The NHO
Medical Guidelines for Non-Cancer Disease
and Local Medical Review Policy:
Hospice Access for Patients with Diseases
Other Than Cancer

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SUMMARY. For much of its history, hospice focused on problems related to malignant disease. Recently, however, non-cancer diagnoses such as congestive heart failure, emphysema and Alzheimer’s disease have comprised an increasing proportion of hospice referrals. This paper details criteria published by NHO and adopted by the US Health Care Financing Administration for hospice eligibility for common non-cancer diagnoses. A provisional list of domains for documenting “evidence of rapid decline,” by which patients with advanced disease who do not meet criteria can still be certified for the Medicare Hospice Benefit, is also outlined. [Article copies available for a fee from The Haworth Document Delivery Service: 1-800-342-9678. E-mail address: getinfo@haworthpressinc.com <Website: http://www.haworthpressinc.com>]

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INTRODUCTION

The first US hospice program opened in 1974, funded by a three-year grant from the National Cancer Institute. Ten years later, when

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Congress passed legislation creating the Medicare Benefit, hospice care was focused mainly on relieving the pain and suffering associated with malignant disease. Today, hospice’s expertise in management of the medical, psychosocial and spiritual aspects of terminal cancer is widely acknowledged.

But over the quarter century since its inception, hospice’s role has broadened. Today non-cancer diagnoses like congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD) account for an ever-larger proportion of hospice enrollments. This growth has challenged hospice and the US Health Care Financing Administration (HCFA) to create workable systems for hospice enrollment, Medicare Benefit certification and reimbursement.

**REIMBURSEMENT EFFECTS ON ELIGIBILITY**

Medicare Hospice Benefit legislation legitimized end-of-life care, making hospice equivalent to other reimbursable medical services. For the first time, care of the dying was institutionalized and publicly supported. However, the new law also placed restrictions on patient eligibility for hospice unlike any other segment of the US health care system. Other Medicare-covered services, even those financed under specialized benefits, i.e., dialysis for End-Stage Renal Disease (ESRD), were provided to patients throughout the course of illness. Eligibility for hospice patients, on the other hand, was restricted to those with “a life expectancy of six months or less, assuming the disease runs its normal course.”

As long as hospice enrolled predominantly cancer patients, this “six-month rule” did not pose much of a problem, since the “normal course” of cancer is characterized by inexorable and obvious clinical decline for several months prior to death. However, from the mid-1980s onward, patients with non-cancer diagnoses comprised an increasing proportion of hospice referrals. This was due to a number of factors including the aging of the US population with an attendant increase in prevalence of chronic disease, growing hospice expertise in management of non-pain symptoms such as dyspnea and agitation, significant capital formation in a number of successful hospice programs linked to effective physician education and targeted marketing for new kinds of referrals, declines in traditional fee-for-service reimbursement to physicians and hospitals making aggressive treatment of
end-stage disease less profitable, and a slowly-growing awareness among physicians and in the culture at large that a well-managed death was an appropriate and positive therapeutic goal.

Continued growth of hospice into the non-cancer arena met with resistance from HCFA in the mid-1990s. Hospice had always viewed late referrals as a major problem, because enrollment extremely late in the disease process resulted in short patient stays with little time for development of relationships critical to hospice’s effectiveness. A landmark study in 1995 documented that up to fifteen percent of new hospice enrollees died within a week of admission.¹

However, the study also showed that about fifteen percent of patients survived longer than six months. These long-stay patients were defined by HCFA as non-terminal and therefore as ineligible for the Medicare Hospice Benefit. This judgment was reinforced as the US Office of the Inspector General’s “Operation Restore Trust” attempted to force certain large hospice programs to refund millions of Medicare Benefit dollars paid for patients surviving beyond 210 days, alleging this revenue was obtained through “fraud and abuse” rather than prognostic uncertainty. Although a few of these patients were victims of breast or prostate cancer, the majority had primary diagnoses of CHF, COPD and Alzheimer’s disease.

