3 Myths About Medicare & Clinical Research

1. **Myth**: Medicare pays for standard of care during research studies

   - **Reality**: Medicare pays for “routine costs” during “qualifying clinical trials.”

2. **Myth**: Medicare is a public health program that invests in scientific progress

   - **Reality**: Medicare is an insurance program created by Congress to pay for acute and chronic care.
3 Myths About Medicare & Clinical Research

3. Myth: NIH, Co-op Groups & CMS coordinate with each other

Basics About Medicare Important to the Clinical Trial Policy

- Two essential points:
  1. Congress limits what services Medicare can reimburse/pay for
  2. Medicare is a federal program administered locally by private contractors
Basics About Medicare Important to the Clinical Trial Policy

- Section 1862 of Social Security Act allows Medicare to pay for:

  “items and services…reasonable and necessary for the diagnosis or treatment of illness or injury….”

- Note: Medicare does not pay for preventive care without an “Act of Congress”

- Note: Medicare does not pay for research services unless it fits within criteria above, or is approved through “Coverage with Evidence Development” process through SSA Section 1142

Words Matter

- “items and services…reasonable and necessary for the diagnosis or treatment of illness or injury”

- Items and services

- Reasonable and necessary

- Diagnosis or treatment

- Illness or injury
Medicare Medical Directors

- Medicare is administered locally by private regional contractors

- Part A & Part B contractors are in process of being combined into Medicare Administrative Contractors (MACs)

- All Medicare local contractors must have a “contractor medical director” who applies clinical analysis to coverage determinations
  - Get to know your local Medicare medical director
  - If CMS has not issued a rule, coverage is deferred to the local Medicare medical director

Medicare Research Billing Rules

- The relevant Medicare rule depends on what is being investigated and who is funding the research:
  - **Drugs**: Clinical Trial Policy (NCD 310.1)
  - **Devices**: Device trial regulations & Chapter 14 of the Medicare Benefit Policy Manual
  - **Procedures**: Deferred to local Medicare contractor
  - **Funded by NIH, CDC, AHRQ, CMS, DOD, VA or Co-op Group**: Clinical Trial Policy