

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-560

In the case of

Claim for

Solari Hospice Care, LLC

(Appellant)

Hospital Insurance Benefits
(Part A)

(Beneficiary)

(HIC Number)

National Government Services

(Contractor)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated October 28, 2010, which concerned Medicare coverage for hospice services that the appellant provided to the beneficiary from November 1, 2009, through November 15, 2009. The ALJ determined that Medicare does not cover the hospice services during the dates at issue, and that the appellant is financially liable for the non-covered costs. The appellant has asked the Medicare Appeals Council (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 appellant's request for review is hereby made a part of the record as Exhibit (Exh. MAC-1). For the reasons set forth below, the Council reverses the ALJ's decision.

Appellant's Contentions

In its request for review, the appellant contends that the beneficiary's medical condition during the dates of service at issue met the guidelines in LCD L25678 for determining whether a

beneficiary has a terminal illness with a life expectancy of six months or less. Exh. MAC-1. Specifically, the appellant asserts that the ALJ did not give adequate weight to how the progression of the beneficiary's disease (end-stage debility) was demonstrated by decreasing anthropomorphic measurements, well documented edema, a low Karnofsky Performance Status (KPS) and a further decline in her Palliative Performance Score (PPS), as well as additional factors. *Id.* Moreover, the appellant contends that the beneficiary's declining clinical status in November 1, 2009, through November 15, 2009, is further illustrated by adverse medical events in December 2009 and January 2010, and the fact that the beneficiary passed away less than six months later, on ***, 2010. *Id.*

Background and Procedural History

The beneficiary, who was then eighty-four years old, entered hospice care on May 28, 2008, at the recommendation of her physicians, after a hospitalization for septic shock, a period of SNF care, and a move to a group home. Exh. 1 at 1-4; Exh. 3 at 80-81. Her admitting diagnosis into hospice care was end-stage debility, and her additional diagnoses included coronary artery disease, chronic obstructive pulmonary disease, chronic atrial fibrillation, dementia, anemia, myocardial infarction, hypertension, and recent sepsis. *Id.* For the next eighteen months, the beneficiary experienced a slow but steady decline in her condition, and was recertified for hospice care every two months. Exh. 1 at 6-7. She passed away on May 11, 2010, less than six months after the dates of service at issue here. Exh. 4 at 8-9 (report and record of death).

In January 2010, the contractor denied the appellant hospice's claim for coverage of the hospice services provided during the first half of November 2009, on the ground that the medical information the appellant provided did not support the claim that the beneficiary's illness was terminal. Exh. 2 at 5, 18. The redetermination the hospice requested also resulted in a denial of coverage, as did the reconsideration by the Qualified Independent Contractor (QIC). Exh. 2 at 1-3; Exh. 3 at 1-5. The QIC's denial of coverage was based on its application of the LCD L25678 criteria for Alzheimer's disease and related disorders. This was error in part because the beneficiary's admitting diagnosis was debility, and her condition should have been evaluated also under Part I ("Decline in clinical status guidelines"). LCD L25678.

On further appeal, the ALJ applied the LCD's Part I guidelines, and concluded that "the totality of the medical evidence does not demonstrate a non-disease specific decline in clinical status." Dec. at 9-10. The ALJ discussed a number of points in the Part I medical guidelines, some of the evidence in the record, and weighed whether the beneficiary's general clinical decline indicated a terminal prognosis of six months or less. *Id.* The ALJ concluded that the record did not indicate a terminal prognosis of six months or less. *Id.* Therefore, the ALJ denied coverage for the two weeks of services at issue, and found the appellant financially liable. *Id.* at 10-11.

Legal Authority

Section 1861(dd) of the Social Security Act (Act) provides for Medicare coverage of hospice care for terminally ill individuals. An individual is considered to be "terminally ill" if the individual has a medical prognosis that the individual's life expectancy is six months or less. Section 1861(dd)(3)(A); see also 42 C.F.R. § 418.3.

Local Coverage Determination L25678 provided, during the dates of service at issue here:

Indications and Limitations of Coverage and /or Medical Necessity Abstract

Medicare coverage of hospice depends on a physician's certification that an individual's prognosis is a life expectancy of six months or less if the terminal illness runs its normal course. This LCD describes guidelines to be used by National Government Services (NGS) in reviewing hospice claims and by hospice providers to determine eligibility of beneficiaries for hospice benefits. Although guidelines applicable to certain disease categories are included, this LCD is applicable to all hospice patients. It is intended to be used to identify any Medicare beneficiary whose current clinical status and anticipated progression of disease is more likely than not to result in a life expectancy of six months or less.

