The High Cost of (Organ) Failure

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Objectives

1. Describe Medicare guidelines regarding coverage of medication under the Hospice Medicare Benefit
2. Discuss Medicare Part D and coverage of nonhospice medications
3. Review two sample disease processes and their usual medications
4. Develop a process to evaluate necessity of medications for chronic illness that impact the prognosis in hospice patients

Medications in Hospice

• Part of the Medicare Benefit
• How did we do this before?
  – Medications related to distressing symptoms covered
  – Only one hospice “diagnosis” determined the coverage, i.e. COPD plus dementia……one or the other
  – “Not on our formulary”
  – You want it (and we don’t want to cover it)….you pay for it

Coverage of Medications in Hospice

• What happened?
• Federal Register Vol. 78 No. 152 pp. 48233-48281 Wednesday August 7, 2013
• Shift to focus on terminal “prognosis” rather than “diagnosis”
• Multiple medical conditions can contribute to the terminal prognosis
• CMS expects “Virtually all” the care needed by terminally ill patients covered

Coverage of Medications in Hospice

• “It is the responsibility of the hospice physician to document why a patient’s medical needs would be unrelated to the terminal prognosis.”

Coverage of Medications in Hospice

• Everybody was watching the Adult Failure to Thrive and Debility issues but what else was involved?
• Over 10 years’ time, these two combined went from 9% all hospice diagnoses to 20%
Coverage of Medications in Hospice

- Federal Register August 7, 2013
- Table 3 (p. 48244) lists chronic conditions of beneficiaries with debility or AFTT
- Many of these are hospice diagnoses in their own right:
  - Alzheimers Disease (66%)
  - Ischemic Heart Disease (63%)
  - Heart Failure (53%)
  - Chronic Kidney Disease (43%)
  - Chronic Obstructive Pulmonary Disease (39%)
  - Stroke/CVA (34%)
  - Cancer (19%)

Part D Medications in Hospice Patients

- In 2010: 773,000 hospice patients were enrolled in Medicare Part D
- 15% received analgesic RX (334K) through part D ($13 M) This was only one class of medications.
- During same time: Medicare hospice beneficiaries received 5.8M RX all classes ($351M)

Drug Coverage in Medicare

- Medicare Part D: Prescription Drug Plan. Add drug coverage to Original Medicare
- Two times per year open enrollment

- Medicare Part C
  - Managed care style plan that covers Part A, Part B, and many cover drugs
  - Two times per year open enrollment
  - Disenrollment period

Part D Payment for RX for hospice patients

- March 10, 2014 Final Guidance
- Drugs and biologics covered under Part A per diem to hospice are excluded from coverage under Part D
- This is where “related” and “unrelated” to terminal prognosis becomes important!

Part D Payment for RX for hospice patients

“Non-covered” medications.
A. Related to the “terminal illness/related conditions” versus
B. Not related to the “terminal illness/related conditions”

Documentation must be clear about relatedness (by hospice physician)
Communication with patients and families regards coverage must also be clearly documented!
Part D Payment for RX for hospice patients
“Non-covered” medications.
A. Related to the “terminal illness/related conditions”:
• If beneficiary still chooses to have meds filled, costs become liability to beneficiary and NOT covered by Part D
• If beneficiary requests a non-formulary med and refuses to try a formulary equivalent first, he/she assumes financial responsibility (not Part D)

B. Not related to the “terminal illness/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 unusual and exceptional circumstances.”

End Stage Liver Disease
• Significant cause of morbidity and mortality in US
• 5.5 Million people have cirrhosis
• 30 Million Americans have some form liver disease
• 32000 patients died of chronic liver disease and cirrhosis in 2010. 12th leading cause of death overall, 7th in people 25-64
• Additional 20000 pts died Hepatobiliary cancer 2010.

What Diseases Impact Prognosis?
• Terminal Illness
• Secondary Conditions
  – Flow from the Primary Condition
• Comorbidities
  – Separate condition that also impacts prognosis and trajectory of illness
• Severe Illnesses that interact with the terminal illness to shorten lifespan

End Stage Liver Disease
• Mode of death:
• Liver failure
• Hepatocellular carcinoma
• GI bleeding
• Sepsis
• Renal failure
• Ascites/Hepatic encephalopathy negatively impact survival rate
End Stage Liver Disease

Prognostic Tools:
• Child’s-Turcotte-Pugh score: 5 variables, each scored 1-3
• Ascites, encephalopathy, Bilirubin, Albumin, increase in seconds from nl PTT
• Scored “Class A” (1 yr survival 95%), “Class B” (1 year survival 80%), “Class C” (1 year survival 45%)

End Stage Liver Disease

Prognostic Tools:
MELD Model for End-stage Liver Disease
Complicated calculation.
Uses Creatinine, Total Bilirubin, INR
At score >30, 40% patients have predicted 6 month survival.

End Stage Liver Disease

Hepatorenal syndrome:
Type 1 HRS: death within 8-10 weeks
Type 2 HRS: prognosis is 6 months

Older age and Hepatocellular Carcinoma also negatively impact prognosis

End Stage Liver Disease

• So….is this diagnosis going to impact the patients “terminal prognosis”, even if not the “primary” hospice diagnosis?