THE CHALLENGE OF NON-CANCER DISEASE

Traditionally, US physicians have not felt comfortable with labeling patients with far-advanced CHF, COPD, Alzheimer’s and other non-cancer diseases as “terminal,” unlike those with end-stage cancer. Exacerbations of non-cancer disease, regardless of severity, have been considered “treatable” or even “curable” until death finally defeats the efforts of the clinician. Contributing to this attitude is the fact that endotracheal intubation and mechanical ventilation can keep patients with end-stage CHF and COPD technically alive until physiologic reserve is completely exhausted.

Physicians also have been reluctant to refer patients to hospice because of the prognostic uncertainty inherent in non-cancer disease. Even when aggressive measures give way to supportive treatment, patients can live for long periods at very low levels of function. With threats of monetary penalties for physicians referring “inappropriate”
patients to hospice, later referrals and diminished lengths of stay have become commonplace.

Prognostic uncertainty in non-cancer patients is a serious problem for hospice. In contrast to patients with advanced cancer, who tend to follow a relatively relentless and therefore predictable downhill course over the last few months of life, those with non-cancer diagnoses tend to remain clinically stable for long periods, then suffer unpredictable exacerbations. These downturns may or may not respond to treatment. Six-month prognosis is therefore extremely difficult to determine in most cases. In fact, prognosis in non-cancer patients is very difficult to determine even in seriously-ill hospitalized patients, whose physicians have easy access to far more data than is usually available to hospice at the time of admission.

In addition, hospice care can stabilize patients with non-cancer disease, thereby prolonging life. This occurs more commonly in non-cancer illness than in cancer, since the medications used for palliation of non-cancer symptoms are frequently the same ones used for active disease-modifying treatment. Whereas in end-stage cancer active chemotherapy and radiation eventually give way to pain relief with opioids, in CHF palliation of dyspnea is best achieved through judicious administration of opioids along with diuretics and angiotensin-converting enzyme (ACE) inhibitors, which have been shown to lengthen life significantly in many studies.

**THE NHO GUIDELINES FOR NON-CANCER DISEASE**

In 1994, under the guidance of the National Hospice Organization (NHO), several hospice medical directors began work on a set of guidelines for hospices to use in deciding whether to certify patients for the Medicare Benefit. The First Edition of NHO’s *Medical Guidelines for Determining Prognosis in Selected Non-Cancer Diseases* was published in 1995, including CHF, COPD and Alzheimer’s disease. The Second Edition of the *Medical Guidelines* was published the next year, with additional criteria for AIDS, liver and renal disease, stroke and coma and amyotrophic lateral sclerosis (ALS).

Contrary to their title, the *Medical Guidelines* do not literally “predict prognosis.” Because they are based on a synthesis of available literature rather than quantitative studies in hospice populations with six-month survival as a measured outcome, they are neither sensitive
nor specific in individual cases. Even with research to optimize their predictive validity, it is questionable whether the Medical Guidelines or any other set of criteria simple enough to be applied in clinical situations will ever predict six-month life expectancy. In fact, experienced investigators have stated that prognosis of mortality will probably never be an exact science.

Nevertheless, shortly after their publication the Medical Guidelines were adapted by HCFA into Local Medical Review Policy (LMRP) as standards for hospice reimbursement, despite protests by NHO, the American Academy of Hospice and Palliative Medicine and others. The five Medicare Fiscal Intermediaries (FI’s) have now created their own LMRP based on the HCFA policies. Considerable effort by hospice and FI Medical Directors over the past two years has been devoted to creating a workable system that does not deny access to hospice-appropriate patients, yet provides the FI’s with valid criteria to prevent true fraud and abuse.

