UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

C&I MEDICAL EQUIPMENT and, SUPPLIES, INC.,

Plaintiff,

v.

KATHLEEN SEBELIUS, Secretary of Health and Human Services,

Defendant.
_____/

Case No. 09-12112

HON. SEAN F. COX
United States District Judge

OPINION & ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT [Doc. No. 15]

Plaintiff C&I Medical Equipment and Supplies, Inc. ("C&I") filed the instant suit against Kathleen Sebelius ("the Secretary"), Secretary of the United States Department of Health and Human Services ("HHS"), challenging the Secretary's decision that durable medical equipment ("DME") C&I supplied to seven Medicare beneficiaries was not covered by Medicare. The case is before the Court on the Secretary's motion for summary judgment [Doc. No. 15]. Pursuant to Local Rule 7.1(f)(2), the Court declines to hear oral argument. For the reasons that follow, the Court **GRANTS** the Secretary's motion [Doc. No. 15].

BACKGROUND

The Medicare Act creates a health insurance program providing benefits to eligible elderly and disabled individuals. 42 U.S.C. §§ 1395-1395hh. Parts A and B include coverage for various items and services, but exclude payment for items and services that "are not *reasonable and necessary* for the diagnosis or treatment of illness or injury. . . ." 42 U.S.C. §

1395y(a)(1)(A) (emphasis added).

Medicare is administered by the Center for Medicare and Medicaid Services ("CMS"). CMS contracts with private insurance companies - in this case, National Government Services ("NGS"), who together with local peer review organizations (collectively known as "Medicare contractors") process claims for Medicare beneficiaries. Essentially, a Medicare claim submitted for payment is approved or denied by a Medicare contractor.

In making coverage decisions, Medicare contractors rely on regulations promulgated by HHS, as well as on National Coverage Determinations ("NCDs") - made by CMS - and Local Coverage Determinations ("LCDs") - made by NGS in this case. The Secretary adopts NCDs to exclude certain items and services from coverage on a national level that are not "reasonable and necessary" under the agency's interpretation of the Medicare statute. *See* 42 U.S.C. § 1395ff(f)(1)(B). These determinations are binding on all Medicare contractors nationwide. When no NCD applies to a claim, Medicare contractors must still apply the "reasonable and necessary" limitations in LCDs in determining whether to pay a claim and in what amount.

Part B coverage of Durable Medical Equipment ("DME") claims is limited to items that are medically "reasonable and necessary" for the diagnosis or treatment of illness. 42 U.S.C. § 1395y(a)(1)(A), 42 C.F.R. § 411.15(k)(1). Although "reasonable and necessary" is not defined in the Medicare statute, Congress has vested final authority in the Secretary to determine what items or services are "reasonable and necessary." *See* 42 U.S.C. § 1395ff(a); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). In accordance with this authority, the Secretary has promulgated regulations relating to the "reasonable and necessary" requirement. CMS has also issued NCDs specifying conditions for Medicare coverage of certain items and services. Finally, contractors

have also issued LCDs and policy guidance to address local coverage issues.

Because of the expense of DME, and due to past abusive acts by DME suppliers, Congress ordered the Secretary to require that suppliers submit documentation sufficient to establish medical necessity before paying claims for DME. *See* 42 U.S.C. § 1395(a)(1)(E). In response, the Secretary promulgated regulations covering DME at 42 C.F.R. § 410.38. CMS has also issued NCDs regarding DME reimbursement, and local carriers like NGS have issued LCDs. If a supplier - here, C&I - is unable to establish medical necessity, its claim will be denied.

A Medicare supplier dissatisfied with the resolution of a claim must pursue the designated administrative appeals process and must exhaust all administrative remedies before filing suit. *See* 42 U.S.C. § 1395u(b)(3)(C); 42 U.S.C. § 1395ff(b); 42 C.F.R. § 405.900. First, the supplier must submit unfavorable determinations to the qualified independent contractor ("QIC") for an informal review. 42 C.F.R. §§ 405.928(b), 405.958, 405.978. Next, if the amount in controversy is at least $120.00, the supplier must appeal the determination to an administrative law judge. 42 C.F.R. § 405.1002. If still unsatisfied, the supplier must then seek leave to appeal the administrative law judge's decision to the Medicare Appeals Council - a division of HHS - which has discretion to hear appeals. *See* 42 C.F.R. §§ 405.1048, 405.1130. The Council's final ruling becomes the Secretary's final agency ruling - though if the Council declines to hear the appeal, the administrative law judge's ruling becomes the Secretary's final agency ruling. Judicial review of the Secretary's final ruling is available as provided in 42 U.S.C. § 1395ff(b). 42 C.F.R. § 405.1136.