Clinical variables with general applicability without regard to diagnosis, as well as clinical variables applicable to a limited number of specific diagnoses, are provided. Patients who meet the guidelines established herein are expected to have a life expectancy of six months

or less if the terminal illness runs its normal course. Some patients may not meet these guidelines, yet still have a life expectancy of six months or less. Coverage for these patients may be approved if documentation otherwise supporting a less than six-month life expectancy is provided.

Section 322 of BIPA amended section 1814(a) of the Social Security Act by clarifying that the certification of an individual who elects hospice "shall be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." The amendment clarified that the certification is based on a clinical judgment regarding the usual course of a terminal illness, and recognizes the fact that making medical prognostications of life expectancy is not always exact.

However, the amendment regarding the physician's clinical judgment does not negate the fact that there must be a basis for a certification. A hospice needs to be certain that the physician's clinical judgment can be supported by clinical information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course.

If a patient improves and/or stabilizes sufficiently over time while in hospice such that he/she no longer has a prognosis of six months or less from the most recent recertification evaluation or definitive interim evaluation, that patient should be considered for discharge from the Medicare hospice benefit. Such patients can be re-enrolled for a new benefit period when a decline in their clinical status is such that their life expectancy is again six months or less. *On the other hand, patients in the terminal stage of their illness who originally qualify for the Medicare hospice benefit but stabilize or improve while receiving hospice care, yet have a reasonable expectation of continued decline for a life expectancy of less than six months, remain eligible for hospice care.*

Indications

A patient will be considered to have a life expectancy of six months or less if he/she meets the non-disease specific **"Decline in clinical status"** guidelines described in Part I. Alternatively, the baseline non-disease specific

guidelines described in Part II plus the applicable disease specific guidelines listed in Part III will establish the necessary expectancy.

Part I. Decline in clinical status guidelines

Patients will be considered to have a life expectancy of six months or less if there is documented evidence of decline in clinical status based on the guidelines listed below. Since determination of decline presumes assessment of the patient's status over time, it is essential that both baseline and follow-up determinations be reported where appropriate. Baseline data may be established on admission to hospice or by using existing information from records. Other clinical variables not on this list may support a six-month or less life expectancy. These should be documented in the clinical record.

These changes in clinical variables apply to patients whose decline is not considered to be reversible. They are examples of findings that generally connote a poor prognosis. However, some are clearly more predictive of a poor prognosis than others; significant ongoing weight loss is a strong predictor, while decreased functional status is less so.

A. Progression of disease as documented by worsening clinical status, symptoms, signs and laboratory results.

Clinical Status:

- a. Recurrent or intractable serious infections such as pneumonia, sepsis or pyelonephritis;
- b. Progressive inanition as documented by:
 1. Weight loss of at least 10% body weight in the prior six months, not due to reversible causes such as depression or use of diuretics;
 2. Decreasing anthropomorphic measurements (mid-arm circumference, abdominal girth), not due to reversible causes such as depression or use of diuretics;
 3. Observation of ill-fitting clothes, decrease in skin turgor, increasing skin folds or other observation of weight loss in a patient without documented weight;
 4. Decreasing serum albumin or cholesterol.
 5. Dysphagia leading to recurrent aspiration and/or

inadequate oral intake documented by decreasing food portion consumption.

Symptoms:

- a. Dyspnea with increasing respiratory rate;
- b. Cough, intractable;
- c. Nausea/vomiting poorly responsive to treatment;
- d. Diarrhea, intractable;
- e. Pain requiring increasing doses of major analgesics more than briefly.

Signs:

- a. Decline in systolic blood pressure to below 90 or progressive postural hypotension;
- b. Ascites;
- c. Venous, arterial or lymphatic obstruction due to local progression or metastatic disease;
- d. Edema;
- e. Pleural/pericardial effusion;
- f. Weakness;
- g. Change in level of consciousness.

Laboratory (When available. Lab testing is not required to establish hospice eligibility.):

- a. Increasing pCO₂ or decreasing pO₂ or decreasing SaO₂;
- b. Increasing calcium, creatinine or liver function studies;
- c. Increasing tumor markers (e.g. CEA, PSA);
- d. Progressively decreasing or increasing serum sodium or increasing serum potassium.

- B. Decline in Karnofsky Performance Status (KPS) or Palliative Performance Score (PPS) due to progression of disease.**
- C. Progressive decline in Functional Assessment Staging (FAST) for dementia (from 7A on the FAST).**
- D. Progression to dependence on assistance with additional activities of daily living (see Part II, Section 2).**
- E. Progressive stage 3-4 pressure ulcers in spite of optimal care.**

F. History of increasing ER visits, hospitalizations, or physician visits related to the hospice primary diagnosis prior to election of the hospice benefit.

