The Non-Clinical Side of Hospice Relatedness Determinations: Substantiating Your Decisions to Stand Up to Government Scrutiny

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Goals

• Understand the legal framework for relatedness decisions and implications of present guidance
• Explore the government’s key tenets regarding relatedness determinations and coverage
• Learn methods for substantiating and defending challenges to relatedness determinations and their implementation
Preface

- This presentation is meant to provide a general review of non-clinical issues regarding making and implementing determinations regarding the items/services related to a patient's terminal illness
- This presentation does not constitute legal advice, and is not intended to take the place of legal advice

What Would You Do?
Hypothetical

• If the government called today, how would you answer these questions?
  – What is your process for determining what is related to the terminal illness and related conditions?
  – How do you support determinations that an item or service is unrelated?
  – How do you communicate relatedness determinations to contracted providers furnishing the service?
  – Are contracted providers correctly implementing your decisions?
  – How do you communicate relatedness determinations to patients and families?

Hypothetical (cont.)

• If the government called today, could you prove your answers through documentation?
  – Process
    • What are your policies and procedures? How do you demonstrate that they are followed in making relatedness determinations?
  – Clinical Support
    • Who makes the decision? What is documented? Who documents it?
  – Communication
    • How are determinations communicated to contracted providers, to patients/families? Who communicates it? What training do they have? How is the communication documented?
  – Implementation
    • How are you ensuring that your relatedness determinations are being correctly acted upon? Can you prove it?
Why Are We Talking About Relatedness Now (And Will Be For Years To Come!)?

Why Are We (And Will Continue) Talking About Relatedness?

- Money
  - Concerns about hospices cost shifting; duplicate payments
  - Concerns about hospices narrowly interpreting the benefit
    - "Terminal illness" and "related conditions"
  - Concerns about hospices avoiding the difficult patient conversations regarding efficacy of medications
How Did We Get Here? The Relatedness Build-Up

• It didn’t just happen; the government has been gathering “facts” for years
  – 2007 OIG Report: Reviewed and determined pharmacy billed Medicaid for drugs that the hospice indicated were related to the terminal illness, and recommended collecting repayment from the pharmacy
  – 2012 OIG Report:
    • Culmination of Work Plan projects from 2007 - 2012
    • Review of payment data indicated Medicare Part D potentially paid about $33.6 million for drugs that may have been related to hospice patients’ terminal illnesses and therefore covered by hospice in 2009
    • Also found that Part D plan sponsors did not have mechanisms in place to identify potentially related drugs

And It Is Not Over: The Relatedness Build-Up Continues

• The government continues to invest in “data” to support its efforts
  – Medicare paid approximately $1 billion “outside” the hospice benefit in 2012 while paying hospices $15 billion “inside” the benefit
  – Specifically, Medicare paid approximately $710 million to Parts A and B
  • About $372 million for physician and NP services
  • About $330 million paid by Part D
  • About $290 million to hospitals (ED, inpatient, observation)
  • About $49 million to DME suppliers
  – Diagnoses with highest costs “outside” the benefit include non-Alzheimer's dementia, debility, and failure to thrive (see the connection to other regulatory changes?)
So Where Are We Now? A Focus On Drugs

- Medicare Part D
  - Plan sponsor audits of pharmacy claims for hospice patients
  - Recent barrage of CMS guidance regarding potential "duplicate payments" for drugs
    - December 2013 memo: Proposed guidance for hospices and Part D plans
      - Proposed prior authorization("PA") process for any drugs billed to Part D for hospice patients
      - Hospice could not give the reason for a drug being unrelated, only the prescriber or hospice physician
      - Clarified that drugs that are related but not medically necessary are the patients' responsibility

So Where Are We Now? A Focus On Drugs (cont.)