The following is a brief description of major guidelines for the main non-cancer diagnoses seen in hospice. For convenience, they are presented as they have evolved in LMRP discussions, in the form adopted recently by Blue Cross of California, the West Coast FI. These criteria are meant to be used for certifying patients for the Medicare Hospice Benefit. They are not portrayed as definitions of hospice appropriateness, since a hospice may choose to admit a patient and provide services outside the Benefit, supported for instance by community contributions.

It is critical to understand that patients who appear to be within six months of death but fall outside these criteria may still be appropriate for hospice enrollment and Medicare Benefit certification. LMRP provide for this by allowing hospices to document “evidence of rapid decline” outside LMRP criteria. This documentation is also useful when considering whether to certify patients for subsequent Benefit periods after the first. Domains for documentation of clinical decline will be discussed further below.

HEART DISEASE

Patients with advanced CHF are considered appropriate for hospice if they are (1) symptomatic at rest (New York Heart Association Class IV) and (2) already optimally treated with diuretics and vasodilators.
The latter medications are usually in the ACE-inhibitor category. If referred patients are not on these medications, the attending physician should be asked why not, because even very advanced CHF patients may benefit significantly both symptomatically and in terms of life expectancy. Fears of worsening renal insufficiency or hypotension with the use of ACE inhibitors may be unfounded even in Class IV heart failure. If these medications have not been considered by the physician, the patient may not be hospice-appropriate unless he or she refuses them. Hospice staff who are experienced in management of volume status, blood pressure and electrolytes may choose, in collaboration with physicians, to titrate dosages of diuretics and ACE inhibitors to control CHF symptoms, although discharge may be necessary if patients stabilize or improve.

CHF patients are usually appropriate for hospice when they have failed trials of intravenous inotropics such as dobutamine or milrinone. Elderly patients with intractable angina who are not candidates for coronary revascularization may also be hospice candidates when they no longer respond well to nitrates, beta- and calcium-channel blockers and other appropriate medications, although these may still be useful along with morphine in relieving cardiac pain.

Other factors supporting hospice eligibility are listed in the Medical Guidelines or LMRP.

Even though prognosis is difficult in CHF, with experience referring physicians and hospice staff can learn to select those patients who are “terminal.” In a recent series of forty CHF patients enrolled in hospice at one of the branches of our agency, only five survived longer than six months. Median survival of the remaining cohort was about two months. Post-death surveys revealed high levels of patient, family and physician satisfaction.

PULMONARY DISEASE

Prognosis is challenging in end-stage lung disease because most patients die of sudden and unpredictable exacerbations rather than chronic decline. Many exacerbations occur in the fall and winter when upper respiratory infections are prevalent.

These patients usually have end-stage obstructive disease, i.e., emphysema or chronic bronchitis, with severe fixed obstruction to expiration. It is important to carefully evaluate patients with reversible ob-
Current Efforts 145

Structive disease, i.e., asthma, because those patients who respond to bronchodilators probably have a better prognosis. Some patients with restrictive disease, e.g., pulmonary fibrosis, may also be eligible.

Pulmonary patients are hospice-appropriate if they have (1) severe and (2) progressive lung disease. They should also have either (3) hypoxemia OR (4) hypercapnia.

Severe pulmonary disease, like heart disease, produces disabling symptoms at rest or with minimal exertion, and results in diminished functional capacity, i.e., bed-to-chair existence. If pulmonary function tests are available, a post-bronchodilator Forced Expiratory Volume in One Second (FEV1) of less than thirty percent of the predicted value is helpful, but not required. Note that performance this poor implies unresponsiveness to bronchodilators by definition.

Progressive disease is evidenced by increasing Emergency Department visits (two in prior six months) or hospitalizations (one in prior year) for pulmonary infections or respiratory failure. Patients are more likely to be within six months of death if they have undergone intubation and mechanical ventilation, or at least continuous positive airway pressure ventilation during an exacerbation, especially if they state they do not want to undergo these procedures again.