PROCEDURAL HISTORY

Plaintiff C&I is a Michigan corporation that provides durable medical equipment ("DME"), and is a "supplier" as defined by 42 C.F.R. § 405.802. C&I filed this lawsuit on June 1, 2009 [*See* Complaint, Doc. No. 2], appealing two separate rulings by the Council that disallowed Medicare reimbursement claims by C&I for DME related to a combined seven Medicare beneficiaries.

The March 26, 2009 Council decision was a consolidated appeal of ALJ William Steele's five September 18, 2008 decisions denying the claims that C&I had submitted for DME supplied to five separate Medicare beneficiaries. [*See* Certified Appellate Record ("CAR") at 81-107, 264-90, 439-64, 623-31, 749-57].

C&I's first claim was for a power wheelchair supplied to beneficiary G.B. on January 9, 2007. [CAR at 208]. NGS denied the claim on August 29, 2007 [CAR at 181], of which C&I requested a redetermination on August 30, 2007, resulting in an unfavorable determination by NGS on October 16, 2007. *Id*. at 163, 181. C&I sought reconsideration by the QIC on April 15, 200, *Id*. at 161, which was denied on June 13, 2008. *Id*. at 127. C&I appealed to the ALJ in a letter received by the ALJ on June 25, 2008. *Id*. at 311 .

C&I's second claim was for a power-operated vehicle ("POV") supplied to beneficiary S.C. on May 23, 2007. [CAR at 365]. NGS denied the claim on August 15, 2007, *Id.* at 350 , of which C&I requested a redetermination on August 28, 2007, resulting in an unfavorable determination by NGS on October 15, 2007. *Id*. at 331, 350. C&I sought reconsideration by the QIC, which was denied on June 13, 2008. *Id*. at 326, 329. C&I appealed to the ALJ in a letter received by the ALJ on June 25, 2008. *Id*. at 311.

C&I's third claim was for a power wheelchair supplied to beneficiary P.D. on February

14, 2007. [CAR at 587]. NGS denied the claim on August 9, 2007, *Id*. at 552, of which C&I requested a redetermination on August 28, 2007, resulting in an unfavorable determination by NGS on October 15, 2007. *Id*. at 533, 552. C&I sought reconsideration by the QIC, which was denied on June 13, 2008. *Id*. at 527, 531. C&I appealed to the ALJ in a letter received by the ALJ on June 25, 2008. *Id*. at 484.

C&I's fourth claim was for a power air mattress supplied to beneficiary E.G. on a rental basis on January 8, February 8, March 8, April 8, May 8, and June 8, 2007. [CAR at 701, 718]. NGS denied the claim on August 22, 2007, *Id*. at 701, of which C&I requested a redetermination on August 27, 2007, resulting in an unfavorable determination by NGS on October 9, 2007. *Id*. at 682, 696. C&I sought reconsideration by the QIC, which was denied on June 13, 2008. *Id*. at 672, 680. C&I appealed to the ALJ in a letter received by the ALJ on June 25, 2008. *Id*. at 651.

C&I's fifth claim was for a seat lift supplied to beneficiary A.M. on June 5, 2007. [CAR at 826]. NGS denied the claim on September 6, 2007, *Id*. at 817, of which C&I requested a redetermination on September 11, 2007, resulting in an unfavorable determination by NGS on October 29, 2007. *Id*. at 797, 815. C&I sought reconsideration by the QIC, which was denied on June 13, 2008. *Id*. at 791. C&I appealed to the ALJ in a letter received by the ALJ on June 25, 2008. *Id*. 777.

