Clinical Research Billing Compliance

Chartley McMaster Bondurant, CHRC – Compliance Projects Manager

IU Office of Research Administration

Purpose of Clinical Trials Billing Compliance

- Reduce billing risks between research and routine care charges
- Ensure appropriate recovery of clinical research study costs
- Reduce the risks of inappropriately billing patients and/or third party payors
- Ensure consistency of payment terms across all study documents

Overview

Clinical trial billing is an increasing issue at community and academic medical centers around the country.

- Heightened stake holder scrutiny
- Recent settlements
- Increased federal oversight
- Research billing data

Compliance Risks

- Billing the subject or third party payor for services that are already paid by the sponsor (double billing)
- Billing for services promised free in the Informed Consent
- Billing for services that are for research purposes only
- Billing for services that are part of a non-qualifying clinical trial
- Inappropriately using research funds to pay for routine care
- Frequency of services required by protocol, including “confirmatory” items/services

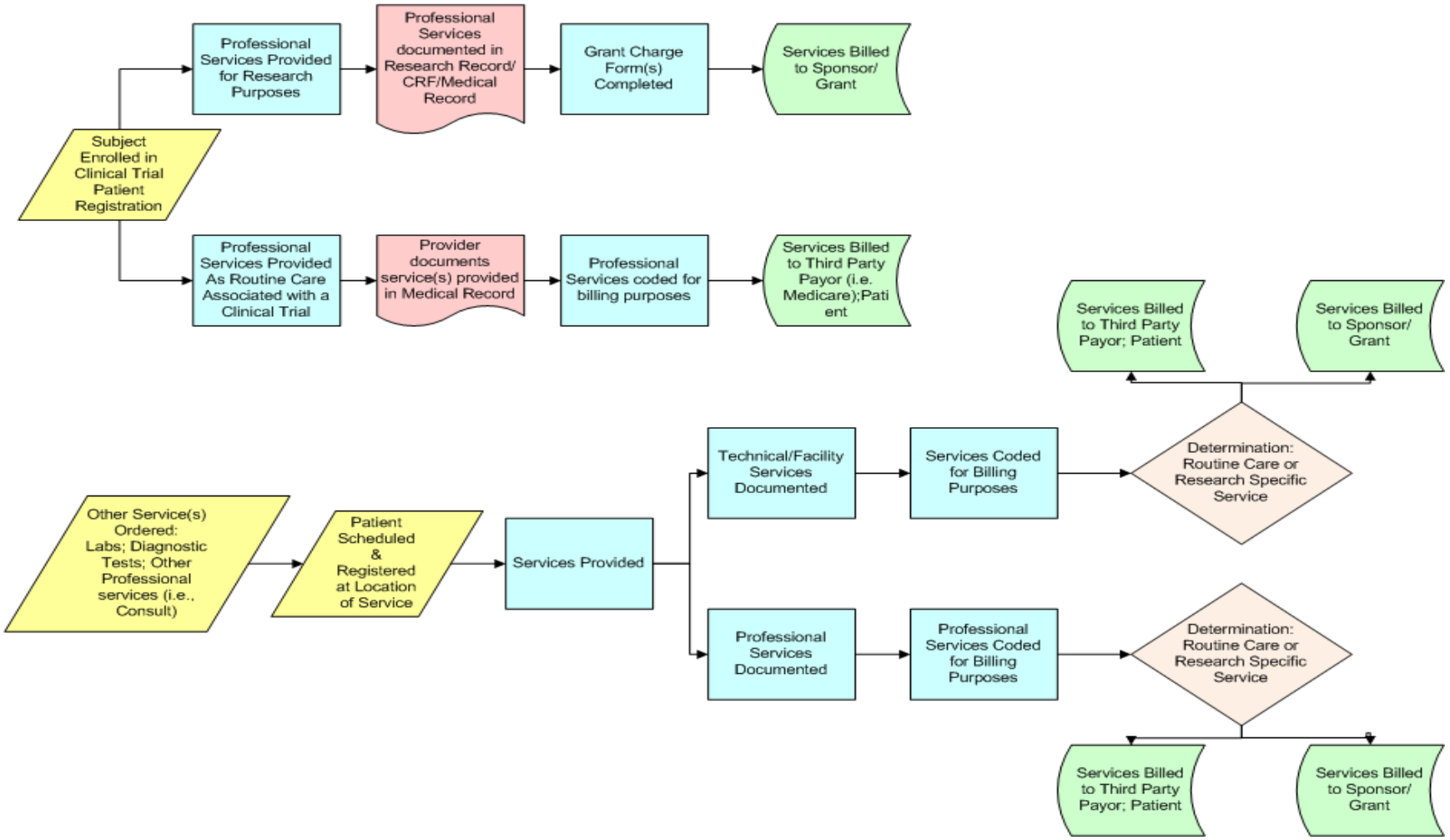
Consequences of Non-Compliance

- Loss of staff time correcting billing errors
- Failure to appropriately recover costs of research studies
- Criminal Penalties
- Financial Penalties
- Potential endangerment of federal funding
- Restrictions on research operations
- Loss of goodwill and community trust
- Corrective action

Office of Research Administration (ORA) Responsibility to the University

- Determine risk to the organization
- Integrate Clinical Research Billing into the Research Compliance Program
- Develop and implement a compliance plan and policies for Clinical Research Billing

Clinical Research Billing Processes



Medicare Regulatory Landscape

On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials." The Health Care Financing Administration (now the Centers for Medicare & Medicaid Services, or CMS) responded to the executive order with the Clinical Trial Policy National Coverage Determination (NCD) issued on September 19, 2000.

Centers for Medicare and Medicaid (CMS) National Coverage Determination for Routine Costs in Clinical Trials (310.1)

Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as **reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials**. All other Medicare rules apply.

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial

EXCEPT:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Medicare Regulatory Landscape

CMS began a reconsideration of the 2000 NCD to address several issues about the policy on July 10, 2006. A final decision memorandum on July 9, 2007 preserved the status quo of the 2000 Clinical Trials Policy (CTP) stated that the policy includes items and services that may be covered under an NCD (Coverage with evidence development), and does not withdraw coverage under local medical review policies (LMRPs) or the regulations on category B investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406.

