

Coverage and Billing Issues for Clinical Research

The Second Annual

Medical Research Summit

Washington, DC, March 24-26, 2002

John E. Steiner, Jr., Esq
Chief Compliance Officer
Cleveland Clinic Health System
Cleveland, Ohio



Medicare

- Covers people 65 years and older, disabled or with end stage renal failure
- Coverage is **not unlimited**, the law provides exclusions
- Covered services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the function of a malformed body member



Medicare

- *The Centers for Medicare and Medicaid Services (CMS)*
- Previously known as: Health Care Financing Administration (HCFA)
- Division of the U.S. Department of Health and Human Services (DHHS)



Medicare Part A

- Covers inpatient hospital care, home health care and hospice
- Fiscal intermediary - AdminaStar Federal
- www.adminastar.com
- Local medical review policies - LMRPs
- “Technical” charges
- Claim form - UB-92



Medicare Part B

- Covers physician services, limited licensed practitioners, clinical laboratory tests, DME, ambulance services
- Carrier - Nationwide Insurance - after 7/1/2002 change to Palmetto Government Benefits Administrators
- www.nationwide-medicare.com
- Medical policies
- “Professional” charges
- Claim form - HCFA 1500



Medicare Part C (Medicare + Choice)

- Covers all services covered by Parts A and B, and possibly more as defined by each plan
- HMOs or managed care organizations
- Each Medicare+Choice organization will have own coverage policies
- Same clinical research coverage as Parts A and B
- UB92 and HCFA 1500



Determine if a Research Item or Service is Covered by Medicare

- Check National coverage policy
- Check Local Part A and Part B coverage policy
- Is it excluded by law?



Medicare Coverage Web Sites

National Policy

- http://www.hcfa.gov/pubforms/06_cim/ci00.Htm
- <http://www.hcfa.gov/pubforms/htmltoc.Htm>
- <http://www.hcfa.gov/coverage/>



Medicare Coverage Web Sites

Local Part A Policy

- <http://adminastar.com/anthem/affiliates/adminastar/index.html>

Local Part B Policy

- <http://www.nationwide-medicare.com/medpol.htm>
- <http://www.palmettogba.com/> (after July 1, 2002)



Medicare National Coverage Determination - Clinical Trials

- Effective date: September 19, 2000
- Medicare covers:
 - *Routine costs* of *qualifying* clinical trials
 - Reasonable and necessary items and services used to diagnose and treat complications arising from participation in a clinical trial



Qualifying Clinical Trials

- Evaluates a Medicare benefit
- Has therapeutic intent
- Enrolls diagnosed beneficiaries
- Has **desirable characteristics**
 - Some trials are **automatically deemed** as having desirable characteristics



Trials Automatically Deemed As Having Desirable Characteristics

- Trials funded by or supported by: NIH, CDC, Agency for Healthcare Quality(AHRQ), HCFA, Department of Defense(DOD), and Veterans Administration(VA)
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD and VA



Trials Automatically Deemed As Having Desirable Characteristics

- Trials conducted under an Investigational New Drug application (IND)
- **IN THE FUTURE:** Trials exempt from having an IND under 21 CFR 312.2(b) (1)
 - Unlike other deemed trials the PI must certify that the IND exempt trials meet the qualifying criteria, once the criteria and self-certification process are established



Future Self-Certification Process

- In the future, a multi-agency federal panel will develop qualifying criteria for other trials that will indicate a strong probability that a trial exhibits the desirable characteristics
- **No trials are covered based on self-certification at this time**



“Routine Costs” Include

- Items or services typically provided absent a clinical trial (i.e., medically necessary conventional care)
- Services required for the provision of the investigational item (i.e., administration of a non-covered chemotherapeutic agent)



“Routine Costs” Include

- Services required for the clinically appropriate monitoring of the effects of the item or service or the prevention of complications
- Services that are medically necessary for the diagnosis and treatment of complications arising from the provision of an investigational drug



“Routine Costs” DO NOT Include

- The investigational item itself
- **Exception** - Commercially sponsored category B investigational device trials are not under this National Coverage Determination
- Items and services:
 - For which there is no Medicare benefit or
 - Are statutorily excluded or
 - Fall under a national non-coverage policy



“Routine Costs” DO NOT Include

- Items and services provided solely to satisfy data collection and analysis needs that are not used in direct clinical management of the patient (i.e., monthly CT scan for a condition usually requiring only one scan)



