Determining “Relatedness”

**Relatedness**
- CMS: “It is our general view that ... hospices are required to provide *virtually all the care that is needed* by terminally ill patients.”

**OIG Report on Part D % Hospice (2012)**
- 4 classes of drugs reviewed
  - Analgesics, anti-emetics, anxiolytics, laxatives
- Part D paid for prescription drugs after the patient elected hospice:
  - 198,543 hospice beneficiaries
  - 677,022 prescription drugs through Part D
  - Part D paid $33,638,137
  - Beneficiaries paid $3,835,557 in copays

**Medicare A and B “Leakage”**
- Outside Hospice Benefit

<table>
<thead>
<tr>
<th>Part A or B Service</th>
<th>Percentage of $s Spent</th>
</tr>
</thead>
<tbody>
<tr>
<td>DME</td>
<td>7.1%</td>
</tr>
<tr>
<td>Inpatient care</td>
<td>28.6%</td>
</tr>
<tr>
<td>Outpatient Part B services</td>
<td>96.9%</td>
</tr>
<tr>
<td>Other Part B services (physician, practitioner, labs and diagnostic tests, ambulance transports, and physician office visits)</td>
<td>37.4%</td>
</tr>
<tr>
<td>Skilled Nursing Facility Care</td>
<td>5.7%</td>
</tr>
<tr>
<td>Home Health Care</td>
<td>4.5%</td>
</tr>
</tbody>
</table>
Part D Expenditures During a Hospice Stay
- CY2012
  - Total Part D spending: $417.9 million
  - Paid by Medicare: $334.9 million
- All drug types
- Paid by:
  - Medicare
  - States
  - Beneficiaries
  - Other payers

Drug Cost per Hospice Pt Day

CMS Comments
- Drug Costs:
  - 2004: $20 per patient-day
  - 2012: $11 per patient-day
- CMS concern about drug costs:
  - ...decline in drug costs is of a magnitude that could suggest that some hospices are not providing, and thus are not incurring the costs for, all needed patient medications.
Determining “Relatedness”

**ER/Observation Stay Data**

<table>
<thead>
<tr>
<th>Beneficiaries</th>
<th>ER Visits/Observation Stays</th>
<th>Cost to Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.8% of hospice beneficiaries</td>
<td>87,720</td>
<td>$268.4 million</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of ER Visits/Observation Stays</th>
<th>% of Beneficiaries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>77.6%</td>
</tr>
<tr>
<td>2-4</td>
<td>20.9%</td>
</tr>
<tr>
<td>More than 5</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

**Frequent Diagnoses**

- Septicemia or severe sepsis
- Kidney and urinary tract infections
- Hip and femur procedures
- Simple pneumonia and pleurisy
- Gastrointestinal hemorrhage

This raises concerns about whether the ER visits/observation stays were actually related to the terminal illness and related conditions and should have been covered by the hospice.

**CMS Comment**

- Some of these frequently occurring DRGs are conditions which are common at end-of-life, and could be attended to in the home or with a GIP level of care.
- We are concerned that patterns of discharge, hospital admission, and hospice readmission do not provide a comprehensive, coordinated care experience for terminally ill patients.
Determining “Relatedness”

CY2012 Non-Hospice Medicare $  
For beneficiaries after hospice election
- Parts A & B: $710.1 million  
- Part D: $334.9 million  
- TOTAL: $1.3 Billion dollars

51.6% of $1.3 billion: 373 hospices
- Average total / beneficiary: $1,289 in non-hospice costs  
- We will continue to monitor non-hospice Medicare spending for beneficiaries in hospice elections.

“Terminal condition”: Then
- Terminally ill means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.
- 418.25 Admission to hospice care.
- (b) In reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider at least the following information:
  - (1) Diagnosis of the terminal condition of the patient.
  - (2) Other health conditions, whether related or unrelated to the terminal condition.

“Terminal condition”: Now
- The principal diagnosis should reflect the condition to be chiefly responsible for the services provided.
- The principal diagnosis reported on the hospice claim form should be determined by the hospice as the diagnosis most contributory to the terminal prognosis.
- It is often not a single diagnosis that represents the terminal prognosis of the patient, but the combined effect of several conditions that makes the patient’s condition terminal.

