Covered vs Non-Covered Medications in Hospice

Jim Joyner, PharmD, CGP
Hospice Medicare Benefit:
Which Drugs Should be Covered?

• Hospice is responsible for coverage of the drugs considered to be “reasonable and necessary” for palliation and management of the terminal illness (hospice diagnosis) and related conditions.*

*Traditionally, this has meant “medically related” conditions.
New guidance changes the scope of responsibility for coverage.

• **NEW CMS guidance:** Hospice is also responsible for coverage of drugs that are necessary to manage unrelated conditions if they are deemed to be contributing to the patient’s terminal decline or status (will be codified in upcoming regulation)

Latest CMS Guidance Effective May 1, 2014

• Part D Medicare plans required to reject all Rx’s for hospice patients

• Hospice may request P.A. consideration for payment from patient’s Part D plan for non-related drugs that are still medically necessary

• Hospice is still responsible for all drugs related to the hospice diagnosis that are deemed medically necessary

• Options for drugs that are not related to hospice diagnosis and no longer “medically necessary”
  – Discontinue drug (often the most appropriate action)
  – Hospice may pay for drug (reasonable option for low cost drugs ?)
  – Patient may pay for drug themselves
First: Obtain the Patient’s Part D Plan Info

- Hospice needs to know all of their patient’s Part D plan sponsor contact info (should be on patient’s Part D insurance card)

- Source if patient does not know Part D plan or can’t produce card:
  - Patient’s primary pharmacy – info in pt. profile
  - Request pharmacy run an eligibility query (E1) thru the CMS Transaction Facilitator on-line
    (caution – accuracy reported estimated at only 70%)

Part D Plan: Steps for Non-Hospice Covered Drugs

- Rejection of Rx by the Part D plan sponsor will usually occur at the pharmacy during dispensing -- Exception: LTC Pharmacies

- Pharmacy will promptly notify prescriber and/or hospice of rejection

- Hospice decision time:
  - Consider obtaining D/C order ?
  - Consider covering the drug ?
  - Initiate P.A. process with Part D plan ?
  - Patient pays out of pocket ?

- Hospice may choose to initiate PA process with patient’s Part D plan

- Expect decision regarding payment from Part D plan within 24 -72hr (after PA is submitted)
The Prior Authorization (PA) Process

- No standard PA form or procedure applicable for all plans.
  - plans may allow verbal phoned-in process or faxed forms
  - each plan may have different procedures

- Expect Part D sponsors to request why certain drugs are unrelated to the terminal diagnosis in order to approve payment
  - input from hospice physician vital here

- PA’s may be initiated after Rx rejection at the pharmacy or prospectively by initiating contact with the Part D provider upon admission to hospice before Rx’s are called to pharmacy

Additional Ramifications for Hospice

- Hospices need to be pro-active in seeking discontinuation of drugs that are no longer “medically necessary” following hospice election

- Hospice must be prepared with appropriate documentation to support non-hospice related, but still medically necessary drugs for Part D plans (medication review)

- Seeking prospective PA’s for non-hospice covered drugs should be encouraged

- Hospice will need to weigh relative costs of paying for non-related drugs against their “internal - costs” of proceeding with the PA process. Evaluate and decide on a case by case basis.
Participation in the Part-D PA Process: What are the “Internal Costs” to the Hospice?

- Physician’s time providing justification of medical necessity and non-related status for drugs to meet Part-D plan requirement
- Staff time filling out, faxing forms – communicating with Part D plans
- Client Relationship Cost: Source of frustration to patients and families associated with delays or interruption of non-hospice related drug therapy
- Negative health consequences to patient due to interruption of non-covered drug therapy

Questions about the CMS guidelines for coverage and Part D??
What is a Palliative Medication?

**Palliative meds:**
- relieve current symptoms of disease
- provide comfort to the patient
- no intention of prolonging life
- no intention of promoting cure
- no intention of achieving long-term positive outcomes

**Definitive Question:**
What troublesome symptom will this medication relieve?

* Any medications that do not help patient/family meet the goals of care or enhance comfort should be D/Ced

Patient Factors that Guide Coverage Decisions

- The patient’s terminal diagnosis (hospice diagnosis)
  - primary factor

- Patient’s current condition
  - functional status
  - quality of life
  - PPS (Palliative Performance Scale) score
  - Karnofsky score
  - Prognosis (months, days?)