The March 31, 2009 Council decision was a consolidated appeal of ALJ Steele's two September 18, 2008 decisions denying the claims that C&I had submitted for DME supplied to two additional Medicare beneficiaries. [CAR at 839-42, 862, 911-37, 1051, 1097-1122].

C&I's first (and sixth for purposes of this appeal) claim was for a POV supplied to beneficiary R.M. on May 1, 2007. [CAR at 1031]. NGS denied the claim on July 18, 2007, *Id*.

at 1005, of which C&I requested a redetermination on August 28, 2007, resulting in an unfavorable determination by NGS on October 16, 2007. *Id*. at 983, 1003. C&I sought reconsideration by the QIC, which was denied on June 13, 2008. *Id*. at 1180-81, 957. C&I appealed to the ALJ in a letter received by the ALJ on June 25, 2008. *Id*. at 983.

C&I's second (and seventh for purposes of this appeal) claim was for a power wheelchair supplied to beneficiary E.S. on July 20, 2007. [CAR at 1225]. NGS denied the claim on September 7, 2007, *Id*. at 1197, of which C&I requested a redetermination on September 11, 2007, resulting in an unfavorable determination by NGS on October 16, 2007. *Id*. at 1187, 1195. C&I sought reconsideration by the QIC, which was denied on June 13, 2008. *Id*. at 1185, 1142. C&I appealed to the ALJ in a letter received by the ALJ on June 25, 2008. *Id*. at 1176.

In its March 26 and March 31, 2009 decisions, the Council conducted a *de novo* review of C&I's documentary evidence and transcripts of hearings. [CAR at 3-6, 839-42]. The Council concluded that, for all seven claims C&I brought related to supplied DME, C&I's documentation did not establish that the supplied DME was reasonable and necessary.

C&I filed this federal question lawsuit on June 1, 2009 [*See* Doc. No. 2], challenging the Council's March 26 and March 31, 2009 decisions that the DME items in questions were not "reasonable and necessary" pursuant to 42 U.S.C. § 1395y(a)(1)(A). At a scheduling conference held by the Court on December 7, 2009 [*See* Doc. No. 13], the parties agreed that no fact discovery was needed beyond the Court's receipt of the Certified Appellate Record [*See* Doc. Nos. 9-11]. The Court entered a scheduling order requiring the parties to file cross-motions for summary judgment no later than February 10, 2010 [*See* Doc. No. 14].

On February 9, 2010, the Secretary filed her instant motion for summary judgment [Doc.

No. 15]. Despite agreeing that the proper method of resolving this cause of action was on cross-motions for summary judgment, C&I has not filed a motion for summary judgment. Likewise, C&I has not filed a brief in opposition to the Secretary's motion, nor has C&I filed a counter-affidavit to the Secretary's affidavit of material facts not in dispute [Ex. 1, Doc. No. 15].

STANDARD OF REVIEW

In *Heckler v. Ringer*, 466 U.S. 602 (1984), the Supreme Court held that the Secretary's determinations regarding whether a particular medical service is "reasonable and necessary" are given substantial deference:

> The Secretary's decision as to whether a particular medical service is "reasonable and necessary" and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions.

Heckler, 466 U.S. at 617. The Sixth Circuit has elaborated as follows:

> Judicial review of the Secretary's decision is limited to determining whether the Secretary's findings are *supported by substantial evidence* and whether the Secretary employed the proper legal standards in reaching her conclusion. Substantial evidence is more than a scintilla of evidence but less than a preponderance and is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. The scope of our review is limited to an examination of the record only. We do not review the evidence *de novo*, make credibility determinations nor weigh the evidence.

Besaw v. Sec'y of Health & Hum. Servs., 966 F.2d 1028, 1030 (6th Cir. 1992) (emphasis added). Thus, the Court reviews the Secretary's determination denying these seven requests for DME reimbursement under the "substantial evidence" standard.

ANALYSIS

Substantial evidence supports the Secretary's decision to deny C&I's seven requests for DME reimbursement in this matter. Therefore, the Court **GRANTS** the Secretary's motion for

summary judgment [Doc. No. 15].

