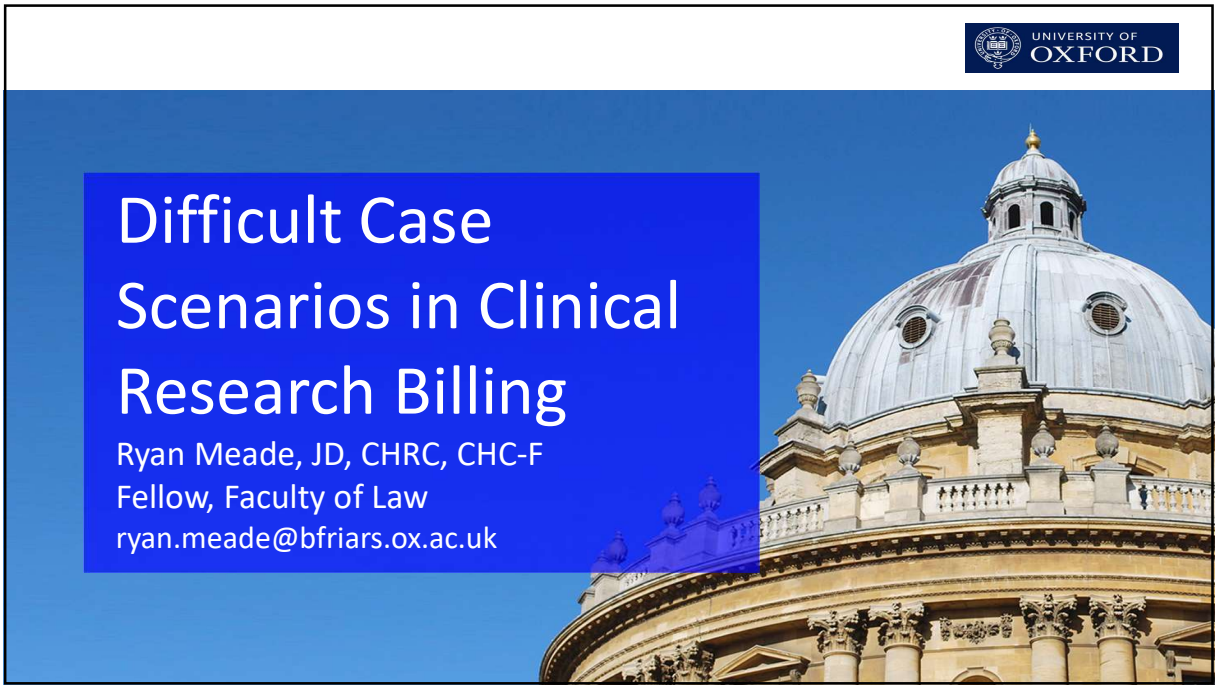

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Overview

- Case Study 1: Confusing Language
- Case Study 2: Screening Labs
- Case Study 3: Variable Billing

2

Recall

- Baseline:
  - Medicare pays for “routine costs” during “qualifying clinical trials.”
  - But remember…”All other Medicare rules apply.”
- NCD 310.1

3

Recall

- Baseline:
  - And don’t forget:
    - What is the sponsor paying for?
    - What is promised free in the informed consent?

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Recall

The coverage analysis needs to address:

1. Qualifying clinical trial status ("approved" status for IDE device trial)
2. Which services are "routine costs"
   a. Conventional care guidelines
   b. Detect or treat side effects
   c. Administration of the investigational article
3. "All other Medicare rules apply"
4. Funding document
5. Informed consent form

These feed into an answer on what is covered – not an easy thing to explain (or do)

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Example 1

"All of the study visit costs are included in the costs outlined above. The Per Patient Visit Costs Section of the budget represents procedures required to be performed on every patient."

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Example 2

"Per Study Subject includes all participant-related costs and participant compensation, as well as non-participant costs such as overhead expenses and administration costs."

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Example 3

- "Neither Institution nor Principal Investigator shall bill any third party for any Study Drug or other items or services furnished by Sponsor in connection with the Study, or any services provided to patients in connection with the Study for which payment is made as part of the Study including, but not limited to, Laboratory Tests, ECG evaluations, CT scans, Bone Marrow Biopsy, and MRI."

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Screening

- Myth: whenever a physician orders something, it is paid
- "Always ordering a lab" does not mean the lab is always paid or even makes it through the revenue cycle edit system
- …and even if it is paid, that does not mean it should have been paid
- Medicare Official Policy: "pay and chase'

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NCD 310.1 allows coverage for “routine costs” including conventional care and detecting and treating complications but NCD 310.1 does not over-rule others NCDs

The most powerful and forgotten sentence in NCD 310.1”

“All other Medicare rules apply.”

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Screening

- CMS interprets these provisions to prohibit coverage of ‘screening’ services, including laboratory test services furnished in the absence of signs, symptoms, or personal history of disease or injury, except as explicitly authorized by statute. A test service might be considered medically appropriate, but nonetheless might be excluded from Medicare coverage by statute.”

  -- CMS, April 2020

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The Medicare program generally groups all services into three categories and can be described as follows:

1. – a t**Therapeutic** – an intervention to improve outcomes or manage condition
2. **Diagnostic** – a test for symptomatic patients or to monitor for progression of disease
3. **Screening** est for asymptomatic patients

- Although there can be many rules which limit coverage for therapeutic and diagnostic tests, there is general coverage for medically necessary therapeutic and diagnostic services but Medicare does not cover what it considers "screening" services.
- Different notion of the term "screening" than is used in general medical terminology or in a research protocol

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Implications

- Budgeting
- Avoiding denials
- Manage "pay and chase" risk
- No payment on same day as hospital E/M

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Packaging

- Which labs are “packaged” in the hospital encounter payment?
- Should these be considered in budgeting?

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