- Goals of care
  - comfort only, non-invasive measures
  - preserving a level of functionality
  - maintaining current quality of life
Symptoms Managed via “Hospice Covered” Medications

- Pain
- Nausea/vomiting
- Anxiety, insomnia, agitation
- Depression (if related to terminal illness)
- Psychotic symptoms (delirium)
- Bowel issues: constipation/diarrhea
- Fluid retention
- Loss of appetite -- ?
- Infection (if related to terminal illness)
- Oro-pharyngeal secretions
- Dyspnea
- Coughing
- Epigastric symptoms (pain, reflux, bloating)
- Seizures (if related to terminal illness)
- Itching

Examples of Non-Palliative Drugs Usually Not Covered by Hospice

No longer “medically necessary” ? ....

- Cholesterol-lowering drugs
  Lipitor, Zocor, Lovastatin, Zetia

- Cognitive enhancing drugs
  Aricept, Exelon, Galantamine, Namenda

- Antihypertensive drugs
  Catapres patch, Diovan, Cardizem

- Thromboprophylaxis drugs (anticoagulants/antiplatelets)
  Lovenox, Fragmin, Plavix, Pradaxa, Coumadin, Aggrenox

- Chemo-therapeutic drugs
Case 1: Dementia

RJ is an 82-year-old female on hospice for end-stage dementia. Patient has experienced a 12% weight loss in the last 6 months. She is fully dependent for all ADLs. PPS is 30%. Daughter is the primary caregiver and administers all meds.

Comorbid conditions (history given by daughter -- this is all she could remember):
Hypertension, Glaucoma, Recurrent UTI

Vitals upon admission:
BP 125/75
HR 50
Temp 98.7

Case 1 Medication List

Aricept 10 mg PO daily
Lexapro 10 mg PO daily
Depakote 250 mg PO BID
Dronabinol 2.5 mg PO BID
Prllosec 20 mg PO daily
Lisinopril 10mg daily
Cosopt Opth. Drops 1 drop O.U. BID
Senna S 1 daily
Morphine 20 mg/mL 0.25 mL PO every 1 hour PRN pain
Lorazepam 2 mg/mL 0.25 mL PO every 4 hours PRN anxiety
Atropine 1% drops 2 drops sublingually every 4 hours PRN secretions
ABH (Ativan/Benadryl/Haldol) gel topically every 4 hours PRN agitation
Zyprexa 5 mg Q12hr routinely

Which meds would you…
A. -Cover, B. -Submit to Part-D, C. -Consider discontinuing?
Diagnosis-Specific Drug Coverage: **Dementia**

- **Antipsychotic drugs**: helpful for hallucinations, paranoia, and agitation (haloperidol, risperidone)

- **Anxiolytic drugs**: helpful for brief periods of time to provide sedation (lorazepam, alprazolam, phenobarbital)  
  (benzodiazepines may worsen confusion in dementia, especially when used routinely for extended periods)

- **Cognitive enhancing drugs** (Aricept, Exelon, Namenda): are not continued in hospice patients with a terminal diagnosis of dementia due to lack of effectiveness in end stage (FAST level 7).  
  (risk for adverse drug effects will outweigh any potential benefit at end-stage)