- Medicare Part D guidance (cont.)
  - March 2014 memo: "Final" guidance on Part D billing
    - Retained PA on any drug billed to Part D for a hospice patient
    - But, allowed hospice to provide information that drug was unrelated (not just physician)
  - July 2014 memo: "Interim" guidance on Part D billing (effective October 1, 2014)
    - PA only for 4 common end-of-life care drugs (analgesics, antinauseants, laxatives, antianxiety drugs)
    - Hospice can inform Part D plan of unrelated drugs at the time of election so the Part D plan could override the PA, allowing unrelated drugs to be filled more timely
    - Have heard reports of inconsistency in implementing PA process among Part D plans
So Where Are We Going?
Extending Beyond Drugs to Other Costs "Outside" The Benefit

• Scrutiny and enforcement likely to extend to other costs billed to Medicare
  – Hospital services and inpatient stays
  – Physician billing
  – DME

So Where Are We Going?
Extending Beyond Drugs to Other Costs "Outside" The Benefit (cont.)

• And the enforcement is already here
• Medicaid
  – Audit hospices for payments Medicaid made to pharmacies
• RAC Audits
  – Auditing contracted provider claims that may be related to hospice patients' terminal illnesses
    • DME
    • Inpatient and outpatient services
    • Physician Part B claims
So Where Are We Going?  
Connecting the Dots

- All this scrutiny and enforcement is leading to (and has already led to) new and forthcoming regulatory changes
  - 2014 Wage Index
    - Reminder that all related conditions must be reported on claims
    - Each fill of prescription drugs must be reported on claim
    - GIP visits must be reported in 15-minute increments
  - 2015 Wage Index
    - Requested comments on very broad definitions of "terminal illness" and "related conditions"
    - Attending physician must be identified on election and change must be completed in writing signed and dated by patient
  - Anticipate additional claims reporting data, possibly based on findings from Abt Report (e.g., DME, outpatient services, etc.)

What Are The Government's Expectations for Hospices?
The Government's Key Tenets

1. Broad coverage: "Virtually all" items and services are related
2. Relatedness is a physician driven, individualized, supported and documented determination
3. Mechanisms to prevent billing errors

Relatedness Determinations: 4 Buckets

Covered Hospice Services: Standard

- Coverage of “related” services codified in statute and regulations
  - Social Security Act (“SSA”): Waiver of Medicare coverage is limited to those items and services related to the condition "with respect to which a diagnosis of terminal illness has been made"
  - Medicare Hospice Regulations: To be covered by the hospice, services must be (42 C.F.R. 418.200):
    - Reasonable and medically necessary
    - For the palliation and management
    - Of (i.e., related to) the “terminal illness” and "related conditions"

The Interpretation of the Coverage Standard

- CMS’s expectation is that it would be rare for an item or service not to be covered by a hospice
  - An item or service needs to be “completely unrelated” to the terminal illness and related conditions (CMS commentary to the 1983 proposed rule on the Medicare Hospice Benefit; December 6, 2013 memo to Part D plans and hospices)
  - Support with 1983 rule commentary that “virtually all” services would be covered by hospices as related to the terminal illness and related conditions
The Interpretation of the Coverage Standard (cont.)

• Interpretation fails to acknowledge changes since 1983:
  – Then: In 1983 hospices cared mostly for cancer patients, there were fewer drugs and no drug coverage outside the benefit
  – Now: Hospice patients often have non-cancer diagnoses, are older with many chronic conditions for which there are more drug treatments available
• CMS's expectation is that non-coverage will be rare because the hospice will discontinue treatments:
  • The role of the attending physician?
  • Must patients choose a palliative approach to all conditions?

Covered Hospice Services: "Terminal Illness" and "Related Conditions"

• Coverage standard uses the terms "terminal illness" and "related conditions" but these are undefined
  – Only "terminally ill" is defined:
    • SSA: An individual who "has a medical prognosis that the individual's life expectancy is 6 months or less" (SSA s. 1861(dd)(3)(A))
    • Medicare Hospice Regulations: An individual who "has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course" (42 C.F.R. s. 418.3)
The Interpretation of the Standard: "Terminal Illness"

- CMS offered a definition of “terminal illness” in FY 2015 Hospice Wage Index
  - Very broad
  - Nearly impossible to apply in practice
    - “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”

The Interpretation of the Standard: "Related Conditions"

