

Clinical Innovation and New Technology

The Rocky Road to the Bedside
in the Medicare Program

Medicare and Clinical Innovation

- Overview
- Strategic Perspective
- New Technology Initiatives
- Coverage and Clinical Trials
- Payment for New Technology

Overview (2005)

- The People
 - 43 million – elderly, disabled, ESRD
 - 49 million – Medical Assistance (states)
- The Program
 - Federal third party payer for health care
- The Pot
 - \$ 333 Billion (Medicare)
 - \$ 173 Billion (Medicaid Federal share)

Vision

Centers for Medicare & Medicaid Services

Achieve a Transformed and
Modernized Health Care System
for the 21st Century

Mission

Centers for Medicare & Medicaid Services

Ensure effective up-to-date health care coverage and promote quality care for Medicare and Medicaid beneficiaries

Key Objectives

High-Value Health Care

Confident, Informed Consumers

Collaborative Partnerships

High Value Health Care

- Quality-oriented and Patient-centered
- For patients: Transparency
empowered and informed consumers
comparative quality and cost information
- For providers: Value-based Payment
Pay-for-Performance (P4P)
reward providers for quality and efficiency

Council on Technology & Innovation

- Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)
- Coordinate coverage, coding, and payment for new technology by Medicare
- Facilitate info exchange about new tech between CMS and other agencies

Coverage

- Coverage vs Benefit
- Coverage Process
- Clinical Trials
- Coverage with Evidence Development

Distinction in Coverage vs Benefit

- Benefit
 - medical services authorized by law
 - only specified categories are included
- Coverage
 - law excludes any items or services not reasonable and necessary for the diagnosis or treatment of illness or injury

Coverage Process within CMS

- Local Coverage Determinations (LCD)
most coverage policies are LCDs
produced by local Medicare contractors
accommodates regional variation in practice
allows gradual diffusion of innovation
- National Coverage Determinations (NCD)
transparent process open to public input

Clinical Trials

- Executive Memorandum (June 7, 2000)
- Payment for routine patient care costs in qualifying clinical trials
- What are “routine patient care costs”?
- What are “qualifying clinical trials”?
- National Coverage Determination issued on September 19, 2000 (re-opened 2006)

Clinical Trials – Routine Costs

- Conventional care and complications
- But NOT items/services that are:
 - investigational or experimental
 - not used for direct patient management
 - used solely for data collection/analysis
 - usually provided for free by the sponsor

Clinical Trials Requirements

- Medicare benefit category is applicable
- Therapeutic intent – not toxicity/safety
- Therapeutic interventions must enroll patients with a clinical condition/illness
- Diagnostic interventions may enroll healthy volunteers for the control group
- Other “desirable characteristics” per NCD

Clinical Trials Automatically Qualified

- Funded by NIH, CDC, AHRQ, CMS, DOD, and VA
- Supported by appropriate centers or groups that are funded by these agencies
- Conducted under IND application by FDA
- IND-exempt under 21 CFR 312.2(b)(1)

Coverage with Evidence Development

- Alternative approach allows patients to benefit from advances in new technology
- NCD in the context of protocol-specified prospective data collection (e.g. registry)
- Draft guidance issued in April 2005
- Goal: speed access to new technologies

Payment for New Technology

- Prospective payment systems (PPS) are “all inclusive” for most items and services
- Hospital inpt: New Technology Add-on separate payments began in FY 2003
- Hospital outpt: New Tech/Pass-Thru payments began in August 2000
- Hospital New Tech Town Hall Workshop FEB 22, 2007 at CMS in Baltimore

Resources

- Websites
www.cms.hhs.gov
www.medicare.gov
- New Tech Town Hall Workshop
http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp
- Contact: Jim Bowman
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