### Functional Assessment Staging of Alzheimer’s Disease. (FAST)

<table>
<thead>
<tr>
<th>STAGE</th>
<th>SKILL LEVEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. No difficulties, either subjectively or objectively. <em>(Normal)</em></td>
<td></td>
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<tr>
<td>2. Complains of forgetting location of objects. Subjective word finding difficulties. <em>(Normal older adult)</em></td>
<td></td>
</tr>
<tr>
<td>3. Decreased job function evident to co-workers; difficulty in traveling to new locations. Decreased organizational capacity. <em>(Early Dementia)</em></td>
<td></td>
</tr>
<tr>
<td>4. Decreased ability to perform complex tasks (e.g., planning dinner for guests), handling personal finances (forgetting to pay bills), difficulty shopping, etc. <em>(Mild Dementia)</em></td>
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</tr>
<tr>
<td>5. Requires assistance in choosing proper clothing to wear for day, season, occasion. <em>(Moderate)</em></td>
<td></td>
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<tr>
<td>6. a. Difficulty putting clothing on properly without assistance. <em>(Moderately Severe)</em></td>
<td></td>
</tr>
<tr>
<td>b. Unable to bathe properly (e.g., difficulty adjusting bath water temperature) occasionally or more frequently over the past weeks.</td>
<td></td>
</tr>
<tr>
<td>c. Inability to handle mechanics of toileting (e.g., forgets to flush the toilet, does not wipe properly or properly dispose of toilet tissue) occasionally or more frequently over the past weeks.</td>
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<tr>
<td>d. Urinary incontinence, occasional or more frequent.</td>
<td></td>
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<tr>
<td>e. Fecal incontinence, (occasional or more frequently over the past week).</td>
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</tr>
<tr>
<td>7. a. Ability to speak limited to approximately six different words or fewer, in the course of an average day or in the course of an intensive interview (the person may repeat the word over &amp; over). <em>(Severe Dementia)</em></td>
<td></td>
</tr>
<tr>
<td>b. Speech ability limited to the use of a single intelligible word in an average day</td>
<td></td>
</tr>
<tr>
<td>c. Ambulatory ability lost (cannot walk without personal assistance).</td>
<td></td>
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<tr>
<td>d. Ability to sit up without assistance lost (e.g., the individual will fall over if there are no lateral rests [arms] on the chair).</td>
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</tr>
<tr>
<td>e. Loss of the ability to smile.</td>
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</table>
ABH Topical Gel Not Absorbed

Clinical Study (reference at bottom of slide):

• 1.0 mL dose of ABH gel applied to the wrist of 10 health volunteers, blood samples obtained at various time points (from 1 to 8 hours)
• No lorazepam or haloperidol was detected in any sample from any of the 10 patients
• Benadryl was detected in 5 patients, but it was absorbed late, at low levels and erratically

The results of this study were presented at the American Society of Clinical Oncology 2011 Annual Meeting.

Symptom Management:
Epigastric Discomfort/Dyspepsia

• Gastric pain, heartburn, reflux are common in hospice patients
• May be related to end-of-life or secondary to a variety of disease states
• May be a side-effect of other hospice-covered meds, like NSAIDs
• Gastric acid blockers are usually covered, unless issue is clearly NOT related to terminal diagnosis, e.g. prior history of GERD or PUD not related to terminal diagnosis
  – PPIs: omeprazole (Prilosec), pantoprazole (Protonix), others
  – H2 antagonists: ranitidine (Zantac), famotidine (Pepcid), others
• PPIs highly overused -- always evaluate for possible discontinuation, especially in patients received from the hospital
Why treat anorexia in hospice patients?

- May reduce anorexia-related symptoms?
  - wasting of muscle mass, fatigue, weakness, lethargy

- May improve impaired QoL?

- Only continue appetite stimulant if demonstrable benefit exists:
  - weight gain due to the drug
  - cessation of weight loss due to the drug

- Often not appropriate in advanced disease with low level function (PPS or Karnofsky of 40 or less)