78 Federal Register 152 (7 August 2013), pp.48236, 48242.
**Determining “Relatedness”**

### Medical directors: diagnoses

- The principal diagnosis ... determined by the _certifying hospice physician(s)_ as the diagnosis most contributory to the terminal decline.
- ... [using] their _best clinical judgment_ ..., based on the hospice comprehensive assessment and review of any and all other clinical documentation.
- ...related versus unrelated ... _remains within the clinical expertise and judgment of the hospice medical director_ in collaboration with the IDG.
- ... _case-by-case_ basis


### Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary diagnosis</td>
<td>The principal diagnosis determined as the diagnosis <em>most contributory</em> to the terminal prognosis.</td>
</tr>
<tr>
<td>Secondary diagnosis</td>
<td>Related to either the terminal prognosis or the primary diagnosis</td>
</tr>
<tr>
<td>Unrelated diagnosis</td>
<td>Condition <em>UNrelated</em> to the terminal prognosis OR the primary diagnosis OR a secondary diagnosis</td>
</tr>
</tbody>
</table>

### Reasonable and Necessary

- The Medicare Hospice Benefit requires the hospice to cover all _reasonable and necessary palliative care_ related to the terminal prognosis and related conditions....
- Section 1862(a)(1)(C) of the Social Security Act (the Act) forbids payment for any items or services which are not _reasonable and necessary for the palliation and management of the terminal illness_. Services which are not needed . . . would not be reasonable and necessary.

78 Federal Register 152 (7 August 2013), p.48236, 48274.
Determining “Relatedness”

Coverage per the CoPs

418.200 Requirements for coverage.
- To be covered, hospice services ... must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions.

418.202 Covered services.
- (f) Medical appliances and supplies, including drugs and biologicals. Only drugs ... which are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered.

Reasonable and Necessary

- If it is ineffective, is it necessary?
  - Or merely desired?
- If it is ineffective, is it reasonable?
  - Polypharmacy
  - Known and unknown side effects (in populations on whom meds rarely, if ever, tested or evaluated)
  - Drug-drug interactions

Choosing Wisely

- Five Things Physicians and Patients Should Question
- Evidence-based recommendations from 30 medical specialty societies regarding tests or procedures commonly used in their fields whose necessity should be questioned and discussed.
- Help physicians and patients to choose care that is:
  - Supported by evidence
  - Not duplicative
  - Free from harm
  - Truly necessary
Choosing Wisely

- Don't routinely prescribe lipid-lowering medications in individuals with a limited life expectancy. (AMDA)
- Don't insert percutaneous feeding tubes in individuals with advanced dementia. Instead, offer oral assisted feedings. (AMDA, AGS, AAHPM)
- Don't use topical lorazepam (Ativan), diphenhydramine (Benadryl), haloperidol (Haldol) ("ABH") gel for nausea. (AAHPM)

Choosing Wisely

- Don't use benzodiazepines or other sedative-hypnotics in older adults as first choice for insomnia, agitation or delirium. (AGS)
- Don't use antimicrobials to treat bacteriuria in older adults unless specific urinary tract symptoms are present. (AGS)
- Don't use glucosamine and chondroitin to treat patients with symptomatic osteoarthritis of the knee. (AAOS)

Choosing Wisely

- Don't use cancer-directed therapy for solid tumor patients with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anti-cancer treatment. (ASCO)
- Don't administer erythropoiesis-stimulating agents (ESAs) to chronic kidney disease (CKD) patients with hemoglobin levels greater than or equal to 10 g/dL without symptoms of anemia. (ASN)
- Avoid transfusions of red blood cells for arbitrary hemoglobin or hematocrit thresholds and in the absence of symptoms of active coronary disease, heart failure or stroke. (SHM)
Determining “Relatedness”

- Part D paid for prescription drugs after the patient elected hospice:
  - 198,543 hospice beneficiaries
  - 677,022 prescription drugs through Part D
  - Part D paid $33.6 M
  - Beneficiaries paid $3.8 M in copays
- 4 classes of drugs reviewed
  - Analgesics, anti-emetics, anxiolytics, laxatives

CMS Memo: Dec 6, 2013
- 4 medication scenarios
  - A – meds started prior to admission; related; hospice provides
  - B – meds started prior to admission; no longer medically necessary; DC med
  - C – med is either related but not formulary, or not necessary but patient wants to continue
  - D – medication is unrelated

Buckets of “Relatedness”
**Payment Responsibility**

- The hospice POC must include all services necessary for the palliation and management of the terminal illness and related conditions.
- As a general rule, hospice providers are expected to cover virtually ALL drugs for hospice beneficiaries during the hospice election.

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**Payment Responsibility**

- Some medications started before hospice admission will be continued, if necessary for the palliation and management of the terminal illness and related conditions. These medications would be covered under the Medicare hospice benefit.