- For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub. 100-03, NCD Manual and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

State of Indiana Medicaid Medical Assistance Program

Medical Policy Manual, VI., pgs 84-97,Indiana Health Coverage Program (IHCP) Clinical Trials Policy

The IHCP covers the routine costs of approved clinical trials as well as reasonable and necessary items and services used to prevent complications and to diagnose and treat complications arising from participation in all clinical trials.

- Would be covered under Indiana Administrative Code and not listed as a non-covered item or service
- Must have therapeutic intent
- Trials of therapeutic intervention must only enroll members with diagnosed disease. Trials including diagnostic interventions may enroll healthy members in order to have a proper control group

Patient Protection and Affordable Care Act

PPACA was signed into law in March 2010. In 2014 new and non-grandfathered health plans will be required to cover clinical trials. Plans may not:

- Deny the individual participation in the clinical trial
- Deny, limit or impose additional conditions on the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
- Discriminate against the individual based on their participation

An individual is eligible to participate in an approved clinical trial according to the trial protocol for cancer or life-threatening disease and if referred by a participating health care provider.

Achieving Compliance with Research Billing Rules

- Coordination of study payment information
- Communication of study payment information
- Clarity in study payment documents
- Understanding the background of the billing rules and documenting items and services

The processes that depend on you:

Financial Responsibility Analysis	Prospectively identify all procedures and determine appropriate billing direction for all billable care events utilizing the 1. Qualifying Trial Analysis (MCA, Carrier Determinations, FDA Documentation); 2. Separation of Allowable Costs (billing plan); 3. Protocol; 4. Schedule of Events; 5. Contract/Budget
Harmonize Study Documents	The IRB application, the grant or contract, the budget and the informed consent forms must all indicate the same information regarding what will be charged to whom.
Implement Study Procedures	Follow the standard processes for registering research participants, using the appropriate research procedure requisition forms, entering visit data into appropriate monitoring systems.
Monitor Research Billing	Review research bills for accuracy making sure that study procedures were billed as planned and partnering in the comprehensive review of research billing activitiy.

