

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.”

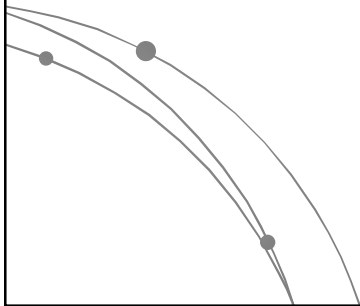
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2. Myth: Medicare is a public health program that invests in scientific progress

- Reality: Medicare is an insurance program created by Congress to pay for acute and chronic care

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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