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General Information - Documentation Requirements

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Documentation submitted may include information from periods of time outside the billing period currently under review. Include supporting events such as a change in the level of activities of daily living, recent hospitalizations, and the known date of death (if you are billing for a period of time prior to the billing period in which death occurred).

LCD L25678 at 2-4, 13 (emphasis added).

Discussion

The beneficiary demonstrated a serious decline in clinical status, before, during, and after the dates of service at issue, in five of the eight applicable categories in Part I of the LCD.¹

In the first LCD category, that of "clinical status," the beneficiary had recurrent or intractable serious infections. See LCD L25678. Although the ALJ's decision acknowledges that the beneficiary had urinary tract infections, the decision also says that "these appear to have been successfully treated with antibiotics with no further recurrence." Dec. at 9. In fact, the record reflects four recurrences of urinary tract infections in nine months, a new onset of abdominal pain, vaginal pain two months later, a respiratory infection two months after that, and then further recurrences of urinary tract infections. Exh. 1 at 21-28, 31, 82.

Also in the first category, that of "clinical status," the beneficiary had decreasing anthropomorphic measurements, as follows:

¹ The other three categories are laboratory findings (which are not required), progressive stage 3-4 pressure ulcers in spite of optimal care (which the beneficiary did not have), and progressive decline in Functional Assessment Staging (FAST) for dementia (from 7A on the FAST). The QIC found that the beneficiary did have a FAST score of greater than 7. Exh. 3 at 4.

Left upper arm circumference:

May 28, 2009	22 cm
Nov. 2, 2009	19 cm
Dec. 21, 2009	19.5 cm
Feb. 2, 2010	18.5 cm
Feb. 18, 2010	18 cm

Thigh circumference:

May 28, 2008	33 cm
May 26, 2009	37.5 cm
Aug. 31, 2009	36 cm
Nov. 2, 2009	37.5 cm
Dec. 21, 2009	35.5 cm
Feb. 2, 2010	26 cm
Feb. 18, 2010	34.5 cm

Exh. 3 at 39, 45, 86; Exh. 1 at 74, 77, 90.

Again, the ALJ's decision acknowledges these signs of clinical decline, yet states, "Additionally, there is no documented observation of ill-fitting clothes or dysphagia limiting oral intake." Dec. at 9-10. Given the marked decline in the circumference of the beneficiary's thigh and upper arm, and the fact that her weight declined from 140 pounds to 108 pounds (a 23% decline) during her first sixteen months in hospice, it is not necessary to determine whether she had ill-fitting clothes. In fact, the LCD states that "observation of ill-fitting clothes" is germane in a patient *without documented weight*. See LCD L25678, Part I.A.b.3. However, this patient had documented weight. In addition, the record is replete with references to the fact that the beneficiary is cachectic (wasting) (see, e.g., Exh. 1 at 74, 77, 91), and is only eating a small part of her meals (see, e.g., Exh. 3 at 41). See LCD L25678, Part I. A.b.5. (listing inadequate oral intake documented by decreasing food portion consumption as another mark of declining clinical status).

From the wording of the ALJ's decision, it appears that the ALJ applied the Part I guidelines so as to require that the beneficiary's condition manifest most if not all of the twenty-seven listed indicia for a decline in clinical status. See Dec. at 9-10. However, the LCD does not require that most or all twenty-seven of the Part I indicia be present. See LCD L25678 at 2-4, 13. Rather, the LCD requires that sufficient indicia or

"variables" be shown to demonstrate a terminal illness with a life expectancy of six months or less. *Id.* In fact, the LCD states that other clinical variables not on the Part I list may also support a six-month or less life expectancy. *Id.*

In the second LCD category, that of "symptoms," the beneficiary had both dyspnea (shortness of breath) with an increasing respiratory rate, and pain requiring doses of major analgesics more than briefly. See LCD L25678, Part I.A. (Symptoms) a. & e. With respect to her shortness of breath, the ALJ's decision notes the dyspnea, yet says that the beneficiary "continued to receive oxygen via nasal cannula at basically the same rate of 3L/min." Dec. at 10. However, the medical records reflect a continuing increase in her shortness of breath (Exh. 3 at 75, 76, Exh. 1 at 14, 16, 18, 64, 73), and an increase in the amount of oxygen she required. Exh. 1 at 76.