“Routine Costs” DO NOT Include

- Items and services customarily provided by research sponsors free of charge
- Items and services provided solely to determine eligibility



FDA Approval

- FDA is charged with reviewing and approving drugs and medical devices prior to their general use
- FDA approval of drugs and devices is a prerequisite for Medicare coverage



FDA/HCFA (CMS) Categorization of Investigational Devices

- Category A - Experimental/Investigational
- Category B - Non-experimental/
Investigational



FDA Category A

- Category A devices are novel, first-of-a-kind technology: innovative devices for which the absolute risk of the device has not been resolved
- The FDA is unsure if the device is safe; therefore, it is *not* covered by Medicare



FDA Category B

- Category B devices are newer generations of proven technology
- Represent evolutionary changes in proven technologies and will be viewed as potentially reasonable and necessary by Medicare and are **eligible** for coverage and payment



AdminaStar Federal Pre-submission Requirements

- *Part A News*, December 2001, Vol. 2, Issue 4, pages 27-28
- Must make submission to Medical Director and receive approval **before** claims can be submitted
- Beginning September 1, 2001



AdminaStar Federal Pre-submission Requirements

- Provider name and provider number
- Name and number of the device (trade name, common or usual name and classification) and a detailed narrative description of the device



AdminaStar Federal Pre-submission Requirements

- A signed copy of the FDA approval letter demonstrating Category B, IDE status and approval from the FDA to the participating company or manufacturer
- The FDA approval letter containing the most current approved number of institutions and subjects, and the number of cases the institution is planning to perform



AdminaStar Federal Pre-submission Requirements

Maintain (do not submit) the following items:

- The protocol and summary of the results
- Agreement between the company and the manufacturer
- At least 2 peer-reviewed publications



AdminaStar Federal Pre-submission Requirements

Maintain (do not submit) the following items:

- Any product literature illustrating the device or procedure
- The protocol used for obtaining informed consent
- IRB approval documentation



AdminaStar Federal IDE Claims Processing Update

- January 21, 2002 memorandum
- Use appropriate HCPCS code - from FDA approval letter
- **Do not** use outpatient PPS passthrough codes (HCPCS that begin with “C”) with revenue code 624. Claim will be denied.



AdminaStar Federal IDE Claims Processing Update

- Submit only the number of claims in the letter as approved by the AdminaStar Medical Director
- Providers exceeding number of specified approved procedures will be subject to further review



Medicare Billing Requirements - Investigational Devices

- The CDMs established for the investigational devices contain:
 - The FDA IDE number in the description field
 - 624 revenue code on the technical charge



Billing Requirements for Qualifying Clinical Trials

- Hospital/technical
- ICD-9 code - V70.5 - “Examination of Participant in a Clinical Trial”
- V code as the third or subsequent diagnosis code



Billing Requirements for Qualifying Clinical Trials

- Physician/professional
- After January 1, 2002
- “QV” modifier - “Item or service provided as routine care in a Medicare qualifying clinical trial”
- V70.7 - not required



Billing Requirements for Qualifying Clinical Trials

Physician/professional - EXCEPTION

- Routine care clinical trial services furnished to healthy control group volunteers participating in a qualifying trial code with QV modifier **and** V70.7



Billing Requirements for Qualifying Clinical Trials

The QV modifier and V70.7 diagnosis code serve as the provider's attestation that the service meets the Medicare Coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation)



Medicare + Choice

- Send professional and technical bills for routine care provided in qualifying clinical trials to AdminaStar and Nationwide
- Not the Medicare+Choice provider



Medicare Advance Beneficiary Notice (ABN) or Waiver

- Must recognize whether a service is potentially non-covered *prior* to providing the service
- An ABN must be signed by the patient before the service is rendered, if you intend to bill a patient for a non-covered service
- Relates to patient financial responsibility on informed consent



Medicare Advance Beneficiary Notice (ABN) or Waiver

- ABN includes the estimated cost to patient and reason for denial
- See a Reimbursement Specialist for ABN procedures
- ABNs are not required for services **never** covered, but are recommended to clarify patient financial responsibility



Research Compliance Checklist

- Complete each question
- Maintain supporting documentation
- Submit to IRB
- Soon submission will be to the Center for Clinical Research