- CMS offered a definition of “related conditions” in FY 2015 Hospice Wage Index
  - Again very broad
  - 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.
Process: Physician-Driven Determinations

- CMS commentary indicates physicians should make relatedness determinations
  - Acknowledge relatedness decisions require "clinical expertise and judgment" of the hospice physician (Commentary to Final FY 2014 Wage Index)
  - Physician involvement in Part D PA process

Process: Individualized Determinations

- Decision should be made on a "case-by-case basis" (CMS commentary to the 1983 final rule on the Medicare Hospice Benefit)
- Based on "the unique physical condition of each terminally ill individual" (CMS commentary to the 1983 final rule on the Medicare Hospice Benefit)
Process:
Documentation and Support

- CMS indicates physicians should document if they determine an item or service is not related
- Conflicting guidance on what documentation will be sufficient
  - "Clear evidence" needed to show that a service is unrelated (CMS commentary to Final FY 2014 Wage Index)
  - Little guidance as to what "clear evidence" would consist of
  - "[A] statement indicating the drug is unrelated to the terminal illness and related conditions is sufficient" (July 2014 CMS memo to Part D plan sponsors and hospices)
- But note that "[h]ospices are expected to maintain a record of the clinical basis for the statement that a drug is unrelated"

Mechanisms to Prevent Billing Errors

- The 2012 OIG report found Part D plans had no mechanisms to prevent billing for related drugs
- Then CMS began implementing measures to identify and prevent potential billing errors:
  - Initiated "return to provider" for claims with debility, AFTT, etc. and reiterated that all related conditions must be reported on claims (2014 Wage Index)
  - Required hospices to report all drugs on claims (2014 Wage Index)
  - Instituted PA for drugs (Various memos to hospices and Part D plans)
What Can You Do Now?

Hypothetical

- If the government showed up tomorrow, how could you improve your answers to the following questions?
  - What is your process for determining what is related to the terminal illness and related conditions?
  - How do you support determinations that an item or service is unrelated?
  - How do you communicate relatedness determinations to contracted providers furnishing the service?
  - Are contracted providers correctly implementing your decisions?
  - How do you communicate relatedness determinations to patients and families?
Process: Considerations

- Real-time decision-making
- Affirmative determinations for both related and unrelated items and services
- Consistent process regardless of the treatment cost
- Consider which physician will be primary decision-maker regarding relatedness
- Physician consultation with IDT and others (e.g., pharmacist)

Process: Considerations (cont.)

- Consider quality assurance measures
  - May want higher level of review for non-coverage of expensive, unique or recently scrutinized services (e.g., analgesics, laxatives, antinauseants, antianxiety)
    - Medical director (if IDT physician makes original determination)
    - Quality review committee
    - Others, with physician
  - Re-evaluate relatedness decisions periodically
Clinical Support: Considerations

• Review standards to consider:
  – "Clear evidence"
  – "Substantial evidence" – Reasonable person would accept evidence as supporting the determination
  – Reasonable degree of clinical certainty
• Documentation takes into account the patient’s particular terminal illness and “related conditions”
• Consider whether coverage determinations are consistent with diagnoses listed on claim
• Having a formulary is not enough

Clinical Support: Considerations (cont.)

• Who is documenting decision?
  – Proof that physician is making determination
  – Role of documentation by others, such as nurse, PBM
• How is decision documented?
  – Conclusory statement vs. narrative explanation
  – Standardized form may help probe reasoning and encourage thorough documentation
• Is there additional clinical support?
  – Assessments, labs, diagnostics
    • Obtaining clinical support vs. patient palliative care goals
  – Journal articles, reference texts
• Do you revisit your related/medical necessity determinations?
  – They may change
Communication: Considerations

- Communicating relatedness/coverage decision to whom:
  - Patient and family
  - Facilities (e.g., nursing home, assisted living)
  - Contracted providers (e.g., PBM, pharmacy)
  - Part D plan sponsors – PA process
- Consider how to document communication
  - Initial determinations of coverage
  - Changes to prior determinations
  - Determinations of coverage for new services

Communication: Considerations (cont.)