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**Payment Responsibility**

- Medications that WERE for the treatment of the terminal illness and/or related conditions prior to hospice admission will be DC'ed as determined by the hospice IDG and discussed with patient/family because medications are no longer effective and/or causing additional negative symptoms.
  - NOT covered under the MHB (not reasonable or necessary for the palliation of pain and/or symptom management).
  - If beneficiary still chooses to have these medications, costs would be a beneficiary liability (not MHB or Part D)
Determining “Relatedness”

Payment Responsibility

If a beneficiary requests a drug for his/her terminal illness or related conditions that is NOT on the hospice formulary...

- and the beneficiary refuses to try a formulary equivalent first...
- or is determined by the hospice to be unreasonable or unnecessary for the palliation of pain and/or symptom management...
- the beneficiary may opt to assume financial responsibility for the drug.
  - No payment for the drug will be available under Part D.

Payment Responsibility

For prescription drugs to be covered under Part D when the enrollee has elected hospice:

- The drug must be for treatment of a condition that is COMPLETELY unrelated to the terminal condition(s) or related conditions.
- The drug is unrelated to the terminal prognosis of the individual.
- "We expect drugs covered under Part D for hospice beneficiaries will be extremely rare."

“Not related” is rare?

Medications used to treat chronic, unrelated medical conditions are generally not covered:

- Allergy medication
- Thyroid replacement
- Estrogen replacement
- Glaucoma medication
- Chronic depression?
- Chronic pain (e.g., failed back syndrome)?
Determining “Relatedness”

### Related and NOT Covered
- Life prolonging, not palliative
- Not effective
  - not "supported by the evidence" or “truly necessary”
- May be harmful for reasons not usually thought of by patients and families
  - “not free from harm”
- Duplicate medications
- Not on hospice formulary or preferred med list
- And pt/family decline an equivalent medication that would be covered

### Dementia Medications
Dementia medications (Aricept™, Namenda™, Exelon™, Razadyne™) are less helpful and more harmful in advanced disease. Side effects: wt loss, bad dreams, sleep disturbances, bradycardia, and increased restlessness.

**NOT indicated or covered** with FAST 7 without clear and ongoing benefit in managing identifiable and distressing behaviors. **May** be covered with FAST 6; discuss goals/outcomes with hospice physician or pharmacist.

• 2 week tapering supply **COVERED** if med discontinued and an additional supply is needed.

### Responsibility for Drugs

<table>
<thead>
<tr>
<th>Hospice</th>
<th>Part D Plan Sponsor</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All reasonable and necessary medications related to the terminal illness and related conditions</td>
<td>• Medications unrelated to the terminal illness and related conditions</td>
<td>• Related, but not reasonable and necessary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Unrelated and no coverage per policy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Unrelated OTCs</td>
</tr>
</tbody>
</table>
Determining “Relatedness”

**Medication Coverage**

At this stage of illness, is this medication:
- Helpful (or anticipated to be helpful), and/or
- “Standard of care,” or
- Offered for a time-limited trial to assess helpfulness? (as approved by Med Director)

- NO, medication is not covered.

- YES, medication is covered. Adjust dose as necessary. Monitor for side effects.

- Offer approved equivalent from Formulary. Cover if accepted.

- If approved equivalent med is declined, medication is not covered. Complete a Medication Coverage form.

**Medication Coverage Form**

- Completed if patient elects the HMB
- Private Insurance and Medicaid?
- Form does not need to be completed if:
  - Hospice is paying for all medications at time of admission
  - Only uncovered medications are OTCs
  - Not covered by Part D
Case: What’s Related?

- 75 year old gentleman with PMH of HTN (controlled x 20yrs), MI (x 1 approx 10 yrs ago), hypercholesterolemia (x 10 yrs), a-fib (x 5 years), hypothyroidism (x 5 years), COPD (x 10 yrs), early dementia (dx’d 2 yrs ago), depression (dx’d 2 yrs ago with dementia), and 50 pack-yr hx of tobacco use presented with L hip pain.
- XR revealed a lesion c/w metastatic disease. Workup revealed primary lung cancer with bony metastases to hip and 2 ribs, but no brain metastasis. Pt and family decline further work-up or disease-directed interventions except XRT to his hip which he tolerated without difficulty.
- Physical sx now include occasional hip pain, dyspnea with moderate exertion, decreased appetite, 10# wt loss, BMI 25, and need for ongoing need for assist with bathing, dressing, and meal preparation. Meds include:

Sx mgmt meds: $256/month

- Enalapril 20 mg
- Metoprolol ER 50 mg
- Atorvastatin 40 mg
- Digoxin 0.25 mg
- Warfarin 2 mg
- Levothyroxine 100 mcg
- Donepezil 5 mg
- Citalopram 20 mg
- Albuterol inhaler
- Tiotropium (Spiriva)
- Fluticasone/salmeterol (Advair) 250/50
- Morphine ER 60 mg BID
- Concentrated liquid morphine
- Desamethasone 4 mg
- Omeprazole 20 mg
Determining “Relatedness”