I. C&I's Claims for Power Wheelchair Reimbursement.

A power wheelchair qualifies as DME under Medicare Part B, but must be reasonable and necessary for beneficiaries to be covered. *See* 42 U.S.C. §§ 1395x(n), 1395y(a)(1)(A). HHS promulgated the following regulation describing coverage conditions for medically necessary power mobility devices - a term encompassing both power wheelchairs and POVs:

> Medicare Part B pays for a power mobility device if the physician or treating practitioner. . . meets the following conditions:
>
> (i) Conducts a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity for the PMD as part of an appropriate overall treatment plan.
>
> (ii) Writes a prescription. . . that is provided to the beneficiary or supplier, and is received by the supplier within 45 days after the face-to-face examination.
>
> (iii) Provides supporting documentation, including pertinent parts of the beneficiary's medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans and/or other information as may be appropriate) that supports the medical necessity for the power mobility device, which is received by the supplied within 45 days after the face-to-face examination.

42 C.F.R. § 410.38(c)(2).

Under 42 C.F.R. § 410.38(c), "to assist in fraud prevention for these expensive items of equipment, and to provide guidance regarding the conditions for Medicare coverage," [Government's Br., Doc. No. 15, p.9], CMS issued an NCD for "Mobility Assistive Devices." [*See* CAR at 88-91]. Under this NCD, a power wheelchair or POV is only medically necessary when the following three prerequisites are met:

> 1) The beneficiary's medical history and living situation must be considered in order to determine his or her functional limitations.
>
> 2) If the beneficiary's functional limitations relate to mobility and impair his or

her ability to participate in mobility-related activities of daily living ("MRADLs"), certain DME may be reasonable and necessary and therefore covered by Medicare.

3) A prescribing physician must undertake a sequential analysis of the beneficiary's condition, impairments, and treating plan, in light of a progressive sequence of DME that could help the beneficiary.

[CAR at 88-89]. Finally, NGS issued an LCD regarding power wheelchairs and POVs, which states that a power wheelchair or POV is not appropriate unless and until all simpler and more inexpensive options have been ruled out, in conjunction with the beneficiary's history, living situation, medical needs, functional limitations, and treatment plan. *Id*. at 92-105. If these steps are not taken by C&I, Medicare will not reimburse C&I for power wheelchairs and POVs provided to Medicare beneficiaries.

A. Beneficiary G.B.

Though no direct argument is made in its complaint [Doc. No. 2], C&I appeals the Secretary's decision to deny reimbursement for a power wheelchair supplied by C&I to beneficiary G.B. The Secretary found that the documentation submitted by C&I did not establish that the power wheelchair was reasonable and necessary. [CAR at 4]. As substantial evidence supports the Secretary's denial of reimbursement of the power wheelchair supplied to G.B., the Court affirms the Secretary's determination.

In this case, though C&I submitted several forms completed by G.B.'s treating physician - Dr. Nwoke - attesting to the medical necessity of a power wheelchair for G.B., those forms were not supported by G.B.'s medical history or treatment notes. Specifically, though Dr. Nwoke noted on one form that G.B. had osteoarthritis of the spine and knee and would need a power wheelchair for the rest of her life [CAR at 189-90], G.B.'s previous medical records made absolutely no mention of osteoarthritis. *See Id.* at 194-205. Further, G.B.'s physical therapist's

notes suggested that G.B. could walk - G.B.'s physical therapy goals included promoting independent ambulation and increasing strength of upper and lower extremities. *Id*. at 195. Further, G.B.'s physical therapist noted that G.B. had "good" rehabilitation potential, *Id*. at 195, buttressed by G.B.'s home health care nurse noting that G.B. had "fair" rehabilitation potential. *Id*. at 203. G.B.'s medical records also showed that she had poor eyesight and a history of dementia - possible safety issues which would need to be considered under CMS's NCD. *See Id*. at 88, 199-200. These factors, however, were not included in, or considered by, Dr. Nwoke in his evaluation and prescription. For these reasons, the Court affirms the Secretary's denial of C&I's claim related to G.B.'s power wheelchair

B. Beneficiary P.D.

Though no direct argument is made in its complaint [Doc. No. 2], C&I appeals the Secretary's decision to deny reimbursement for a power wheelchair supplied by C&I to beneficiary P.D. The Secretary found that the documentation submitted by C&I did not establish that the power wheelchair was reasonable and necessary. [CAR at 4]. As substantial evidence supports the Secretary's denial of reimbursement for the power wheelchair supplied to P.D., the Court affirms the Secretary's determination.

