelchair and related accessories to a Medicare beneficiary on May 13, 2011. Cigna Government Services (CGS), the DME Medicare Administrative Contractor (MAC) in the Appellant’s jurisdiction, paid for the wheelchair and all accessories except the power seat elevation system billed with E2300, which it denied because “its primary use is not for medical purposes.” Exh 3 at 12-13. The items were billed with modifiers “NU,” which means “new equipment” and “KX,” which means “requirements specified in the medical policy have been met.” Id. at 13. See LCD L11451.

On appeal, the Appellant argued “the power seat elevation system is necessary and has a medical purpose.” Exh 4 at 15. In its November 7, 2011 redetermination decision, CGS upheld the denial, because, “based on the facts we have now, we find the item you billed does not meet Medicare’s meaning of DME.” Id. at 18. In its request for reconsideration, the Appellant argued that the power seat elevation was “medically necessary as prescribed by the physical therapy who did the evaluation.” Exh 5 at 21.

In its May 25, 2012 decision letter, C2C Solutions, the DME qualified independent contractor (QIC) cited LCD L11451 and related Policy Article A20284 finding a “power seat elevation feature (E2300) and power standing feature (E2301) are noncovered

2 LCDs and Policy Articles are available online at http://www.cms.gov/medicare-coverage-database/.
because they are not primarily medical in nature.” Exh 5 at 31. The QIC held the beneficiary liable for the denied item. *Id.*

The Appellant requested an ALJ hearing. Exh 6 at 38. Pursuant to 42 C.F.R. § 405.1038(a) the ALJ issued a fully favorable on the record decision in which he determined, based on “the unique circumstances of this case, the items must be covered for the Beneficiary.” ALJ decision at 4. The ALJ reasoned:

There is no dispute in this case that the items in question meet the definition of DME. There is also no dispute that the wheelchair and accessories at issue are medically necessary. According to NCD 280.1, Medicare Part B will cover DME if the item is reasonable and necessary for the individual patient. Medically necessary wheelchair accessories are routinely covered when the power wheelchair meets Medicare requirements for coverage.

While there is no LCD or NCD that is directly applicable to this case, NCD 280.4 addresses coverage of a seat lift, which is an item that has a similar purpose to the power seat elevation although it is not a wheelchair accessory. The NCD for Seat Lifts states as follows:

Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular diseases when it has been determined the patient can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift, the evidence must show that the item is included in the physician’s course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient’s condition, and that the severity of the condition is such that the alternative would be chair or bed confinement.

Although it is not directly applicable to this case, NCD 280.4 demonstrates to the ALJ that Medicare policy should consider the medical condition of a beneficiary and whether he or she benefits therapeutically from an item before outright denying it because it can dually be considered a convenience item.

Here, the Appellant is profoundly physically disabled. He has been in a wheelchair since age 5 and cannot walk. He has some use of his right arm but little use of his left arm, and requires bracing to sit up. As a result, the Enrollee is dependent on a power wheelchair for mobility and ADLs. A power seat elevation (E2300) and power standing feature (E2301) were among the accessories prescribed by his physician and added to the new wheelchair he received on April 22, 2011. He can maintain a higher level of physical activity and independence with the use of these accessories. The use of these items does not merely make transfers easier or more convenient as it might for someone with fewer physical limitations. Rather, the items function to raise and lower him so that he can transfer to his bed, use the shower, and transfer on and off of the toilet. These are activities he could not reasonably perform independently without these items.

Thus, the power seat elevation and power standing features are not merely convenience items. Instead, they allow the Beneficiary to perform ADLs necessary to his health and safe well-being. With these accessories, the Beneficiary can perform crucial activities without
relying on a home health aide or other routine, and likely more costly, assistance. Thus, the power seat elevation (E2300) and power standing feature (E2301) accessories meet the requirements for coverage under Medicare Part B in the circumstances of this case.

Id. at 4-5 (emphasis supplied by ALJ).

Applicable Law, Regulation, and Medicare Policy:

1. Coverage of Durable Medical Equipment

The scope of benefits under Part A and Part B is defined in the Act. See § 1812 (scope of Part A), § 1832 (scope of Part B); and § 1861(s) (definition of medical and other health services). Specific health care services must fit into one of these benefit categories to be eligible for coverage under the Medicare program. Section 1832(a) of the Act provides that benefits under Medicare Part B include “medical and other health services.” Section 1861(s)(6) of the Act defines “medical and other health services” to include durable medical equipment (DME). DME is defined as equipment that:

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- 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.

