2019 SMP/SHIP
NATIONAL CONFERENCE

Putting the "No" in Notice

Or a funny thing happened on the way to Washington

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Session Objectives

- Share a story about Elayne, a SHIP client
- Identify the procedural issues
  - Notice issues
  - Appeal issues
- Identify the systemic problems
- Address SHIP role in response to issues
  - Local SHIP, SHIP TA Center, ACL

SHIP's Statutory Charge:

42 USC §1395b-4(b)(2)(B),(H)

- …establish a system of referral to appropriate Federal or State departments or agencies for assistance with problems related to health insurance coverage (including legal problems)…
- …make recommendations concerning consumer issues and complaints related to the provision of health care to agencies and departments of the State government and the Federal Government responsible for providing or regulating health care.

Elayne's Case: An Overview

- Screening vs. diagnostic procedure
- Denial for a non-covered service
- Advance Beneficiary Notice (ABN)
- Administrative Law Judge (ALJ) decision
- Inadequate notice
- National Coverage Determination complaint
- Congressional testimony
- Bureaucratic barriers

Elayne’s Story: The Essentials

- Screening Colonography on Oct. 27, 2016
  - 74 year old beneficiary
  - Colonography
    - CT scan of colon, aka “virtual colonoscopy”
  - Tortuous Colon
    - Probably related to hysterectomy
    - No prior or current indications of colorectal cancer
  - Unsuccessful colonoscopy on record

Colonoscopy
Colon polyp
Light
Colonoscope
Lens
Irrigation
Instrument port
Light
Colonoscope

Elayne’s Story: Appeal Levels 1 & 2

- Medicare Summary Notice (MSN)
  - Denial sent on Feb. 16, 2017
  - Message 16.10: “Medicare does not pay for this service or item”
  - Beneficiary liability: $2,239.65
  - “Blind-sided”
- MAC redetermination letter
  - Denial affirmed on March 7, 2017
- QIC reconsideration letter
  - Denial affirmed on December 1, 2017

Larry Gets a Call

- Confusing QIC correspondence
  - "Medicare Physician Fee Schedule Database (MPFSDB) status indicator N=Not covered by Medicare based on statutory exclusion. These codes represent an item or service that is not in the statutory definition of physician services for fee schedule purposes. No payment can be made…."
  - Huh?
- Should I appeal to the ALJ?

Elayne’s Story: Appeal Level 3

- Administrative Law Judge (ALJ)
  - Telephone hearing
    - Medical necessity
    - Failure to issue Advance Beneficiary Notice (ABN)
- ALJ Notice of Decision letter
  - Unfavorable decision issued April 25, 2018
  - Statutory exclusion constraint
  - “It doesn’t make sense!”

Larry Calls Mike

- Advance Beneficiary Notice (ABN)?
  - When must providers ABNs?
  - Why did the ALJ decide that Elayne is liable?
- What does an "N code" mean?
- Should we take it to the next level?
  - Medicare Appeals Council (Council) review?
    - Part of the HHS Departmental Appeals Board
    - File within 60 days of ALJ decision

What's a Statutory Exclusion?

General Exclusions from Coverage

No payment can be made under Part A or Part B for certain items and services, when the following conditions exist:

- Not reasonable and necessary
- Not provided within United States
- Personal comfort
- Routine services and appliances
- Custodial care
- Cosmetic surgery
- Charges by immediate relatives or members of household
- Dental services
- Excluded foot care services and supportive devices for feet

What does “Not Reasonable & Necessary” Mean?

- National Coverage Determination (NCD)
  - CMS develops NCDs to describe the circumstances for Medicare coverage nationwide for a specific medical service procedure or device. NCDs generally outline the conditions for which a service is considered to be covered (or not covered)….
- Local Coverage Determinations (LCD)
  - An LCD is a determination by a Medicare Administrative Contractor (MAC) whether to cover a particular service on a MAC-wide, basis. Coverage criteria is defined within each LCD, including lists of procedure and diagnosis codes for which the service is covered or considered not reasonable and necessary.
- NCDs and LCDs are sometimes the basis for denials!