- Consider how to distinguish between "not related" vs. "not medically necessary" in communication
- Written policy/procedure
- Educate staff and retain copies of training materials
Implementation: Considerations

- Responsibilities for ensuring coverage decisions regarding "related" and "unrelated" are correctly implemented

- Types of errors:
  - Contracted provider bills patient or third party payor for "related" items or services
  - Contracted provider bills hospice for "unrelated" items or services
  - Contracted provider bills third party payor for "unnecessary" items or services

Implementation: Considerations (cont.)

- Beyond communication of coverage decision, consider implementing safeguards at each level:
  - The patient/family
    - Verbal communication (e.g., explain "related" coverage at admission)
    - Written communication (e.g., explain patient's role in admission materials)
    - Specific written information (e.g., care plan with coverage determination at home)
Implementation: Considerations (cont.)

• The facility
  – Written notice of relatedness decisions (e.g., care plan)
  – Reminders (e.g., medical record stickers)
  – Contract obligations (e.g., confirm with hospice item or service "unrelated" before arranging, providing or billing)

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Implementation: Considerations (cont.)

• Contracted providers
  – Document communication of:
    • Hospice status
    • Coverage determinations
  – Contract obligations (e.g., confirm with hospice item or service "unrelated" before providing or billing)
  – Education

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Implementation: Considerations (cont.)

• Consider ways to audit and monitor implementation
  - Look for anomalies in cost or number of services
  - Spot check billing
    • New patients
    • Change in plan of care
  - Target monitoring on "root causes"

Implementation: Considerations (cont.)

• Work with payment processors (e.g., PBM) on monthly activity reports
• Work with contracted providers (e.g., pharmacies, hospitals, DME providers) to return duplicate payments
  - Error if billed "related" item or service to third party payor
  - Payment for "related" item or service governed by contract
Implementation: Considerations (cont.)

- Appeals Process
  - Expect independent reviewers for Part D
- Coordinate appeals of challenges to hospice’s "unrelatedness" determinations
  - If contracted provider billed as "unrelated," recoupment may be sought from contracted provider, how do you support them?

A Few Things to Remember…
Remember…

1. Accept that this is the "new normal"
   - Regulatory challenges, scrutiny and focus on cost reduction
2. The statutory limits on waiver exist for a reason, so "virtually all" cannot mean "all"
   - Relatedness and medical necessity is driven by physician judgment and there is a place for a thoughtful process and decision-making
3. Be prepared to be challenged and be able to "prove it up"

Remember… (cont.)

4. Prepare staff to have difficult conversations and do it well
   - It's not just about relatedness, but also "medical necessity"
5. See the big picture – Know how your data aligns with your decision-making
   - How many diagnoses are on the claim form?
   - How do these align with your coverage determinations?
   - How do these align with your physician's certification and physician narrative?
Questions?

Thanks!

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Selected Resources
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Selected Resources (cont.)

- CMS Memorandum to Part D Plan Sponsors and Hospices, "Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice," July 18, 2014
- CMS Memorandum to Part D Plan Sponsors and Hospices, "Part D Payment for Drugs for Beneficiaries Enrolled in Hospice – Final 2014 Guidance," March 10, 2014
- CMS Memorandum to Part D Plan Sponsors and Hospices, "Part D Payment for Drugs for Beneficiaries Enrolled in Hospice – Request for Comments," Dec. 6, 2013
- CMS Memorandum to Part D Plan Sponsors, "Preventing Part D Payment for Hospice Drugs," Oct. 22, 2010
- CMS, Change Request 8358, "Additional Data Reporting Requirements for Hospice Claims," Reissued January 31, 2013
Selected Resources (cont.)

- CMS, Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice (Proposed Rule), 79 Fed. Reg. 27823 (May 10, 2014)

- CMS, Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice (Final Rule), 79 Fed. Reg. 50452 (Aug. 22, 2014)

- CMS, Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform (Proposed Rule), 78 Fed. Reg. 27823 (May 10, 2013)

- CMS, Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform (Final Rule), 78 Fed. Reg. 48234 (Aug. 7, 2013)