RESEARCH
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HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

Medicare Coverage Analyses:
The Nuts and Bolts of Building and Conducting a Coverage Review

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AGENDA

- Introduction to Medicare Coverage Analyses (MCA)
- Creating an MCA document
- Finding supporting information
- Who is the right person to create MCA's?
- Using an MCA

"Plans are only good intentions unless they immediately degenerate into hard work"

— ***Peter Drucker,*** *writer, management consultant, self-described "social ecologist"*

Introduction to Medicare Care Coverage Analysis

- In September 2000, CMS issued a National Coverage Decision (NCD) which extended Medicare coverage to "routine costs" of "qualifying" clinical trials, as well as "reasonable and necessary" items and services used to diagnose and treat complications from participating in clinical trials
- In July 2007, the NCD was renamed the Clinical Trial Policy (CTP) and included some modifications:
  - Payment for the investigational item if it is covered outside of a trial; and
  - Coverage of the trial items and services if CMS issues a separate NCD using Coverage with Evidence Development (CED)
- The NCD explicitly states that all other Medicare rules apply
  - Items that fall under a non-coverage decision are not covered
  - Items that do not fall into a Medicare benefit category are not covered
- What are the key questions to ask to determine if patient care costs in a clinical trial are billable to Medicare?
  - Is it a qualifying clinical trial?
  - Are the items and services routine costs?
  - Are the routine costs reasonable and necessary? (i.e., does Medicare generally cover the services outside a clinical trial?)

Introduction to Medicare Care Coverage Analysis

- A Coverage Analysis (CA) is a systematic review of research-related documents to determine the qualifying status of the study per CMS rules and the billing status of the items and services provided to the research subjects over the course of the research study
- Why is it important to perform a CA?
  - Growing focus of attention from CMS
  - Medicare rules tend to set the trend for the Payor industry
  - Almost every study has the potential to enroll for Medicare patients as participants
  - Double billing or improper billing to Medicare can result in fines, sanctions, or suspension
  - Attention to accurate budgeting to ensure appropriate use of research dollars
  - Assurance that all research dollars are captured (under billing is as or more common than over billing)

Creating MCA's

- From Simple to Complex
- Determining the qualifying nature of a clinical trial
- Eliminating sponsor or grant-supported items and services
- Eliminating items and services promised for free in the ICF
- Establishing routine-care determinations
- Using National Coverage Determinations and Local Coverage Determinations to establish coverage precedence.
- Using non-coverage determinations to establish precedence.

A Simple Qualifying Coverage Analysis Algorithm

Following the CMS Clinical Trials Policy:

1. Does the trial investigate a covered Medicare Benefit?
2. Does the trial have **therapeutic intent?**
3. If therapeutic intent, are subjects enrolled with diagnosed disease or are healthy subjects used as a control group?
4. Is this a "deemed" trial by CMS standards? Must meet one of these criteria:
   - Funded by NIH, CDC, AHRQ, CMS, DOD, or the VA
   - Supported by centers and/or cooperative groups which are funded by one of the above listed agencies
   - Conducted under an IND reviewed by the FDA
   - IND exempt
   - Trials covered under Coverage with Evidence Development (CED).

- How and where are these answers being documented?
- What are the Standard Operating Procedures around trials that fall out of this Qualifying Analysis?

Therapeutic Intent Quandary

- To qualify for Medicare reimbursement, trials must have therapeutic intent (TI) and not be designed exclusively to test toxicity or disease pathophysiology
- This is a gray area of the CTP and is not well defined
- June 2006 Conference: At Forum on Regulation of the Association of Academic Health Centers (AAHC), CMS official states that in order to meet the therapeutic intent standard, the ***"primary objective" of the research study must be measurement of therapeutic benefit***
- December 2006 MedCAC Hearing: "…there is in general the assumption that ***many Phase Ones, if not most Phase Ones, currently aren't covered in the clinical trial policy***." Steven Phurrough, MD, Director of CMS Coverage & Analysis Group (CMS Transcript, p. 182)
- August 2007 Open Door Forum: [In response to a question on the therapeutic intent standard] "For those trials that are currently under way, they will have to live under whatever confusion they think there is around the current policy, the 2000 and the July 9th policy, and we will not attempt to clarify that any more than it is currently clarified." Dr. Phurrough (CMS Audio recording)

Sample MCA form

	Visit 1	Visit 2	Visit 3	Visit 4
CBC				
Chem 7				
Chest X-ray				
Head CT				
ECG				
PK sampling				
Study Drug				
Study Drug Administration				

Sample MCA form

Eliminating sponsor or grant-supported items and services

	Visit 1	Visit 2	Visit 3	Visit 4
CBC	**RESEARCH**			
Chem 7	**RESEARCH**		**RESEARCH**	
Chest X-ray	**RESEARCH**			**RESEARCH**
Head CT		**RESEARCH**	**RESEARCH**	
ECG				
PK sampling	**RESEARCH**	**RESEARCH**	**RESEARCH**	**RESEARCH**
Study Drug	Non-Billable	Non-Billable	Non-Billable	Non-Billable
Study Drug Administration				

Sample MCA form

•Eliminating items and services promised for free in the ICF

	Visit 1	Visit 2	Visit 3	Visit 4
CBC	*RESEARCH*			
Chem 7	*RESEARCH*		*RESEARCH*	
Chest X-ray	*RESEARCH*			*RESEARCH*
Head CT	**ICF Research**	*RESEARCH*	*RESEARCH*	**ICF Research**
ECG				
PK sampling	*RESEARCH*	*RESEARCH*	*RESEARCH*	*RESEARCH*
Study Drug	*Non-Billable*	*Non-Billable*	*Non-Billable*	*Non-Billable*
Study Drug Administration				

Sample MCA form

Establishing routine-care determinations

	Visit 1	Visit 2	Visit 3	Visit 4
CBC	*RESEARCH*	[redacted]	[redacted]	[redacted]
Chem 7	*RESEARCH*	[redacted]	*RESEARCH*	[redacted]
Chest X-ray	*RESEARCH*	[redacted]	[redacted]	*RESEARCH*
Head CT	**ICF Research**	*RESEARCH*	*RESEARCH*	**ICF Research**
ECG	[redacted]	[redacted]	[redacted]	[redacted]
PK sampling	*RESEARCH*	*RESEARCH*	*RESEARCH*	*RESEARCH*
Study Drug	*Non-Billable*	*Non-Billable*	*Non-Billable*	*Non-Billable*
Study Drug Administration	[redacted]	[redacted]	[redacted]	[redacted]

Finding Supporting Information

- Establishing routine-care determinations
  - Use National therapeutic groups and associations
  - Standardize this list for repeated use on similar trials
  - Use peer-reviewed journal articles
- Using National Coverage Determinations and Local Coverage Determinations to establish coverage precedence.
  - **http://www.cms.hhs.gov/mcd/search.asp?from2=search.asp&**
  - **Individual FI/Carrier or MAC websites**
- Using non-coverage determinations to establish precedence.

Who is doing the MCA work?

- Helpful experiential background
  - Understanding of Clinical Trials Policy
  - Research coordination experience
  - Coding and billing background

What to do with MCA's

- Who should have access to the MCA's
- What is the research enterprise using them to do?
- Referencing the MCA for billing and validation

"It is always easier to talk about change than to make it"

- Alvin Toffler, *writer, futurist*

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