Medicare HMO Search

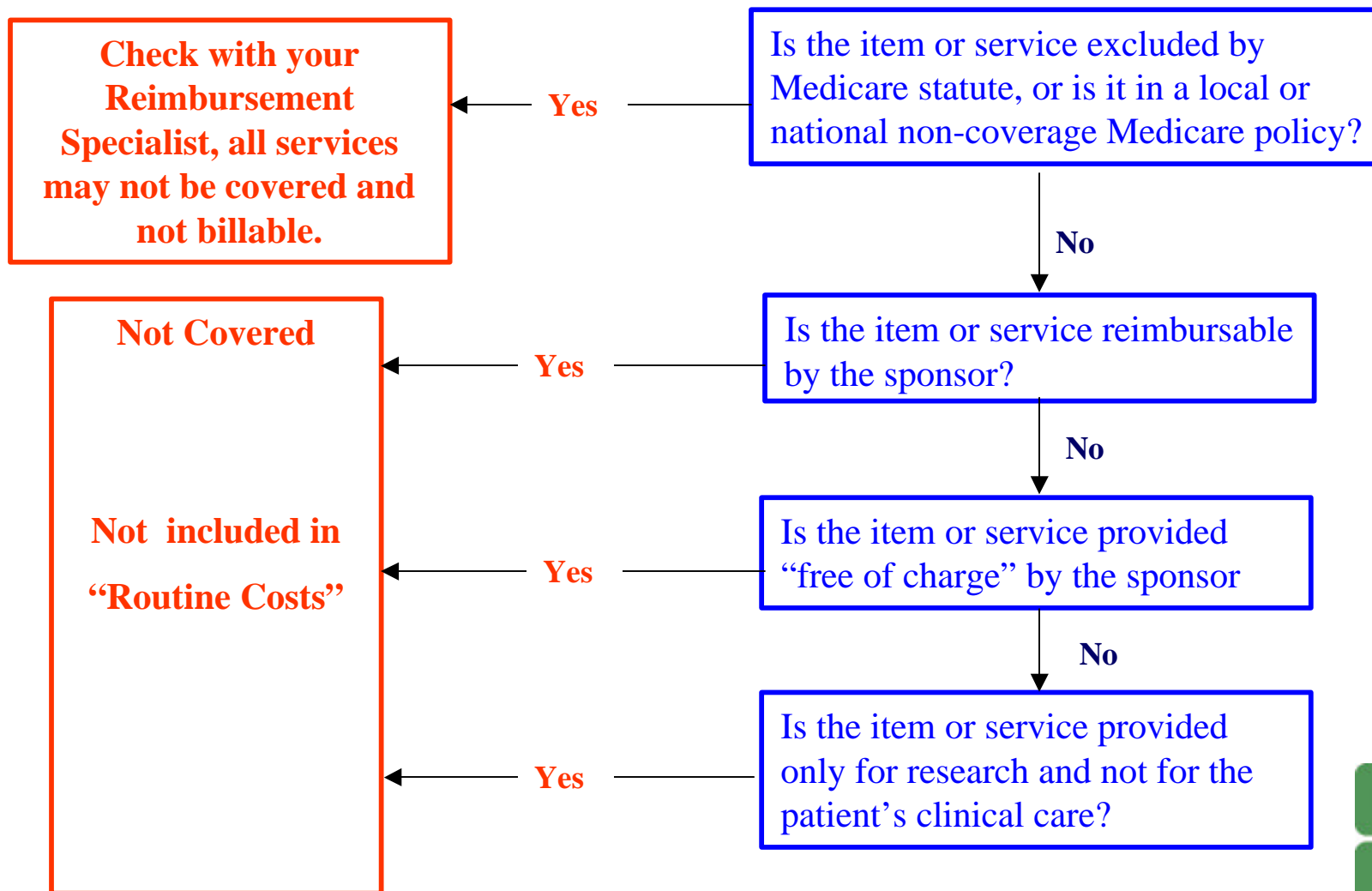
Determine if an insurance company is a
Medicare HMO

<http://www.medicarehmo.com/mchmsrch.htm>



Medicare Coverage Decision Process

Ask these questions for each service provided in the research protocol to determine if an item or service is covered and billable to Medicare. The review is usually completed by the Clinical Research Coordinator working with the Department Reimbursement Specialist



See page 2 for additional questions



Medicare Coverage Decision Process

Ask these questions for each service provided in the research protocol to determine if an item or service is covered and billable to Medicare. The review is usually completed by the Clinical Research Coordinator working with the Department Reimbursement Specialist.