With respect to the beneficiary's pain medications, there was a significant change over time. By September 2009, she was taking both methadone and Roxanol. Exh. 1 at 34-35. This continued through November, December, and January, at least, according to the medical records. See *id.* at 64, 84, 86, 90. According to the National Institute of Health website:

Morphine [Roxanol] is used to relieve moderate to severe pain. Morphine is in a class of medications called opiate (narcotic) analgesics. It works by changing the way the body senses pain.

See <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000334/>.

Morphine is a major analgesic, which the beneficiary was taking on an ongoing basis starting in September 2009.

In the third LCD category, that of "signs," the ALJ acknowledges that the beneficiary had ongoing lower extremity weakness and edema, consistently documented as 1-2+. Dec. at 10, *citing* Exh. 3 at 45, 49, and 87. The ALJ notes that there were no significant changes in the beneficiary's edema. *Id.* However, the LCD does not require that there be changes or a worsening in the edema, in order for edema to be a relevant variable. Moreover, when the beneficiary was admitted to the hospital again on December 8, 2009, she had acute pulmonary edema, as well as acute respiratory failure and atrial fibrillation. Exh. 3 at 94-99.

With respect to the third LCD category, there is also evidence that the beneficiary had a change in her level of consciousness during her hospice care. See LCD L25678, Part I.A. (Signs) g. The medical documents report ongoing, and increasing, signs of confusion on her part. See, e.g., Exh. 3 at 74, 76, 78.

In the next category, labeled "I.B.," the beneficiary had a decline in her Palliative Performance Score (PPS), due to the progression of her diseases. Her PPS declined from 70% in November 2008 to 50% in September 2009. Exh. 1 at 13, 8. A 50% PPS score is representative of a condition in which the beneficiary mainly sits and lies down, is unable to do any work, has extensive disease, requires considerable assistance for self-care, has normal or reduced intake, and is either fully conscious or confused. LCD L25678 at 15-16. By December 2009, the beneficiary had declined sufficiently that her PPS score would have been 40%, because she was mainly in bed, unable to do most activity, had extensive disease, was hospitalized for a number of days, required assistance for all self-care, had reduced food intake, and was often confused. See *id.* at 16; see also Exh. 3 at 64-70, 72-75. Her Karnofsky Performance Score (KPS) remained at 40% from November 20, 2008, through September 10, 2009. Exh. 1 at 11, Exh. 3 at 39. A Karnofsky Performance Score of 40% characterizes an individual who is disabled and requires special care and assistance. LCD L25678 at 14-15.

In category "I.D.," the beneficiary experienced a progression to dependence on additional assistance with activities of daily living. The beneficiary entered hospice care in May 2008 dependent for help with all activities of daily living. Exh. 1 at 3. However, her condition still worsened in this respect. On November 2, 2009, she was able to ambulate a short distance with a walker. *Id.* at 15. By December 21, 2009, she was no longer ambulatory. She required transfers from bed to chair, and she was unable to reposition herself in bed. *Id.* at 75, 89; CD Recording of ALJ Hearing (October 12, 2010), Testimony of Kathy Lopez, RN, at 1:14 to 1:15 p.m., 1:20 p.m. The beneficiary's ability to participate in her own care also declined. On September 10, 2009, she was able to shower three times a week, with an aide's assistance. By January 2, 2010, she was only able to shower once a week, and needed a bath in bed the other two times. Exh. 1 at 89; CD Recording of ALJ Hearing, Testimony of Kathy Lopez, RN, at 1:22 p.m.

Overall, the beneficiary became increasingly ill and debilitated, from when she entered hospice to the following

summer (2009), from that summer to fall (2009), from that fall to winter, and that winter to spring (2010), when she died on May 11, 2010. Exh. 4 at 8-9. The records do not reflect any period of stability or improvement, particularly given the severity of her symptoms and clinical signs when she entered hospice. The fact that she died within six months of the dates of service at issue here has significant probative value. The LCD specifically provides that documentation may include information from periods of time outside the billing period under review, and cites "supporting events such as a change in the level of activities of daily living, recent hospitalizations, and the known date of death" as important in weighing Medicare coverage for hospice services. LCD L25678 at 13. The Council concludes that the record establishes that during November 2009 the beneficiary had a terminal illness with a life expectancy of six months or less.

DECISION

Therefore, the Council reverses the ALJ's decision, and determines that the hospice services provided by the appellant to the beneficiary from November 1, 2009, through November 15, 2009, are covered by Medicare.

MEDICARE APPEALS COUNCIL

/s/ Stanley I. Osborne, Jr.
Administrative Appeals Judge

/s/ Susan S. Yim
Administrative Appeals Judge

Date: June 3, 2011