Research: A SHIP Competency

- Which coverage policy based on the "not reasonable & necessary" exclusion caused the coverage denial?
  - Was it in the MSN, QIC letter or ALJ notice of decision? NO!
- Where to turn?
  - Medicare Coverage Database
  - National Coverage Determination Manual
  - www.cms.gov

NCD 210.3 - Colorectal Cancer Screening Tests

- Nationally Non-Covered Indications
  - All other indications for colorectal cancer screening not otherwise specified in the Act and regulations, or otherwise specified above remain nationally non-covered. Noncoverage specifically includes:
    - (2) Screening computed tomographic colonography (CTC), effective May 12, 2009.

An Inconsistency

- What if the denial had been based on a Local Coverage Determination (LCD)?
  - MSNs identify the LCD and add this message:
    - We used a Local Coverage Determination to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN billing code for the "CPT/HCPCS Code") and send with information from your doctor. MSN Message 15.19, Claims Processing Manual
  - Erringer case (2001), Center for Medicare Advocacy

Adequate Notice?

- Denial Message Guidance
  - "Explanatory and Denial messages appear under the claims section of the MSN. Their purpose is to concisely communicate essential information to the beneficiary regarding claim determinations or to serve as an educational tool."
  - "All denied or reduced services must have an explanation."
    - *Claims Processing Manual, Chap. 21, §40*

What about the ABN?

- The Advance Beneficiary Notice of Noncoverage (ABN) is issued by providers, physicians, practitioners, and suppliers to Original Medicare beneficiaries in situations where Medicare payment is expected to be denied. The ABN is issued in order to transfer potential financial liability to the Medicare beneficiary in certain instances.
- Beneficiary owes nothing if provider fails to issue ABN when required; called "waiver of liability."

Limitation on Liability in Medicare

- The Limitation On Liability protections of §1879 of the Act apply only when a provider believes that a Medicare covered item or service may be denied in a particular instance because it is not reasonable and necessary under §1862(a)(1).... §1879 of the Act requires a provider to notify a beneficiary in advance when s/he believes that items or services will likely be denied as not reasonable and necessary.... If such notice (in the form of an ABN) is not given, providers may not shift financial liability to beneficiaries for these items or services if Medicare denies the claim. *Claims Processing Manual, Chapter 30, §50.2.1*

But…

- ABNs are not required for care that is either statutorily excluded from coverage under Medicare (i.e. care that is never covered) or most care that fails to meet a technical benefit requirement…. However, the ABN can be issued voluntarily … for care that is never covered such as:
  - Care that fails to meet the definition of a Medicare benefit
  - Care that is explicitly excluded from coverage under §1862 of the Social Security Act. Examples include:
    - Services for which there is no legal obligation to pay;
    - Services paid for by a government entity other than Medicare (this exclusion does not include services paid for by Medicaid on behalf of dual-eligibles);
    - Services required as a result of war;
    - Personal comfort items;
    - Routine eye care; Dental care; and
    - Routine foot care.

An NCD Complaint?

- 42 CFR §426.100, et. seq.
  - Outlines appeal procedures to challenge “reasonableness” of LCDs and NCDs
  - Departmental Appeals Board (DAB) reviews statements from treating physician and aggrieved party; considers clinical or scientific evidence
  - Filing deadline: 120 days of initial determination notice.