42 C.F.R. § 414.202. This definition is repeated in the Medicare National Coverage Determinations Manual (MNCDM) (CMS Pub 100-4), § 280.1, the Medicare Benefit Policy Manual (MBPM) (CMS Pub 100-2), Chapter 15, § 110.1, and the MCPM, Chapter 20, § 10.1.1. Examples of DME include wheelchairs, canes, oxygen regulators, hospital beds and nebulizers. The MBPM explains, “Medical equipment is equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury.” Chapter 15, § 110.1. If development is necessary to determine whether an item constitutes medical equipment, such “development would include the advice of local medical organizations (hospitals, medical schools, medical societies) and specialists in the field of physical medicine and rehabilitation.” Id. Furthermore, presumptively nonmedical equipment includes:

Equipment which is primarily and customarily used for a nonmedical purpose may not be considered “medical” equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use.

Id. at § 110.1.B.2.

3 CMS manuals are available online at http://www.cms.hhs.gov/Manuals/IOM/list.asp#TopOfPage.
DME is reimbursable if the following three requirements are met:

- The equipment meets the definition of DME;
- The equipment is necessary and reasonable for the treatment of the patient’s illness or injury or to improve the functioning of his or her malformed body member; and
- The equipment is used in the patient’s home.

Id. at § 110.

2. **Applicability of Local Coverage Determinations and Related Policies**

Section 1869(f)(2)(B) of the Act defines local coverage determination as a determination by a fiscal intermediary or a carrier under part A or part B respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with § 1862(a)(1)(A) of the Act. According to the Medicare Program Integrity Manual (MPIM) (CMS Pub 100-08):

LCDs specify under what clinical circumstances a service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions. Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community.

Chapter 13, § 13.1.3. CMS has instructed contractors to communicate information not pertaining to whether the service was reasonable and necessary (e.g., benefit category, statutory exclusion, and coding provisions) in policy articles. Id.

A revision to CGS’s LCD L11451 states “The following items are noncovered: power seat elevation feature (E2300), power standing feature, electronic interface for lights/other electrical devices.” The related Policy Article A20284, effective on the date of service, states, “A power seat elevation feature (E2300) and power standing feature (E2301) are noncovered because they are not primarily medical in nature.”

42 C.F.R. § 405.1062 provides that, while ALJs and the Medicare Appeals Council (the Council) are not bound by LCDs, LMRPs, or CMS program guidance, they must give substantial deference to these policies if they apply to a case. If the ALJ does not follow an LCD, the ALJ must explain the reasons why the policy wasn’t followed. An ALJ’s decision not to follow a policy applies only to the specific claim on appeal and does not have precedential effect.

Section 1879 of the Act provides financial liability protections to beneficiaries and providers by allowing payment for certain items and services for which Medicare payment would otherwise be denied. Section 1879 applies to claims that are denied as not reasonable and necessary (§ 1862(a)(1)) or denied as custodial care (§ 1862(a)(9)). In these situations, § 1879 allows payment when the beneficiary and/or provider did not
know and could not reasonably have been expected to know that the items or services would be excluded from coverage.

Discussion:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) meet other applicable Medicare statutory and regulatory requirements, and 3) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. An item or service must fall under a covered benefit category before the question of medical necessity is reached.

The ALJ stated, “There is no dispute in this case that the items in question meet the definition of DME.” ALJ decision at 4. However, this is precisely the dispute here.

DME is defined as equipment, furnished by a supplier or home health agency that (1) can withstand repeated use; (2) is primarily and customarily used to serve a medical purpose; (3) generally is not useful to an individual in the absence of an illness or injury; and (4) is appropriate for use in the home. 42 C.F.R. § 414.202 (emphasis added). Items “primarily and customarily used for a nonmedical purpose may not be considered ‘medical’ equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use.” MBPM, Chapter 15, § 110.1. NCD 280.1 contains a reference list for DME items. The list states that bathtub lifts, bed elevators, elevators, grab bars, and raised toilet seats are not primarily medical in nature and thus do not meet the definition DME. The MBPM explains that equipment that basically serves comfort or convenience functions, such as elevators, stairway elevators, and posture chairs, do not constitute DME. Chapter 15, § 110.1 B. Like the E2300 at issue, these items all assist with activities of daily living.

