Clinical Trials:
Top 5 Reimbursement Issues

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Disclosures

• I do not intend to discuss an off-label use of a product during this activity.

• I have not had any relevant financial relations during the past 12 months to disclose.

Objectives

• Differentiate between third party payers: identify those that have, or, are mandated to have, reimbursement policies friendly to clinical trial and those that don’t.

• Summarize the process to generate a budget synchronized with a Medicare Coverage Analysis (MCA)
Objectives Cont..

- Identify negotiating strategies that may be successful in seeking coverage approval for patients seeking to enroll in a cancer clinical trial.
- Analyze the “current state” of your organization’s culture: Identify strategies to become more successful in seeking reimbursement for routine costs of cancer care provided within a clinical trial protocol.

Top 5 Reimbursement Issues:
As far as I’m concerned there is only one!

How do we help patients receive coverage from third party payers, for the routine costs of cancer care, when care is provided through a clinical trial protocol?
What are your top Issues?

• Take a few minutes and write down your most pressing concern / issue
• We’ll discuss some of these at the end of the talk and see if we can identify strategies to minimize the problem

The list (My* Top 5)

*With a little help from my friends at the Siteman Cancer Center

1. Budget coordinated with a Medicare Coverage Analysis (MCA)
2. Affordable Care Act: what happens now
3. Securing pre-approval from payers: How do we respond “We don’t cover experimental TX”
4. Organization culture: can it make a difference in reimbursement? YES!!!
5. Translational and Genomic Research: How fast will the costs of these gains become “routine”
#1 The Budget & MCA

- Budgets accomplish several objectives
  - PIs evaluate procedures & determine which are “routine care” and which are research
  - Discrepancies between site & sponsor’s determination of routine care identified and reconciled
  - Research procedures budgeted
  - Procedures identified as routine costs validated via a MCA

Why is the Budget / MCA such a Big Deal

- Strategy should be to expect third party payers to cover the **routine cost of cancer care** for patients enrolled in a clinical trial.
- This expectation is based on
  - Medicare’s National coverage decision
  - ACA language
  - State Laws mandating Clinical Trial coverage

*Slides that follow with legal detail are for reference and will not be discussed in detail*
What are “routine patient costs”?

“Routine patient costs” include all items and services consistent with the coverage provided in the plan that is typically covered for a qualified individual who is not enrolled in a clinical trial. Routine patient costs do not include 1) the investigational item, device or service itself; 2) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and 3) a service that is clearly inconsistent with the widely accepted and established standards of care for a particular diagnosis. Plans are not required to provide benefits for routine patient care services provided outside of the plan’s network area unless out-of-network benefits are otherwise provided under the plan.

Most clinical trials involve drugs or devices, and those drugs or devices are generally provided without cost during the trial period.

National Coverage Decision:

Medicare Clinical Trial Policies

The current Clinical Trial Policy can be found by clicking the link below (under Related Links inside CMS) labeled “Current Policy - July 2007 NCD”. Clinical trials are key to understanding the appropriate use of medical interventions of all types and informing payers about what services to cover. Only a very small percentage of American seniors participate in clinical trials, although the elderly bear a disproportionate burden of disease in the United States.

On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials." The Health Care Financing Administration (now the Centers for Medicare & Medicaid Services, or CMS) responded to the executive order with the clinical trial policy national coverage determination (NCD) issued on September 19, 2000. The 2000 policy may be found through the link below labeled, "2000 Clinical Trial Policy".

CMS began a reconsideration of the 2000 NCD to address several issues about the policy in July 2006. We issued a final decision memorandum on July 9, 2007 that preserves the status quo of the 2000 CTP with the exception of the following changes:

- Clarification that items that are covered outside the trial are covered inside the trial
- Addition of coverage of clinical trials under an NCD (Coverage with Evidence Development)
- On July 19, 2007, CMS began a reconsideration of the 2000 CTP which proposed that the CTP be renamed the Clinical Research Policy and that a process be established that clinical research study sponsors/principal investigators must use to certify to CMS that their study meets the scientific and technical standards described in the proposed policy.
- Based on a thorough review and consideration of comments from the public and the recent enactment of the Food and Drug Administration Amendments Act of 2007 (FDA AA 2007), the Agency decided that no change to the July 9, 2007 policy was appropriate at the time. On October 17, 2007, CMS closed the reconsideration with a final decision memorandum that retained the July 9, 2007 policy.
States with legislation requiring payers to cover the routine cost of a clinical trial

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http://www.cancer.gov/clinicaltrials/learningabout/payingfor/laws#Anchor-Ma-60501

Bold Underscored states have laws supporting cancer clinical trials

#2 Affordable Care Act

- Great news “Your covered” but there is some bad news
- The Act includes similar language as the Medicare National Coverage Decision
- The bad news is that current plans are “grandfathered in” as is.
- All in all, This act will increase the number of payer that are clinical trial friendly
Affordable Care Act


- Coverage for Individuals Participating in Approved Clinical Trials
- In general, PHS Act section 2709(a), as added by the Affordable Care Act, states that if a group health plan or health insurance issuer in the group and individual health insurance market provides coverage to a qualified individual (as defined under PHS Act section 2709(b)), then such plan or issuer: (1) may not deny the qualified individual participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; (2) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and (3) may not discriminate against the individual on the basis of the individual’s participation in the trial.
  - A qualified individual under PHS Act section 2709(b) is generally a participant or beneficiary who is eligible to participate in an approved clinical trial according to the trial protocol with respect to the treatment of cancer or another life-threatening disease or condition; and either: (1) the referring health care professional is a participating provider and has concluded that the individual’s participation in such trial would be appropriate; or (2) the participant or beneficiary provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate.