NCD Complaint: Research

- Decision Memo on Screening CTC in 2009
  - "[A] pivotal, overarching concern is the generalizability of these main study results to the Medicare population. The mean age of participants in these studies (57.8 years, 57 years and 58.3 years) … was considerably younger than the Medicare aged population (mean age of 75.5 years in 2007), not including disabled beneficiaries…."
  - "The evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test…. CT colonography for colorectal cancer screening remains noncovered."
    - Decision Memo issued by CMS Coverage and Analysis Group

NCD Complaint: Partnerships

- Mayo Clinic
  - Guidelines for Prevention & Surveillance of Colorectal Cancer
  - Treating physician statement
- American College of Radiology
  - Background on administrative advocacy effort
  - Encouragement & feedback

NCD Challenge: Building a Case

- What's missing in CMS' Coverage Analysis?
  - "The Difficult Colonoscopy," a journal article posted to NIH's website
    - Women and colorectal cancer screening
  - Preventive Services Task Force (USPSTF) revised colorectal cancer screening recommendation in 2016
  - Anecdotal information

NCD Complaint: Presenting the Case

- Scientific: "The female colon is longer, with a transverse colon that is, on average, 8 cm longer than the male colon, and that more frequently dips into the pelvis. The female colon is therefore more likely to be acutely angulated and tortuous." *Canadian Journal of Gastroenterology*
- Clinical: Mayo Clinic colorectal cancer screening guidelines.
- Personal: "After my painful experience with screening colonoscopy in 2006, I would not undergo the procedure again unless I absolutely needed it to remove pre-cancerous growths. Without CTC, I would have avoided colorectal cancer screening altogether." *Aggrieved party statement*
- Policy: "About one-third of eligible adults in the United States have never been screened for colorectal cancer, and offering choice in colorectal cancer screening strategies may increase screening uptake." *USPSTF 2016*

NCD Complaint: Results

- "Denial of Request for Extension of Time"
  - "…the applicable regulations do not expressly authorize an extension—for "good cause" (or any other reason) for filing a Complaint."
  - The DAB dismissed the complaint and made no decision on the merits
- CMS' failure to identify NCD 210.3 prevented Elayne from meeting the 120 day filing deadline
  - Denied her statutory right to DAB review
  - Violated her right to due process under the Constitution

Then some funny things happened…

- Congressional Testimony
  - Elayne invited to testify!
  - CT Colonography Screening for Colorectal Cancer Act (S.3465, HR1298) introduced in last Congress
- Call with CMS' Division of Appeal Operations
  - "No problem here. Providers notify patients about non-covered services."

The Problem is Real

- MSNs denials: No notice about NCDs
- Appeal letters: No notice about NCDs
- ABNs: Optional for statutory exclusions
  - "The voluntary ABN serves as a courtesy to the beneficiary in forewarning him/her of impending financial obligation."
    - *Claims Processing Manual, Chapter 30 §50.3.2*
  - Not required for denials based on LCD & NCD
    - Items and services viewed as "never covered"

What's Next?

- Establish a protocol for referrals and recommendations from SHIPs:
  - To appropriate Federal departments or agencies (e.g., CMS, OMHA) for assistance with problems related to health insurance coverage (including legal problems)
  - To implement SHIP's statutory directive

Our Test Case

- **42 CFR §405.921 - Notice of initial determination.**
  - (a) (1) The notice must be written in a manner calculated to be understood by the beneficiary…
  - (a)(2) Content of the notice. The notice of initial determination must contain all of the following:
    - (i) The reasons for the determination, including whether a local medical review policy, a local coverage determination, or national coverage determination was applied.

Rules in Conflict?

- Mandatory ABNs
  - The following provisions necessitate delivery of the ABN:
    - §1862(a)(1) of the Act (not reasonable and necessary);
      - *Claims Processing Manual, Chapter 30, §50.3.1*
- Voluntary ABNs
  - ABNs are not required for care that is statutorily excluded from coverage under §1862 of the Social Security Act (i.e. care that is never covered) ….
      - *Claims Processing Manual, Chapter 30, 50.3.2*

Resources

- For help with confounding cases and quagmire questions:
  - medicarehelp@shiptacenter.org
- For Medicare's Manuals and Coverage Policies
  - Internet Only Manuals (IOM)
  - Medicare Coverage Database
    - Search for LCD, NCD, Coverage Analysis, etc.

Questions??

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