Appetite Stimulants in Hospice

<table>
<thead>
<tr>
<th>Drug/Initial Dosage:</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dronabinol (Marinol) 2.5 mg bid</td>
<td>- also helps with nausea</td>
</tr>
<tr>
<td></td>
<td>- adverse mental status changes</td>
</tr>
<tr>
<td></td>
<td>- very expensive</td>
</tr>
<tr>
<td>Cyproheptadine (Periactin) 4 mg tid</td>
<td>- drowsiness, weak efficacy relative to others</td>
</tr>
<tr>
<td>Megestrol (Megace) 400-800 mg qd</td>
<td>- demonstrated efficacy in cancer pts.</td>
</tr>
<tr>
<td></td>
<td>- risk for DVT and PE in elderly or history of cardiovascular disease (Avoid in these patients)</td>
</tr>
<tr>
<td>Mirtazapine (Remeron) 15 mg qHS</td>
<td>- effective, well tolerated</td>
</tr>
<tr>
<td></td>
<td>- helps with insomnia</td>
</tr>
<tr>
<td>Dexamethasone (Decadron) 4 mg qd</td>
<td>- also helps with nausea, mood</td>
</tr>
<tr>
<td></td>
<td>- SE: fluid retention, hyperglycemia, infection, psychosis (doses &gt; 10mg)</td>
</tr>
</tbody>
</table>
Questions about **Case 1** (dementia) ??

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**Case 2: Heart Failure**

BB is a 70-year old man admitted to hospice with end-stage heart failure. PPS is 40%.

**Comorbid conditions:**
- Atrial fibrillation
- COPD
- Hyperlipidemia
- GERD
- Type 2 Diabetes
- Osteoarthritis

**Vitals on admission:**
- BP 135/85
- HR 72
- Temp 99.1
Case 2 Medication List

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage/Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin</td>
<td>0.125 mg PO daily</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>10 mg PO daily</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>50 mg PO BID</td>
</tr>
<tr>
<td>KCL</td>
<td>20meq daily</td>
</tr>
<tr>
<td>Lasix</td>
<td>40 mg PO QAM, 20 mg PO at 2 pm</td>
</tr>
<tr>
<td>Lipitor</td>
<td>40 mg PO QHS</td>
</tr>
<tr>
<td>Nexium</td>
<td>40 mg PO daily</td>
</tr>
<tr>
<td>Phenergan</td>
<td>25 mg PO Q 6 hours PRN nausea</td>
</tr>
<tr>
<td>Warfarin</td>
<td>5mg daily</td>
</tr>
<tr>
<td>Metformin</td>
<td>500 mg PO BID</td>
</tr>
<tr>
<td>Glipizide</td>
<td>5 mg PO daily</td>
</tr>
<tr>
<td>Advair 250/50</td>
<td>1 puff inhaled BID</td>
</tr>
<tr>
<td>Spiriva</td>
<td>1 puff daily</td>
</tr>
<tr>
<td>Albuterol HFA</td>
<td>2 puffs every 4 hours PRN shortness of breath</td>
</tr>
<tr>
<td>Celebrex</td>
<td>200 mg PO daily</td>
</tr>
</tbody>
</table>

Which meds would you...
A. -Cover,       B. -Submit to Part-D,   C. -Consider discontinuing?

Diagnosis-Specific Drug Therapy:  Heart Failure

- Standard maintenance therapy is considered both disease modifying and palliative for HF
- Hospice should cover these categories and drugs for ES CHF:
  - Diuretics (and potassium supplement) - Anti-arrhythmics
  - ACE inhibitors or ARBs - Nitrates
  - Beta-blockers - Other vasodilators
  - Digoxin
- Statins are no longer medically necessary hospice care and should be D/C'ed
Guidance for Anticoagulants/Antiplatelets in Hospice – When to D/C

For the majority of patients, anticoagulants and antiplatelets should be discontinued upon hospice admission.

- Not palliative (not relieving any symptom)
- Typically used for preventative or prophylactic purpose
- May require invasive administration method or lab monitoring
- Have significant potential for adverse effects
  - Hospice patients are at increased risk for serious bleeding episodes
  - A serious bleed can lead to loss of function or death
- Numerous drug interactions (warfarin)

Anticoagulants in Atrial fibrillation:

- Anticoagulants do not reduce symptoms of AF
- Anticoagulants reduce stroke risk by about 4% per year on average*
- Actual reduction in stroke risk for hospice patient is very low

* Archives of Internal Medicine 1994; 54: 1449-1457.