Hypoxemia is defined as having a pO2 of less than or equal to 55 mm Hg on arterial blood gases (ABG), or oxygen saturation (SaO2) of less than or equal to 88% on oximetry. These values should be obtained on room air, off supplemental oxygen. Hypercapnia is evidenced by a pCO2 of greater than or equal to 50 mm Hg on ABG. Note that oximetry, which can be performed at the bedside in the patient’s home, is all that is required. ABG values, however, may often be obtained from Emergency visits or recent hospitalizations.

Other helpful information includes evidence of cor pulmonale, i.e., right heart failure due to lung disease, not CHF or valvular disease; weight loss of greater than 10% in 6 months; and resting tachycardia of greater than one hundred beats per minute. This last item is a physical finding that is easily assessed at the bedside.

DEMENTIA

As dementia becomes more severe, mortality rises, but it is very hard to predict when patients are within six months of dying because the dementing process is not the primary cause of death. Dementia
patients die from secondary medical complications, not from the dementia itself. Conversely, some patients are so demented they score zero on mental status tests, yet live for years with meticulous care.

Hospice criteria for dementia include: (1) dementia of sufficient severity and (2) the first occurrence of medical complications.

Dementia severity qualifies for hospice when the patient has passed Stage 7-C of the Functional Assessment Staging (FAST) scale. Briefly, these patients have lost the ability to ambulate independently and carry on meaningful conversation. They also have lost the ability to carry out most or all Activities of Daily Living (ADLs) and are at least occasionally incontinent of urine and/or stool.

Medical complications herald significant downturns in most demented patients. Those most often seen include aspiration pneumonia, upper urinary tract infection often including sepsis, worsening multiple stage 3-4 decubiti, fever recurrent after a course of antibiotics or greater than ten percent weight loss over six months.

Because of prognostic uncertainty in advanced dementia, these criteria are somewhat restrictive. Many demented patients, particularly those with other comorbid conditions, may be clearly terminal and still not qualify. These patients should be admitted to hospice with clear documentation of comorbidities and evidence of rapid decline. They may then be discharged if they stabilize.

**HIV DISEASE**

With the advent of protease inhibitors, AIDS mortality has declined. However, not all patients respond to these agents, and many cannot or will not comply with demanding drug regimens.

Patients with HIV disease are considered hospice-appropriate if they have both:

- **CD4+ (T-cell) count** of less than or equal to 25 and
- **Viral load** of greater than or equal to 100,000 copies/ml.

In addition, they should have a decreased functional status corresponding to less than or equal to 50 on the Karnofsky Performance Status (KPS) scale, as well as at least one of the following AIDS-related conditions:

- Central nervous system or poorly responsive systemic lymphoma.
• Wasting: loss of more than thirty-three percent of lean body mass.
• Mycobacterium avium complex (MAC) bacteremia.
• Progressive multifocal leukoencephalopathy (PML).
• Refractory visceral Kaposi’s sarcoma (KS).
• Renal failure in the absence of dialysis.
• Refractory cryptosporidium infection.
• Refractory toxoplasmosis.

Other factors supporting hospice eligibility are listed in the Medical Guidelines and LMRP.

**LIVER DISEASE**

Cirrhosis is the final common pathway for most of the conditions that cause liver cell death of sufficient degree to overwhelm the liver’s considerable capacity for regeneration. The criteria below thus refer mainly to end-stage cirrhosis, although other diagnoses such as sclerosing cholangitis may also be appropriate. Patients awaiting liver transplant are hospice-eligible but should be taken off the Medicare Benefit through revocation or discharge if a donor organ becomes available. As with other conditions, cirrhotic patients who appear terminal but whose laboratory data do not qualify them can still be enrolled if comorbidities and evidence of rapid decline can be documented.

Patients are hospice-appropriate when their *laboratory values* include both:

• *Prothrombin time* elevated more than five seconds over control, or International Normalized Ratio (INR) greater than 1.5, and
• Serum *albumin* less than 2.5.