End Stage Liver Disease

• Symptoms to control:
• Pain
• Dyspnea
• Fatigue
• Itching
• Depression
• Nausea
• Edema
• Ascites
• Hepatic encephalopathy/delirium

End Stage Liver Disease

• Pain:
• Opiates transformed in liver: codeine, tramadol, morphine, oxycodone
• Oxidation/reduction reactions (CYP) P450
• Conjugation/glucuronidation
• Fentanyl not as affected.
• Try to avoid tramadol, codeine, oxycodone
• Reduce dose and frequency of other opiates
• Consider adjuvants
End Stage Liver Disease

- Itching:
  - Cholestyramine (timing other meds+ constipation)
  - Oral antihistamines (sedating)
  - Rifampin (hepatotoxic)
  - Doxepin (hepatoxic and anticholinergic)
  - Naltrexone (withdrawal)
  - Steroids
  - Sertraline (primary biliary cirrhosis)

- Ascites
  - Most common complication ESLD
  - Interventions:
    - Large volume paracentesis
    - Additional practice of adding IV albumin to ?delay reaccumulation but $$cost and efficacy not shown

- Hepatic Encephalopathy
  - Most disturbing to patient and family
  - 60-70% patients with ESLD
  - Treatment of choice: lactulose/lactitol
  - Converts ammonia to ammonium chloride (excreted in stool). 4 stools/day
  - If refractory/intolerant to lactulose, Alternatives are Neomycin 1-2 g/d (toxic)
  - Metronidazole 250 mg 2-3 times/d
  - Rifaximin 550 mg BID(FDA approval 2010)
ES Congestive Heart Failure

- Most common diagnosis coded in hospitalizations in US
- ES Heart disease 4th leading diagnosis in hospice (CHF within this category)
- 5.1 Million people in US have heart failure, costing $32 Billion per year
- By 2030, additional 3 million persons with CHF
- By 2030, 40.5% of US population projected to have some form of CVD (Hypertension, Coronary Heart Disease, CHF, Stroke)

ES Congestive Heart Failure

- 1 in 9 deaths in 2009 included HF as contributing cause
- Risk factors/causes:
  - Atherosclerotic heart disease/AMIs
  - Cardiomyopathy
  - Arrhythmias
  - Hypertension
  - Diabetes mellitus
  - Hypercholesterolemia
  - Others: obesity, sedentary life, smoking

ES Congestive Heart Failure

- Mode of Death:
  - Congestive Heart Failure with Reduced Ejection Fraction:
    - Most deaths are cardiac
  - Congestive Heart Failure with Preserved Ejection Fraction:
    - Many deaths are cardiac, not all
  - Sudden cardiac death due to arrhythmia, decompensated heart failure, AMI

ES Congestive Heart Failure

- Prognosis based upon functional status and symptoms
  - EF <= 20%
  - Additional conditions worsen prognosis:
    - Cachexia, diabetes, cirrhosis, cancer, cerebrovascular disease, renal disease, HIV cardiomyopathy, anemia can impact prognosis

ES Congestive Heart Failure

- Prognosis based upon functional status and symptoms
  - NYHA I-IV (functional); II: 10% 1 yr mortality, III: 15% 1 year mortality, IV: 30-40% 1 year mortality
  - AHA/ACC staging system A-D
    - A= “pre-heart failure”
    - B= NYHA I
    - C= NYHA II, III
    - D= NYHA IV

ES Congestive Heart Failure

- So….is this diagnosis going to impact the patients “terminal prognosis”, even if not the “primary” hospice diagnosis?
ES Congestive Heart Failure

- Symptoms:
  - Dyspnea
  - Fatigue
  - Edema
  - Angina
  - Pain
  - Depression
  - Anorexia/Cachexia
  - Pleural effusions

ES Congestive Heart Failure

- Tremendous number of medications recommended to treat CHF, plus any other conditions that underlie the dx
  - Diuretics
  - ACE Inhibitors
  - ARBs if ACEI intolerant
  - Beta blockers
  - Digoxin if CHFREF
  - Aldosterone antagonist: Spironolactone
  - Nitrates/hydralazine

ES Congestive Heart Failure

- Pain
  - Opiates are appropriate—no specific opiate needed unless comorbidity
  - Discontinue NSAIDs as they can worsen CHF
  - Nitrates for angina/variants in addition to opiates
  - Opiates also acceptable for dyspnea

ES Congestive Heart Failure

- Many symptoms similar to other hospice diagnoses:
  - Anxiety
  - Insomnia
  - Dyspnea (angina variant? COPD?)
  - Constipation
  - Cognitive dysfunction

ES Congestive Heart Failure

- Interventions you may encounter:
  - Thoracentesis for pleural effusions (recurrent)
  - AICD/Pacemaker to reduce possibility of sudden cardiac death
  - Biventricular pacemaker
  - LVAD
  - Inotropic infusions
ES Congestive Heart Failure