In this case, though C&I submitted several forms completed by P.D.'s treating physician - Dr. Nwoke - attesting the medical necessity of a power wheelchair for P.D., those forms were not supported by P.D.'s medical history or treatment notes. Specifically, P.D.'s home health care physical therapist noted that, although P.D. had difficulty walking, he was able to ambulate with a cane. [CAR at 575-76]. P.D.'s medical records also showed that he had Alzheimer's disease and was forgetful and disoriented - possible safety issues which would need to be

considered under CMS's NCD. *See Id*. at 88. These factors, however, were not included in, or considered by, Dr. Nwoke in his evaluation and prescription. For these reasons, the Court affirms the Secretary's denial of C&I's claim related to P.D.'s power wheelchair.

C. Beneficiary E.S.

C&I's complaint [Doc. No. 2, ¶¶14-17] appeals the Secretary's decision to deny reimbursement for a power wheelchair supplied by C&I to beneficiary E.S. The Secretary found that the medical documentation submitted by C&I did not establish the medical necessity for this DME because the documents did not address E.S.'s functional limitations or the extent of the weakness in her upper and lower extremities. As substantial evidence supports the Secretary's denial of reimbursement for the power wheelchair supplied to E.S., the Court affirms the Secretary's determination.

In this case, though C&I submitted several forms completed by E.S.'s treating physician - Dr. Nwoke - attesting the medical necessity of a power wheelchair for E.S., those forms were not supported by E.S.'s medical history or treatment notes. [CAR at 1205-11]. Specifically, E.S.'s medical records show that E.S. was able to walk with assistance. *Id*. at 843. Other information was provided by Dr. Nwoke after the date E.S. had already received the power wheelchair, *see Id*. at 1214-15, a violation of 42 C.F.R. § 410.38(c)(4). Finally, none of the documents provided by C&I show evaluation and planning by Dr. Nwoke in light of an overall plan of care for E.S. - a violation of 42 C.F.R. § 410.38(c)(2)(i). For these reasons, the Court affirms the Secretary's denial of C&I's claim related to E.S.'s power wheelchair.

II. C&I's Claims for Power-Operated Vehicle Reimbursement.

A POV qualifies as DME under Medicare Part B, but must be reasonable and necessary

for beneficiaries to be covered. *See* 42 U.S.C. §§ 1395x(n), 1395y(a)(1)(A). POVs are subject to the same HHS regulation - 42 C.F.R. § 410.38(c) - as well as the NCD promulgated by CMS and the LCD promulgated by NGS, described *supra*, that apply to power wheelchairs. As the Secretary argues in her brief, "[b]ecause POVs generally require greater ability on the party of beneficiary to transfer and maintain stability than a power wheelchair would, and POVs cost less, the required analytical progression proceeds from manual wheelchairs to POVs to power wheelchairs. [Government's Br., Doc. No. 15, pp.14-15, citing CAR at 270-87].

A. Beneficiary S.C.

Though no direct argument is made in its complaint [Doc. No. 2], C&I appeals the Secretary's decision to deny reimbursement for a POV supplied by C&I to beneficiary S.C. The Secretary found that the documentation submitted by C&I did not establish that the POV was reasonable and necessary. [CAR at 4-6]. As substantial evidence supports the Secretary's denial of reimbursement for the POV supplied to S.C., the Court affirms the Secretary's determination.

In this case, S.C.'s face-to-face examination with the prescribing physician - Dr. Asebebiyi - occurred on June 1, 2007, *after S.C. had already received the POV*. [*See* CAR at 362-63, 365]. Further, in prescribing the POV, Dr. Asebebiyi did not provide an assessment of S.C.'s upper body strength, *Id*. at 360-63 - a necessary element in the progressive analysis of appropriate DME for a Medicare beneficiary. *Id*. at 272-73. S.C.'s functional mobility evaluation also included, in the Secretary's characterization, "numerous incomplete and unexplained answers, including the omission of necessary information such as functional limitations, and how these impact the beneficiary's performance of MRADLs." [Government's Br., Doc. No. 15, p.15, citing CAR at 362-63]. S.C.'s medical process notes also stated that S.C.

was able to ambulate using a cane and by holding onto walls. [CAR at 364]. For these reasons, the Court affirms the Secretary's denial of C&I's claim related to S.C.'s POV.