In addition, the patient should have one or more of the following *medical conditions associated with advanced liver failure*:

• Ascites despite diuretics.
• Episode of spontaneous bacterial peritonitis.
• Hepatorenal syndrome.
• Hepatic encephalopathy despite lactulose.
• Recurrent bleeding esophageal varices despite therapy.

Other factors supporting hospice eligibility are listed in the Medical Guidelines or LMRP.

**RENAL DISEASE**

Every patient discontinuing renal dialysis for end-stage renal disease (ESRD) should be considered for hospice. All anuric post-dialysis patients die within days, but those who produce even small amounts of urine may have residual renal function that can enable them to live for weeks or, in rare cases, months. Six-month survival, of course, is extremely rare.

*Laboratory criteria* for hospice eligibility include:

- Serum *creatinine* greater than or equal to 8.0 mg/dl.
- *Creatinine clearance* less than or equal to 10 ml/min (15 ml/min. for diabetics).

To avoid collecting a twenty-four hour urine collection, creatinine clearance may be calculated according to the following formula:

$$\text{Creatinine Clearance} = \frac{(140 - \text{age in years}) \times (\text{body weight in kilograms})}{72 \times (\text{serum creatinine in mg/dl})}$$

For women, multiply result by 0.85.

The same laboratory values apply for patients in *acute renal failure*. This condition may occur in the elderly as a result of sepsis, myocardial infarction or other insult, or in younger patients from massive trauma or other cause of circulatory collapse. These patients are often hospitalized, so if the patient is not dialyzed, inpatient hospice may be appropriate, or hospice services can be provided at home after discharge.

**STROKE AND COMA**

Patients who present in coma after cerebrovascular accident (CVA) rarely survive if the coma persists beyond three days, and thus are appropriate for hospice. Of course, post-CVA patients with complete
dysphagia who do not receive feeding tubes are eligible as well. Caution should be exercised in evaluating patients immediately post CVA for hospice if they have stabilized or begun to improve neurologically, since further improvement is likely unless the area of infarction recurs or extends.

In the chronic phase after CVA, i.e., after the patient has progressed through convalescence or rehabilitation to a stable condition, criteria for hospice include either (1) post-stroke dementia equivalent to Stage 7-C of the FAST scale as detailed above under DEMENTIA, (2) poor functional status corresponding to a KPS of 40 or less, or (3) weight loss of ten percent over six months or less, or serum albumin less than 2.5.

Patients in coma are eligible for hospice if they show any three of the following four findings:

- Abnormal brain stem response.
- No response to verbal stimuli.
- No withdrawal to painful stimuli.
- Serum creatinine greater than 1.5 mg/dl.

The same medical complications listed under DEMENTIA also support, but are not necessary for, hospice eligibility. Diagnostic imaging findings that also support hospice appropriateness are listed in the Medical Guidelines and LMRP.

**DETERMINING HOSPICE ELIGIBILITY FOR PATIENTS WHO DO NOT FIT LMRP CRITERIA**

Research is now underway to determine the predictive validity of the Medical Guidelines and LMRP, and to include psychosocial and spiritual as well as medical variables. However, results will not be available for several years. Until then, hospice must make do with LMRP selection criteria, bearing in mind that they are not based on empirical data. Until these policies become evidence-based, they will probably not be either sensitive or specific—not sensitive, because they will disqualify certain patients who will die within six months, and not specific, because they will qualify others who will survive longer than six months.

Efforts to increase both sensitivity and specificity, characteristics of
any set of selection criteria, are generally in opposition. That is, attempts to make criteria more specific can cause them to be less sensitive, and vice versa. In LMRP terms, “tightening up” eligibility criteria for hospice, i.e., requiring patients to be sicker in an attempt to increase specificity, might indeed result in fewer six-month survivors. However, fewer patients would be enrolled overall and more would die within six months without ever becoming eligible for hospice. The writers of the NHO Medical Guidelines and those who drafted LMRP therefore tried to strike a middle course between the extremes of sensitivity and specificity.