**Sx + all pulm meds: $907/month**
- Enalapril 20 mg
- Metoprolol ER 50 mg
- Atorvastatin 40 mg
- Digoxin 0.25 mg
- Warfarin 2 mg
- Levothyroxine 100 mcg
- Donepezil 5 mg
- Citalopram 20 mg
- Albuterol inhaler
- Tiotropium (Spiriva)
- Fluticasone/salmeterol (Advair) 250/50
- Morphine ER 60 mg BID
- Concentrated liquid morphine
- Dexamethasone 4 mg
- Omeprazole 20 mg

**All meds: $1200/month**
- Enalapril 20 mg
- Metoprolol ER 50 mg
- Atorvastatin 40 mg
- Digoxin 0.25 mg
- Warfarin 2 mg
- Levothyroxine 100 mcg
- Donepezil 5 mg
- Citalopram 20 mg
- Albuterol inhaler
- Tiotropium (Spiriva)
- Fluticasone/salmeterol (Advair) 250/50
- Morphine ER 60 mg BID
- Concentrated liquid morphine
- Dexamethasone 4 mg
- Omeprazole 20 mg

**Medical Directors: Diagnoses**
- The principal diagnosis should be the condition determined by the certifying hospice physician(s) as the diagnosis most contributory to the terminal decline.
- Certifying physicians should use their best clinical judgment in determining the principal diagnosis and related conditions, based on the hospice comprehensive assessment and review of any and all other clinical documentation.

Determining “Relatedness”

Related Conditions

- ... unless there is clear evidence that a condition is unrelated to the terminal prognosis; all services would be considered related.
- ...“all of a patient’s coexisting or additional diagnoses” related to the terminal illness or related conditions should be reported on the hospice claim.

78 Federal Register 152 (7 August 2013), pp. 48236-7, 48240.

Medical Directors: Documentation

- It is the responsibility of the hospice physician to document why a patient’s medical needs would be unrelated to the terminal prognosis.
- Hypothyroidism and early dementia dx/meds not related to px or palliation/mgmt of metastatic lung cancer.

Medical Directors: Documentation

- Must have a place and a process to determine and document
  - Relatedness of diagnoses
  - Medication: related, reasonable, necessary, covered
  - Timely and accessible to the IDG
- Useful
  - Wording must designate reasons for coverage decisions
- Defensibility
Determining “Relatedness”

Medical Directors: Documentation
- Consistent reasoning that staff can understand and communicate to others
- May challenge interdisciplinary teamwork
  - Hard to say “no”
  - Hard conversations for some staff

Correct Choices are Important
- Patients may have financial liability for some medications
  - A challenge for hospice staff to implement and explain:
    - Need expanded knowledge base of regulations
    - Need to collaborate more with medical director prior to admission
    - Need “the words” to explain regulatory and medical rationales
      - Hard to manage “financial” issues
      - Easier to say “yes”—and not have to tell patients they may need to pay for some things if they want them
      - Need to change/increase documentation
  - Financial impact to hospice for increasing medication and services coverage
  - Referral impact if medications are reviewed and not covered

Correct Choices are Important
- Patient/family/community trust
- “Do no harm!”
- Financial consequences to the patient
- Financial consequences to the hospice
- Potential legal and/or compliance consequences
- Incur the wrath of Medicare
Determining “Relatedness”

Definition of Terminally Ill

- CMS states:
  “Because hospice care is unique in its comprehensive, holistic, and palliative philosophy and practice, we want to ensure that the hospice services under the Medicare hospice benefit are preserved and not diluted, or unbundled in any way.”

Proposed Definition of Terminal Illness

- “Abnormal and advancing physical, emotional, social and/or intellectual processes which diminish and/or impair the individual’s condition such that there is an unfavorable prognosis and no reasonable expectation of a cure;
- Not limited to any one diagnosis or multiple diagnoses, but rather it can be the collective state of diseases and/or injuries affecting multiple facets of the whole person, are causing progressive impairment of body systems, and there is a prognosis of a life expectancy of six months or less.”

Proposed Definition Related Conditions

- “Those conditions that result directly from terminal illness; and/or
  - result from the treatment or medication management of terminal illness; and/or
  - which interact or potentially interact with terminal illness; and/or
  - which are contributory to the symptom burden of the terminally ill individual; and/or
  - are conditions which are contributory to the prognosis that the individual has a life expectancy of 6 months or less.”