B. Beneficiary R.M.

C&I's complaint [Doc. No. 2, ¶¶11-13] appeals the Secretary's decision to deny reimbursement for a POV supplied by C&I to beneficiary R.M. The Secretary found that the medical documentation submitted by C&I did not establish the medical necessity for this DME. As substantial evidence supports the Secretary's denial of reimbursement for the POV supplied to R.M., the Court affirms the Secretary's determination.

In this case, R.M.'s prescribing physician - Dr. Nwoke - failed to meet the regulatory period in which, pursuant to 42 C.F.R. § 410.38(c)(2)(ii), the face-to-face examination needed to occur. R.M.'s face-to-face exam was conducted on January 24, 2007, while the prescription was not provided until April 30, 2007 - 97 days later. [*See* CAR at 1015-19]. Further, at the January 24, 2007 face-to-face examination, Dr. Nwoke noted that R.M. was capable of ambulating with a walker or with a cane. *Id*. at 1017. Dr. Nwoke also noted on the face-to-face exam form that R.M. did not have the upper body support strength to use a POV - the exact equipment prescribed to R.M. by Dr. Nwoke only three months later. *Id*. at 1019. For these reasons, the Court affirms the Secretary's denial of C&I's claim related to R.M.'s POV.

III. C&I's Claim for Power Air Mattress Reimbursement.

Though no direct argument is made in its complaint [Doc. No. 2], C&I appeals the Secretary's decision to deny reimbursement for a power air mattress supplied by C&I to beneficiary E.G. The Secretary found that the medical documentation submitted by C&I did not establish the medical necessity for this DME. As substantial evidence supports the Secretary's

denial of reimbursement for the power air mattress supplied to E.G., the Court affirms the Secretary's determination.

A power air mattress qualifies as DME under Medicare Part B, but must be reasonable and necessary for beneficiaries to be covered. *See* 42 U.S.C. §§ 1395x(n), 1395y(a)(1)(A). HHS promulgated the following regulation describing coverage conditions for a medically necessary power air mattress:

> Medicare Part B pays for medically necessary equipment that is used for treatment of decubitus ulcers if - -
>
> (1) The equipment is ordered in writing from the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the equipment; and
>
> (2) The prescribing physician has specified in the prescription that he or she will be supervising the use of the equipment in connection with the course of treatment.

42 C.F.R. § 410.38(d).

Under 42 C.F.R. § 410.38(d), NGS issued LCD L5068 concerning the reimbursement of "Pressure Reducing Support Surfaces." [*See* CAR at 627-30]. Under LCD L5068, a power air mattress of the category prescribed to E.G. is only medically necessary when the beneficiary meets one of three medical and treatment circumstances:

> 1) "Multiple stage II pressure ulcers located in the trunk or pelvis," where the "[p]atient has been on a comprehensive ulcer treatment program for at least the past month which has included the use of an appropriate group 21 support surface," and "[t]he ulcers have worsened or remained the same over the past month.";
> 2) "Large or multiple stage III or IV pressure ulcer(s) on the trunk or pelvis."; or
> 3) "recent myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis (surgery within the past 60 days)," and where "[t]he patient has been on a group 2 or 3 support surface immediately prior to a recent discharge from a hospital or nursing facility (discharge within the past 30 days)."

[CAR at 627-28]. Thus, pursuant to LCD L5068, the power air mattress prescribed to E.G. is only covered by Medicare if E.G. has *some diagnosis related to ulcers*.