Pursuant to longstanding Medicare policy, power seat elevation systems are never covered by Medicare because they do not meet the regulatory definition of DME. The QIC cited LCD L11451 and relevant policy article A20284. The LCD states, “the following items are noncovered: power seat elevation feature (E2300), power standing feature, electronic interface for lights/other electrical devices.” Policy Article A20284 states, “A power seat elevation feature (E2300) and power standing feature (E2301) are noncovered because they are not primarily medical in nature.” In a case presenting similar issues and coverage policies as the present case, the Council upheld an ALJ’s decision that a power standing system used with a power wheelchair did not meet the definition of covered DME and thus did not fall under a Medicare benefit category. In the Case of S.C.S., Medicare Appeals Council (January 20, 2011), online at http://www.hhs.gov/dab/divisions/medicareoperations/macdecisions/scs_partb.pdf. In addition to the contractor’s LCD and Policy Article regarding wheelchair accessories, the Council cited the contractor medical director’s hearing testimony explaining:
the two primary and customary uses for a PSS are to allow access to higher surfaces in the home (such as countertops) and to facilitate social interactions by permitting eye-level interactions with others.

Id. at 5. The medical director testified further:

that representatives of the Centers for Medicare & Medicaid Services (CMS) and contractors had recently met with representatives of the Rehabilitative Engineering and Adaptive Technology Society of North America (RESNA) to review Medicare’s position on the use of standing systems. He testified that CMS and the contractors did not find that current medical literature supports a change in Medicare coverage for [power standing system] devices.

Id. Internal citations omitted. Thus, CMS has recently reviewed and declined to revise its noncoverage policy regarding power seat elevation systems. See also In the Case of National Seating and Mobility, Medicare Appeals Council (September 20, 2011), online at http://www.hhs.gov/dab/divisions/medicareoperations/macdecisions/11-2045.pdf (“The Council finds that the power seat elevation feature (E2300) and electronic connection components (E2310) are not covered by Medicare”).

In finding the power elevation system met coverage requirements, the ALJ reasoned:

Although it’s not directly applicable to this case, NCD 280.4 demonstrates to the ALJ that Medicare policy should consider the medical condition of a beneficiary and whether he or she benefits therapeutically from an item before outright denying it because it can dually be considered a convenience item.

ALJ decision at 5. However, the threshold issue is not whether an individual beneficiary benefits therapeutically from an item but whether the item constitutes covered DME. Specifically in this case, the pertinent standard is whether the item “is primarily and customarily used to serve a medical purpose” pursuant to 42 C.F.R. § 414.202, MNCDM, § 280.1, MBPM, Chapter 15, § 110.1, and MPCM, Chapter 20, § 10.1.1. According to the MPCM, “items that do not meet the definition of durable medical equipment … can never be covered even though in an individual case they may seem medically necessary because of the patient’s condition.” MPCM, Chapter 30, § 20.2.2.

The Appeals Council similarly determined In the Case of S.C.S.:

the relevant inquiry in this case is not whether the PSS may be of medical benefit in the beneficiary’s individual case. Here, the contractor, the QIC, and the ALJ determined that the PSS is not DME because it does not “primarily and customarily” serve a medical purpose as required by 42 C.F.R. § 414.202. Such a determination represents a conclusion regarding how PSS devices are most often used across a wide spectrum of Medicare beneficiaries.

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4 Power standing system.

5 We also note that NCD 280.4 also requires evidence showing “that the item is included in the physician’s course of treatment [and] that it is likely to effect improvement, or arrest or retard deterioration in the patient’s condition....” Thus, NCD 280.4 contemplates that a patient will “benefit therapeutically” from a device if it improves, or slows deterioration of, the patient’s medical condition.
Moreover, the contractor has exercised its delegated authority on behalf of CMS by memorializing this determination in LCD L11462 and Policy Article A19846.

The ALJ erred as a matter of law in allowing coverage on the basis that the beneficiary benefitted therapeutically from the feature. The correct standard for determining whether the power seat elevation system is covered is whether such equipment is primarily and customarily used to serve a medical purpose. See 42 C.F.R. § 414.202 and NCD 280.1. The ALJ also erred in failing to consider CGS’s LCD L11451 and Policy Article A20284, which state that power seat elevation systems are never covered by Medicare because they are not presumptively medical in nature and do not meet the definition of DME. Although ALJs are not bound by LCDs, they must give substantial deference to these policies if they apply to a case. 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy, the decision must explain the reasons why the policy was not followed. 42 C.F.R. § 405.1062(b).

If services are not covered on the basis that they are not reasonable and necessary under § 1862(a)(1)(A) of the Social Security Act, then § 1879 of the Social Security Act provides financial protection to both providers and beneficiaries where neither knew or could be expected to know that services were not covered. However, these financial liability protections do not apply to services that are not covered because they do fall into a statutory benefit category. Because “items that are primarily not medical in nature” are noncovered as a matter of law, the financial protection of § 1879 of the Act does not apply and the supplier cannot be held responsible for the payment.