#3 Securing 3rd party pre-approval

- How do we respond - “We don’t cover experimental treatment”
  - Clinical trials are not experimental
  - Language in CMS and the ACA support this stance
  - Question to ask: Does your client’s policy cover the routine cost of cancer care?

- What does the NCI have to say?
How to Manage Insurance Issues

- There are several steps you can follow to deal with insurance coverage issues when deciding to enter a clinical trial. Here are some things to try:
  - **Work closely with your doctor.** Ask your doctor if there is someone on his or her staff who can help with health insurance issues. This person might be a financial counselor or research coordinator. Or, this person might work in the hospital’s patient finance department.
  - **Work closely with the research coordinator or research nurse.** Ask the research coordinator or nurse if other patients have had problems getting their health insurance companies to cover their costs. If so, you might ask the research coordinator or nurse for help in sending information to your health insurance company that explains why this clinical trial would be appropriate for you. This package might include:
    - Medical journal articles that show possible patient benefits from the treatment that is being tested
    - A letter from your doctor that explains why the trial is medically necessary. Or a letter from the researcher that explains the clinical trial.
    - Support letters from patient advocacy groups
  - **Helpful Hint:** Be sure to keep your own copy of any materials that are sent to your health insurance company.

Work with your health insurance company.

- If your doctor does not have a staff person to help with insurance issues, call the customer service number on the back of your health insurance card. Ask to speak to the benefit plan department.
- The following are important questions:
  - Does the health insurance plan cover routine patient care in clinical trials?
  - If so, is an authorization required? An authorization means the health insurance company will review information about the clinical trial before deciding to cover it.
  - If your health insurance company requires an authorization, what information do you need to provide? Examples might include copies of your medical records, a letter from your doctor, and a copy of the consent form for the trial. (It is a good idea to get the name and contact information of the person you are talking to.)
  - If an authorization is not required, you don’t have to do anything else. But, it is a good idea to request a letter from your health insurance company that states an authorization is not needed for you to take part in the clinical trial.
Helpful Hint: Every time you call your health insurance company, make a note of who you are speaking with, the date, and the time.

- Understand the costs related to the trial. Ask your doctor or the trial's contact person about the costs that must be covered by you or your health insurance.
- Work closely with your employer's benefits manager. This person may be able to help you work with your health insurance company.
- Give your health insurance company a deadline. Ask the hospital or cancer center to set a target date for when you should start treatment. This can help to ensure that coverage decisions are made promptly.
- What you can do if your claim is denied after you begin taking part in a trial
  - If your claim is denied, contact the billing office for help. The billing manager may know how to appeal your health insurance company's decision.
  - You can also read your health insurance policy to find out what steps you can follow to make an appeal. Ask your doctor to help you. It might help if he or she contacts the medical director of your health plan.

#3 Securing Pre-approval

- The patient pamphlet from cancer.gov suggests a lot of common sense strategies
  - Work closely with your doctor
  - Work closely with the research coordinator or research nurse
  - Work with your health insurance company
  - Work closely with your employer's benefits manager.
#4: Organization Culture:
Can it make a difference in reimbursement

• Do you believe! Do you really believe
• If you really believe then you should be prepared to advocate for your patients.
  – Is your organization one of those mentioned in the pamphlet that this sentence refers to
    • If your doctor does not have a staff person to help with insurance issues, call the customer service
• Will your physicians call the medical advisor of the patients health plan

#4: Organization Culture (Cont.)

• Do you routinely share scientific articles to bolster your case
• What about the plan for your own staff Our University and partner hospital had language that inhibited enrollment in a clinical trial.
  – Education of HR executives who relied on insurance experts plans paid big results
  – So did the experience of a few senior leaders who experienced first hand cancer care of loved ones
#4: Organization Culture (Cont.)

- **Self Assessment**
  - Is participation in clinical trials a component of your mission statement?
  - What resources are available to patients
  - Is participation rates monitored and discussed?
  - How do you rate your organization's commitment to supporting enrolment in clinical trials

#5 Translational & Genomic Research:

How fast will these costs become *routine*?

- This is coming fast a furious
- Probably hitting academic centers harder as this technology rapidly advances
- Published early success probably the best hope for broad coverage
- Our Medical director has called the CEOs of patients employers advocating coverage
Who has an issue not covered in this discussion

Objectives revisited

• Third party payers, Self funded plans require the most effort
• A budget the clearly differentiates between the routine costs and research costs and is reviewed by (MCA) is a great asset in working to secure insurance approval.
Objectives Cont..

- Staff who routinely assist patients in securing clinic trials coverage approval build skills and relationships that help secure enrollment coverage.

- A critical skill is the ability to counter “we don’t cover experimental care”.
  - Ok but you do cover the routine costs of cancer care don’t you? That’s all we are asking you to do. The study will cover all the research expense all we want for you to cover is what you would cover for routine care

- Physician support is critical