• Interventions you may encounter:
  • Thoracentesis for pleural effusions (recurrent)
    – Procedure based upon symptoms and not upon frequency
  • Pacemakers: no need to discontinue (although some patients/families request)
  • AICD: discontinued as ineffective at EOL and due to concerns for comfort

ES Congestive Heart Failure

• Interventions you may encounter:
  • LVAD
    – Often seen in hospice at discontinuation of device shortly prior to death
    – Was previously a “bridging” device for transplant, now a “destination” device
  • Inotropic infusions
    – May be used to get patient home.
    – Agreement with pt/family not to manipulate the infusion other than to discontinue
    – Used less often

Pharmacy Coverage Process: Terminal Prognosis

• Is this disease process contributing to the patient’s terminal prognosis?
• What is the patient’s prognosis?
• What are the patient’s and family’s goals of care?
• What other disease processes does the patient have?
• What is the patient’s functional status?
• Do any medications treat more than one condition?

Pharmacy Coverage Process: Symptom Management

• Does a medication/intervention treat more than one symptom?
• What is the burden of taking the medication?
• What is the burden of the intervention?
• Is the medication/intervention effective against the symptom it is prescribed to improve?
• Are there adverse effects of this medication? Do they require medications in turn?

Pharmacy Coverage Process: Formulary/Efficacy

• Is this medication on your hospice formulary? How difficult to obtain if not?
• If the medication is not on your formulary, what are the alternatives?
• For the alternative: What is the burden of this medication? Can it be effective? Could it treat more than one symptom?
• If your team decides the medication is not effective, how has this been discussed with patient/family?

Pharmacy Coverage Process: Not Related Determinations

• If you determine the medication/intervention is not related to the terminal condition, how will you explain/“defend” this to a Part D Sponsor or Insurer (in case of an intervention)?
Reducing Medications/Interventions

• Streamlining meds a practice of Palliative Medicine
• Reduces medication interactions
• Reduces chance of medication errors
• Reduces side effects
• Minimizes burden of pills/taking meds or undergoing procedures
• Allows patient and family to focus on time together
• See Bibliography for articles

Case 1

• Mr. H, a 67 year old man with ES cirrhosis of liver, also known to have Hepatocellular Carcinoma. His MELD score: 28. He has significant bilateral LE edema, and ascites. He complains of RUQ and back pain. He also has hypertension. He has insomnia and is “acting a little funny” per his wife.

• He comes to hospice on the following medications:
  • Hydromorphone 4 mg q 4 hours prn severe pain
  • Hydrocodone/APAP 10/325 po q 4 hours prn
  • Lactulose 30 mg twice a day
  • Lorazepam 1 mg q 4 hours prn
  • Lasix 80 mg q day, KCl 20 meq twice a day
  • Carvedilol 6.25 po bid
  • Sertraline 50 mg q day
  • Zofran 8 mg po q 6 hours prn
  • Ambien Cr 12.5 mg q HS

Case 1 Mr. H

• Mr. H’s delirium is worsening.
• What do you want to do now? What questions will you be asking?
• What medications do you wish to add or subtract?
• What coverage decisions will you be making?
• How do you document those in your record?

Case 1

• What medications do you anticipate “covering” under the Hospice Medicare Benefit?

Case 2 Mrs. B

• Mrs. B is a 68 year old woman with Stage IV Breast cancer, metastatic to bone (spine). She has additional diagnoses of Congestive Heart Failure, Hypothyroidism, Glaucoma.
• She complains of fatigue, occasional LE edema, rare shortness of breath, pain in her back
• Her medication list is:
  • Captopril, Furosemide 40 mg q am, KCl 20 mEq q AM, Digoxin 0.125 qod, Levothyroxine 0.05 q AM, Azopt ophthalmic drops 1 drop OU BID. Morphine ER 30 mg q 12, Morphine IR 15 mg q 2 hours prn, Senna 8.6 mg BID, ASA 81 mg q AM, Simvastatin 40 q day, Zofran 8 mg q 6 hours prn N/V
Case 2 Mrs. B

- What medications do you plan to cover under the Medicare Hospice Benefit?
- She will be using Hospice Physician as Primary Care provider.
- How will you be handling the Part D medications?

Case 2 Mrs. B

- Mrs. B’s back is worsening and she is asking about Ibuprofen.
- What is your answer?

Case 2 Mrs. B

- As Mrs. B’s illness advances from PPS 60% to 40% to 30%, she has more difficulty with swallowing “all those meds”.
- What do you do now?
- How do you discuss with her College Professor daughter?

Summary

- Know which diseases are contributing to the patient’s terminal prognosis.
- Determine which medications are related to the terminal condition.
- Weigh relative risks and benefits of each medication.
- Streamline medications whenever possible.
- Review periodically for change in “relatedness” of disease processes

Summary

- Ascertain patient’s and family’s goals of care and how the plan of care fits
- Communicate and document discussions about non-covered medications and whose responsibility for payment
- Be prepared to elaborate on a noncovered medication to a Part D Sponsor.
- Consult other palliative care professionals/pharmacists regards effective alternatives to a treatment the patient desires

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