Until LMRP allow more accurate prediction of six-month life expectancy–assuming acceptable predictive validity is attainable–these problems must be confronted by providers of care. Since LMRP do not possess either specificity or sensitivity to allow hospice to predict six-month survival in advance, hospice must compensate on a concurrent basis. Unfortunate effects of LMRP non-specificity and insensitivity can both be avoided, although the means are not optimal scientifically, or from a patient care perspective.

Specificity is optimized when few patients are kept on the Benefit beyond six months, unless they are clearly declining. The only way to achieve this is to discharge patients who stabilize during the first or second Benefit periods. On further decline, these patients can be re-enrolled and certified for another Benefit period. Theoretically, with recent changes in the law abolishing the Third and Fourth Benefit periods and substituting an unlimited number of renewable sixty-day periods, discharges and readmissions can be readily accomplished. In practice, continuity of care suffers with this approach. Also, anecdotally many patients who are discharged because they appear stable under hospice care die shortly thereafter.

Sensitivity is of great concern to hospice, because it is synonymous with access to hospice services. Insensitive eligibility criteria deny hospice services to patients who will die within six months. In order to allow eligibility for patients who do not fit LMRP criteria but are apparently terminal, the policies provide for enrollment with documentation of “evidence of rapid decline.”

**EVIDENCE OF RAPID DECLINE**

Medicare Medical Review personnel are trained to look for evidence
of clinical decline in the hospice medical record to document eligibility. They seek clinical information, both from the referring physician’s records sent by hospice and from the initial and subsequent evaluations by hospice staff, to differentiate the hospice patient’s “terminal” course from that of chronic illness. Documentation is required of the tangible medical reasons for enrollment, rather than a description of care delivered, even though the latter information may be vital to remain in compliance with other regulations. This information is also useful to hospice staff to document whether patients should be certified for subsequent Benefit periods when the patient survives the first.

The clinical parameters shown in Table 1 have been useful in documenting clinical decline. Both objective and subjective elements are included, since individualized narrative information is needed to provide a detailed clinical picture to Medicare medical reviewers. The data may be gathered as a baseline on admission evaluation and, if the

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patient remains alive, again after two and five months to help with certification decisions for Benefit periods subsequent to the first. It may also be helpful on initial evaluation to ask about the status of each parameter one to three months previously to provide historical comparison.

Although many elements that may impact survival are gathered together here, not all of them apply to each case. “Anthropometric measurements,” for instance, are useful for documenting decline in patients who cannot get out of bed to be weighed. This information is useful for patients with “Debility and Decline,” i.e., no formal diagnosis, or those with Alzheimer’s disease.
Table 2 provides sample data for a patient with CHF. Clinical findings from both history and physical exam are emphasized, because they give a picture of disease severity and therefore some indication of survivability, although there is not a strict correlation between the two. Under “Other” may be listed further concise narrative that specifically describes how the patient is withdrawing or declining. Relevant psychosocial material that fleshes out the clinical picture may be documented here.

Because the goal of this documentation is to provide a unique picture of the patient’s clinical status to a reviewer, the data is narrative

**TABLE 2. Sample data for a patient with CHF.**

in form. However, after review and revision, a list such as this could be standardized and used to gather programmed data using 5-part Likert or other quantitative scales from hospice programs across the US. Such data could be used to learn more about the relationship of clinical, functional and nutritional status to life expectancy, thus further refining the methodology of prognosis.

**CONCLUSION**

Hospice’s growth into non-cancer disease is a significant step toward extending end-of-life care to all patients, regardless of diagnosis. Considerable work remains to be done. However, assuming hospice continues to upgrade medical knowledge and skills, and good-faith negotiations continue with Medicare Fiscal Intermediaries to standardize documentation, a workable national system of care for the dying, and its reimbursement, are within our grasp.

**NOTES**

8. Unpublished data.