Symptom Management: Pain

- Analgesics always covered unless pain clearly NOT related to terminal illness or decline
- Non- hospice covered examples:
  - NSAIDs for rheumatoid arthritis
  - Lidoderm patch for shingles pain
  - Gout medications: colchicine, indomethacin, allopurinol
  - Migraine headache meds: Imitrex, Cafergot, Excedrin Migraine

- Conversely, cover “adjuvant analgesics” if treating pain related to the terminal illness
  - Tricyclic antidepressants (e.g., nortriptyline)
  - Steroids (e.g., dexamethasone)
  - Anticonvulsants (e.g., gabapentin)
  - Muscle relaxants (e.g., baclofen)
Questions about Case 2 (heart failure) ??

Case 3

TN is a 55-year-old woman on hospice for breast cancer with mets to the brain and bone. PPS is 50%.

Comorbid conditions:
Pulmonary embolism (thought by oncologist to be secondary to cancer)
Depression
Anorexia
Parkinson’s disease

Vitals on admission:
BP 115/70
HR 60
Temp 97.9
Case 3 Medication List

OxyContin 80 mg PO BID
Oxycodone 10 mg PO every 2 hours PRN pain
Gabapentin 300 mg PO TID
Dexamethasone 4 mg PO daily
Keppra 500 mg PO BID
Lovenox 45 mg (1 mg/kg) subcutaneously BID
Tamoxifen 20 mg PO daily
Megace 40 mg/mL 20 mL PO daily
Ambien 5 mg PO QHS PRN insomnia
Nystatin 100,000 units/mL swish and swallow 5 mL 4 times daily for 14 days for thrush
Multivitamin with minerals 1 qd
Sinemet 25/250 QID
Senna S 2 tablets PO BID

Which meds would you…
A. -Cover, B. -Submit to Part-D, C. -Consider discontinuing?

Diagnosis-Specific Drug Coverage:

Cancer

- **Brain cancer/mets**: anticonvulsants, corticosteroids
- **Lung cancer/mets**: bronchodilators (inhaled), steroids (oral and/or inhaled), expectorants, antitussives, mucolytics
  - Significant overlap between Lung CA and COPD symptoms
  - Majority of Lung CA patients also have COPD
- **Pancreatic cancer**:
  - Digestive enzymes (if pt. still eating regular meals)
  - Insulin (pancreatic CA strongly associated w/ hyperglycemia)
- **Esophageal or stomach cancer**: acid blockers (PPIs, H2RAs, antacids), sucralfate.
- **Bone cancer/mets**: steroids, NSAIDs
- **Liver cancer/mets**: diuretics, lactulose, Xifaxan, cholestyramine for itching (Questran)
Guidance for Anticoagulants/Antiplatelets in Hospice – When to Continue

Possible exceptions to stopping therapy - when continued anticoagulants may be warranted in hospice:

• Reasonable current level of function (PPS ≥ 40) that we would like to preserve…
• And a reasonable QoL …
• And patient is deemed to be at high risk for further thromboembolic event
  - Patients w/cancer are at increased risk for DVT/thromboembolism
  - Thromboembolic event may result in serious debility or death

• OR, we are actively treating a clot that is symptomatic or otherwise negative impacting QoL

Questions about Case 3 (cancer) ??
Guidelines for Diabetic meds in Hospice:
Prognosis & Diabetes Type Matters

Prognosis of a couple months or more:
• **Type 1 diabetic**: continue insulin to maintain blood glucose (BG) target of 180-250mg/dL

• **Type 2 diabetic on insulin and oral hypoglycemic drugs**: may stop insulin and just use the oral agents unless prone to hyperosmolar hyperglycemic state (HHS). BG >750mg/dL

Prognosis of weeks:
• **Type 1 diabetic prone to DKA**: continue insulin, preferably long-acting basal insulin

• **Type 2 diabetic on oral hypoglycemic drugs**: stop taking all of them unless prone to HHS

Prognosis of less than one week (final days):
• **For most patients**: all insulin and oral hypoglycemic drugs can be discontinued in the final days of life when patient may have significantly decreased oral intake & alteration of consciousness

• **Exception**: Type 1 diabetics prone to DKA may develop this condition (DKA) within days of insulin being stopped & some may need to continue on low-dose once-daily doses of long-acting basal insulin through the final days.

• **Questions ??**

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