CTIs and Regulatory Review

Innovation and Excellence in Advanced Illness at End of Life
41st Annual Hospice & Palliative Care Conference – September 2017 – Asheville, NC

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Pheidippes

- 490 BC, ran 26 miles to Athens to deliver the message “Nenikikameri!” (Rejoice-We conquer!) “We have won” regarding the victory over the Persians
- Today we remember this event based on where his run originated: Marathon
Prior to that....

• Lucullus executed by Tigranes for giving reports that were “far from pleasing” about the war around him
• Ad hominem logical fallacy
• Don’t kill the messenger!

Why All The Fuss?
Issue of terminal illness is a major focus:

• “Evercare Hospice and Palliative Care will pay $18 million to resolve False Claims Act allegations that it claimed Medicare reimbursement for hospice care for patients who were not eligible for such care because they were not terminally ill.” DOJ Press Release, July, 2016

• Hospice of Citrus County - $3,000,000 – patients not terminally ill, length of stay greater than 1,000 days. 2016

• Guardian Hospice of Georgia LLC - $3,000,000 – patients not terminally ill. 2015

Novus Health Services

• Feb. 28, 2017

• “Sixteen Individuals Charged in $60 Million Medicare Fraud Scheme”

• 5 Physicians

• “Novus medical directors would sign certificates of terminal illness indicating that they had determined that a beneficiary was eligible for hospice services regardless of whether this was true or not; prepare re-certifications of terminal illness for beneficiaries already on hospice, which falsely indicated that the beneficiaries continued to be hospice eligible;”

https://www.justice.gov/usao-ndtx/pr/sixteen-individuals-charged-60-million-medicare-fraud-scheme
Patient Eligibility

• Terminally ill
• Issue of terminal illness is a major focus:
  – OIG, CMS and others believe hospices are intentionally admitting patients before they are terminally ill.
    • Longer length of stay
    • More lucrative

https://oig.hhs.gov/oei/reports/oei-02-10-00492.asp
Intentional Deception
Bending the Rules
Inefficiencies
Mistake

Error
Waste
Abuse
Fraud

Incorrect Coding
Medically Unnecessary Service
Improper Billing Upcoding
Billing Services Not Provided
• “An individual is considered to be “terminally ill” if the individual has a medical prognosis that the individual’s life expectancy is 6 months or less.”
• “[t]he individual’s attending physician ... and (II) the medical director (or physician member of the interdisciplinary group ... of the hospice program providing (or arranging for) the care, each certify in writing, at the beginning of the period, that the individual is terminally ill... and based on the physician’s or medical director’s clinical judgment regarding the normal course of the individual’s illness, (ii) in a subsequent 90 or 60-day period, the medical director or physician ... recertifies ... that the individual is terminally ill based on such clinical judgment.”


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**Terminally Ill**

• The statute expressly states this is a clinical judgment of the professional. Benefit policy manual expressly recognizes this. Medicare Benefit Policy Manual, Chapter 9, Section 10.

• A patient may live longer than six months and still be terminally ill in the physician’s medical judgment.
Certificate of Terminal Illness

• Physician needs to document basis for decision.
• Patient’s clinical record needs to support this conclusion.
• Clear, detailed documentation is extremely important.

**Burden of proof is on the provider!**

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**LCDs**

• **Local Coverage Determinations.** Although relied upon by auditors and CMS, LCDs are below statutes and regulations in terms of authority. They are not formally promulgated.
• Although MACs, etc. consider them to be binding, they are not. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II)
• However, they can provide guidance as to how to clearly support the medical necessity of the claim.
The MACs have all issued LCDs regarding terminal illness of hospice patients.

They make clear the level of detail auditors (and others) expect when reviewing clinical documentation.

**Know your local LCDs!!**

Although the LCDs are not “binding” or determinative for coverage purposes, they should inform how you assess patients and document their conditions.

The more of the detail outline in the LCD you have, the stronger your case for terminal illness will be.
The document discusses the importance of documenting in light of LCDs (Local Coverage Determinations) to support physician certifications. It is noted that auditors or investigators may disagree with these certifications if documentation does not clearly track the factors indicated in published guidance. Clear documentation is crucial, especially since auditors or investigators are unfamiliar with the patients being treated.