In this case, the Council determined that C&I's documentation on behalf of beneficiary E.G. failed to support the medical necessity of the power air mattress supplied. [CAR at 5-6]. Reviewing under the "substantial evidence" standard, the Court agrees. E.G. did not fall into any of the three medical and treatment circumstances supporting the prescription in accordance with LCD L5068. The January 8, 2007 prescription submitted by E.G.'s attending physician included the diagnoses of "bed sore," as well as debility/muscle atrophy - no mention was made, however, regarding the "stage" of E.G.'s ulcers, or about E.G.'s ulcer treatment plan. *See Id.* at 708, 711-13. For this reason, the Court affirms the Secretary's denial of C&I's claim related to E.G.'s power air mattress.

IV. C&I's Claim for Seat Lift Reimbursement.

Though no direct argument is made in its complaint [Doc. No. 2], C&I appeals the Secretary's decision to deny reimbursement for a seat lift supplied by C&I to beneficiary A.M. The Secretary found that the medical documentation submitted by C&I did not support the information included by A.M.'s physician on the Certificate of Medical Necessity ("CMN"). As substantial evidence supports the Secretary's denial of reimbursement for the seat lift supplied to A.M., the Court affirm the Secretary's determination.

A seat lift qualifies as DME under Medicare Part B, but must be reasonable and necessary for beneficiaries to be covered. *See* 42 U.S.C. §§ 1395x(n), 1395y(a)(1)(A). HHS promulgated the following regulation describing coverage conditions for a medically necessary seat lift:

> Medicare Part B pays for a medically necessary seat lift if it - -
>
> (1) Is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, *and the written order is furnished to the supplier before the delivery of the seat-lift*;
>
> (2) Is for a beneficiary *who has a diagnosis designated by CMS* as requiring a seat-lift; and
>
> (3) Meets safety requirements specified by CMS.

42 C.F.R. § 410.38(e) (emphasis added).

Under § 410.38(e)(2), CMS issued NCD 280.4 for seat lifts, requiring that the beneficiary must have "severe arthritis of the hip and knee," that the seat lift would benefit the person by affecting improvement or arresting or retarding deterioration, and "that the severity of the condition is such that the alternative would be chair or bed confinement." NGS also issued an LCD requiring that the beneficiary must be "completely incapable of standing up from a regular armchair in the home," and once standing "must have the ability to ambulate." [CAR at 754-55].

In this case, the Council determined that C&I's documentation on behalf of beneficiary A.M. failed to support the medical necessity of the seat lift supplied. [CAR at 5-6]. Reviewing under the "substantial evidence" standard, the Court agrees. A.M.'s CMN was dated ten days *after* the date A.M. received the seat lift - a violation of 42 C.F.R. § 410.38(e)(1)'s requirement that the written order be furnished to the supplier "before delivery of the seat-lift." *Id*. at 783, 826. The CMN also included diagnosis code 715.90 - a diagnosis relating to *unspecified osteoarthritis*, not "severe arthritis of the hip and knee" as required by NCD 280.4. *Id.* at 750, 824.

Though A.M.'s treating physician answered affirmatively on the CMN that A.M. had severe arthritis of the hip and knee, these diagnoses are not supported by any records in A.M.'s medical history. [*See* CAR at 822-23]. Several Circuit Courts have affirmed the Secretary's

refusal to simply take a prescribing physician's word that certain DME is reasonable and necessary - especially where such an opinion is not supported by the patient's medical history. *See, e.g., Maximum Comfort, Inc. v. Sec'y of Health & Hum. Servs.*, 512 F.3d 1081, 1087-88 (9th Cir. 2007); *MacKenzie Med. Supply, Inc. v. Leavitt*, 506 F.3d 341, 347-48 (4th Cir. 2007); *Gulfcoast Med. Supply, Inc. v. Sec'y of Health & Hum. Servs.*, 468 F.3d 1347, 1351 (11 Cir. 2006). For these reasons, the Court affirms the Secretary's denial of C&I's claim related to A.M.'s lift seat.

CONCLUSION

For the reasons above, the Court **GRANTS** the Secretary's motion for summary judgment [Doc. No. 15].

IT IS SO ORDERED.

s/Sean F. Cox
Sean F. Cox
United States District Judge

Dated: June 9, 2010

I hereby certify that a copy of the foregoing document was served upon counsel of record on June 9, 2010, by electronic and/or ordinary mail.

s/Jennifer Hernandez
Case Manager