Resources:
- [https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=373&name=&DocType=Active&ContrVer=1&CntrctrSelected=373*1&s=All&bc=AggAAAIAAAAAA%3d%3d&#ResultsAnchor](https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=373&name=&DocType=Active&ContrVer=1&CntrctrSelected=373*1&s=All&bc=AggAAAIAAAAAA%3d%3d&#ResultsAnchor)
Content of Written Certifications

1. The statement that the individual’s medical prognosis is that the beneficiary’s life expectancy is 6 months or less if the terminal illness runs its normal course
   - Guidance: A simple statement on the certification/recertification that states, the beneficiary has a medical prognosis of 6 months or less if the terminal illness runs its normal course.

Content of Written Certifications

2. Patient-specific clinical findings and other documentation supporting a life expectancy of 6 months or less
   - Guidance: The certification should give specific clinical findings, for example, signs, symptoms, laboratory testing, weights, anthropomorphic measurements, oral intake.
Content of Written Certifications

3. The signature(s) of the physician(s), the date signed, and the benefit period dates that the certification or recertification covers (for more on signature requirements, see the “Medicare Program Integrity Manual,” Chapter 3, Section 3.3.2.4).

Guidance:

- **Physician signature and date signed**: The physician must sign and make an appropriate date entry for his/her signature, for example, John Smith M.D. MM/DD/YY. If the physician signature is not legible, you may type or print the name below the signature. Another alternative to ensure a legible signature is to submit a signature log with the physician’s printed name and signature. Also, note that the location of the physician signature for the narrative and attestation is important.

- **Certification/ Recertification benefit period**: Make an entry on the certification that gives the specific “from” and “through” dates, for example, benefit period date MM/DD/YY to MM/DD/YY. Simply stating benefit period 3 is not acceptable documentation. The “from” and “through” dates must appear on the certification.
Content of Written Certifications

4. As of October 1, 2009, the physician’s brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less is part of the certification and recertification forms, or is an addendum to the certification and recertification forms.

Guidance

• If the narrative is part of the certification or recertification form, then the narrative must be located immediately above the physician’s signature.

• If the narrative exists as an addendum to the certification or recertification form, in addition to the physician’s signature on the certification or recertification form, the physician must also sign immediately following the narrative in the addendum.

• The narrative shall include a statement directly above the physician signature attesting that by signing, the physician confirms that he/she composed the narrative based on his/her review of the patient’s medical record or, if applicable, his or her examination of the patient. The physician may dictate the narrative.

• The narrative must reflect the patient’s individual clinical circumstances and cannot contain check boxes or standard language used for all patients. The physician must synthesize the patient’s comprehensive medical information in order to compose this brief clinical justification narrative.
Content of Written Certifications

5. Face-to-Face Encounter and Attestation. For recertification’s on or after 1/1/2011, a hospice physician or hospice nurse practitioner must have a face-to-face encounter with each hospice beneficiary prior to the beginning the beneficiary’s third benefit period, and prior to each subsequent benefit period. The face-to-face encounter (when applicable) is a part of the recertification. For additional information and guidance on the face-to-face encounter, refer to the “Medicare Benefit Policy Manual,” Chapter 9, Section 20.1.

Common errors that may preclude payment:

• Predating physician’s certification signature
• No signature from the hospice medical director, physician member of IDG, or attending physician on initial cert
• Physician narrative is omitted
• Attestation statement is omitted
• No verbal cert (if applicable)
• Illegible signatures
• Physician did not date signature
• No clearly defined dates of certification period
Practical Tips

• The narrative must be composed by the physician performing the certification
• The narrative cannot contain standardized or preprinted language
• The narrative cannot have check boxes for completion

Practical Tips

• The physician narrative is not a summary of the medical record facts.
• It maps out the physician’s rationale as to how the facts justify the prognosis
• The purpose of the narrative is for the physician to support the conclusion of his/her prognosis of six months or less
• Purpose is not to just simply sign a form
Practical Tips

• The narrative must stand alone and explain the physician’s rationale as to why the patient is terminally ill, regardless of other entries in the chart
  – Pertinent information that supports a terminal prognosis that is in other parts of the medical record must be re-written within the narrative itself.

Practical Tips

• Narrative should be written in sentence format
  – A list of findings is not an explanation of the physicians rationale in determining terminal prognosis
  – Bullet points or lists are not considered acceptable
Practical Tips

• Speak to LCDs
• Focus on changes over the past 2-6 months
• “end stage”
• “as evidenced by”

Practical Tips

• Patient’s age
• Primary terminal diagnosis (should match ICD coding, or explain why not)
• Related conditions also affecting prognosis
• Comorbidities also affecting prognosis
• Functional impairments (PPS, dependence for ADLs) and that these are because of/related to the terminal illness
Practical Tips

• Nutritional impairments (albumin, weight loss, MAC, % meal with associated times)
• Cognitive impairments (FAST in dementia)
• Disease specific sx’s (Dyspnea at rest, angina at rest, etc.)

Practical Tips

• Staging of malignancy
  – Failed previous chemo/xrt
  – Progressing despite chemo, etc.
  – No other treatments available
  – Electing for palliative treatment only
Practical Tips

• Weight loss
  – When documenting weight loss, use absolute numbers and associated dates or time frames
  – Weight = 120 lbs 3/1/17, wt = 100 lbs 5/12/17:
  – Specifically state that no reversible causes of weight loss identified, and that it is likely related to progression of disease

Practical Tips

• If being admitted to GIP or CC, explicitly state reasons why in narrative also
Practical Tips

• Add a specific statement composed by the physician regarding the patient's prognosis within the narrative
  – “Pt is unlikely to survive six months”
  – “Pt’s prognosis is less than six months”
  – “This pt’s life expectance is less than six months if the disease runs its usual course”

• Very useful on external review if stated above and beyond the preprinted statement of prognosis on the certification itself

Practical Tips

• Add a specific statement within the body of the narrative that you personally and independently reviewed the medical record

• References to the source of supportive information within the narrative can be helpful

• Be prepared to potentially have to prove it (EMR access records)

• Discussion of the case in IDT by itself does not fulfill this requirement
Practical Tips

• Example: 92 yo F, with end stage CAD, as evidenced by refractory angina at rest, O2 dependence, ..... **On my review of the medical record**, the terminal nature of her illness is confirmed by failure of previous maximal medical therapy and NYHA IV classification..... The pt’s ongoing decline is **confirmed by the social worker’s note dated 2/5/17** showing increased dependence for ADLs,......

Practical Tips

• The narrative should contain language that references the findings of the F2F encounter if applicable.

• Example: I have reviewed the findings of the nurse practitioner’s F2F encounter on 5/1/17 that paint the picture of a severely cachectic, minimally responsive individual with visible cutaneous metastatic lesions eroding through the axilla...
Practical Tips

• Death is not proof of hospice eligibility
  – Should be included in the narrative
  – “Pt has died” is not sufficient
  – “The patient’s death soon after admission confirms that his prognosis was six months or less at the time of hospice admission”

Practical Tips

• Some items are not helpful
  – Avoid “hospice appropriate” or “hospice eligible”
  – Avoid irrelevant information or diagnosis (glaucoma, hypothyroid, remote ortho procedures, etc.)
  – Avoid anticipated treatment plans unless they directly affect the prognosis
    • The narrative is about prognosis, not management
Practical Tips

• Avoid statements that question the patient’s prognosis and that a discharge from hospice is a potential future plan

AseraCare

• Recent False Claims Act case
• Government alleged that the hospice was providing care to patients it knew were not terminally ill.
• Two issues in the case:
  – Use of sampling/extrapolation by government.
  – Experts difference of opinion as proof of false claims.
AseraCare

- The Government did not put on evidence regarding all 2,000+ claims, but only a sample of those claims.
- This is problematic, because it allowed the government to attribute intent to cases in which it offered no proof.
- Intent is a claim by claim matter, not something to be extrapolated.

AseraCare

- Bigger Issue: Proof of Terminal Illness.
  - The government alleged the patients were not terminally ill. Its only proof was testimony from an expert witness that the patients were not terminally ill. Aseracare offered its own expert testimony that the patient’s were terminally ill.
  - Despite this clear disagreement, the jury found FOR the government.
AseraCare

• Although the Judge had originally allowed the case to go to the jury, she reversed the jury and her previous decision. She ruled that a difference of opinion amongst experts was not sufficient evidence to prove fraud.

• This is a huge win for the industry, but the government is appealing.

• If the government prevails, this could be extremely problematic for providers.

Why is this important to me?

• The arguments made by the government in the AseraCare case demonstrate how aggressively the government is pursuing claims based on patient eligibility.

• Documenting clinical findings that support the certification of terminal illness is extremely important in an environment where a relator may go forward on a mere difference of opinion.