Coverage Analysis

The Clinical Trials Coverage Analysis includes four (4) components:

1. Qualifying Trial Determination: Medicare Coverage Analysis (MCA), Device requirements
2. Separation of Allowable Costs
3. For those services for which coverage is not yet established, a Supplemental Coverage Review by the Medicare Carrier Medical Director or Fiscal Intermediary
4. Ensure consistent cost allocation language in all study documents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Clinical Trials Contracting
ORA Home > Clinical Trials Contracting > Regulatory Budget Requirements > Medicare Coverage Analysis
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Getting Started
Regulatory Budget Requirements
Allowable Costs
Indirect Rate Policy
Budget Samples, Tips & Guides
Medicare Coverage Analysis
Managing Your Trial
Research Affiliates
ClinicalTrials.gov
Policies
Contact us: Clinical Trials Contracting
Regulatory Budget Requirements
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Medicare Coverage Analysis
The Medicare Coverage Analysis (MCA) is required for all clinical research studies anticipating third party billing for costs associated with items and services related to routine care. In order to bill Medicare for routine costs of items and services that are reasonable and necessary to diagnose or treat illness or injury[1] as related to participation in a clinical trial, a clinical trial must meet certain criteria to qualify for reimbursement. Some trials are already qualified to receive Medicare coverage if they are funded by certain federal agencies or meet the Seven Desirable Characteristics.[2] To determine whether your clinical trial meets the requirements for reimbursement by Medicare for routine costs, the MCA
Medicare Coverage Analysis
Access:
Medicare Coverage Analysis Worksheet
Trusted sites

Medicare Coverage Analysis

Part 1 – The study must be one of the following:

1. Studies funded by NIH, CDC, AHRQ, CMS, DOD, or VA;
2. Studies supported by centers or cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, or VA;
   Medicaid also includes-FDA,NHLBI, National Human Genome Research Institute, NCI, NIDDK, NIMH and other sources
3. Studies being conducted under an IND application; or
4. IND exempt studies

Medicare Coverage Analysis

Part 2 – All three of the following must be met:

1. The study must investigate an item or service already paid for by Medicare and is not statutorily excluded from coverage.

2. Trials of therapeutic interventions may only enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in a control group if a control group is scientifically necessary.

3. The study must have therapeutic intent. It must not be designed exclusively to test toxicity or disease pathophysiology.

Device Trial Qualifying Analysis

- IDE Category A devices: Yes, with Medicare medical director approval if used in “immediately life threatening disease or condition”
- IDE Category B devices: Yes, with Medicare medical director approval
- HUD: Only if approved by Medicare medical director
- Post-marketing approval FDA-required studies: Yes, with Medicare medical director approval
- Off-label use of FDA-approved device: Generally, no; needs IDE categorization

Device Trials

- In order to bill routine care costs for Category A/B device trials you need to obtain Medicare contractor approval prior to billing.
- Even when device is provided without charge, Medicare contractor must still approve study for “routine costs” to be billable.
- When Medicare medical director approves a device trial, the study qualifies for coverage but all Medicare rules still apply – many services, including the main procedure may not be covered by Medicare

Coverage Analysis Documents

1. Protocol
2. Funding Information:
   - Contract/Budget
   - NOGA
   - Other financial sources
   - Allocation through internal budgets
3. Informed Consent
4. Separation of Allowable Costs Template
5. FDA Documents
   - IND application status (drugs)
   - IDE category assignment (devices)

Separation of Allowable Costs Allocation Analysis

The Principal Investigator (PI) is responsible for:

- The terms and conditions of the research project and its related budget
- Compliance with all rules for billing Medicare, Medicaid and third party insurers for services provided in the context of clinical research.
- Identifying which services are billable to insurance and which services will be covered by the grant/sponsor.

Determining Cost Allocation

- Regardless of what kind of trial it is, Medicare will not pay for items that are not **medically necessary**.
- "items and services…reasonable and necessary for the diagnosis or treatment of illness or injury" SSA 1862(a)(1)(A)

  Items and services

  Reasonable and necessary

  Diagnosis or treatment

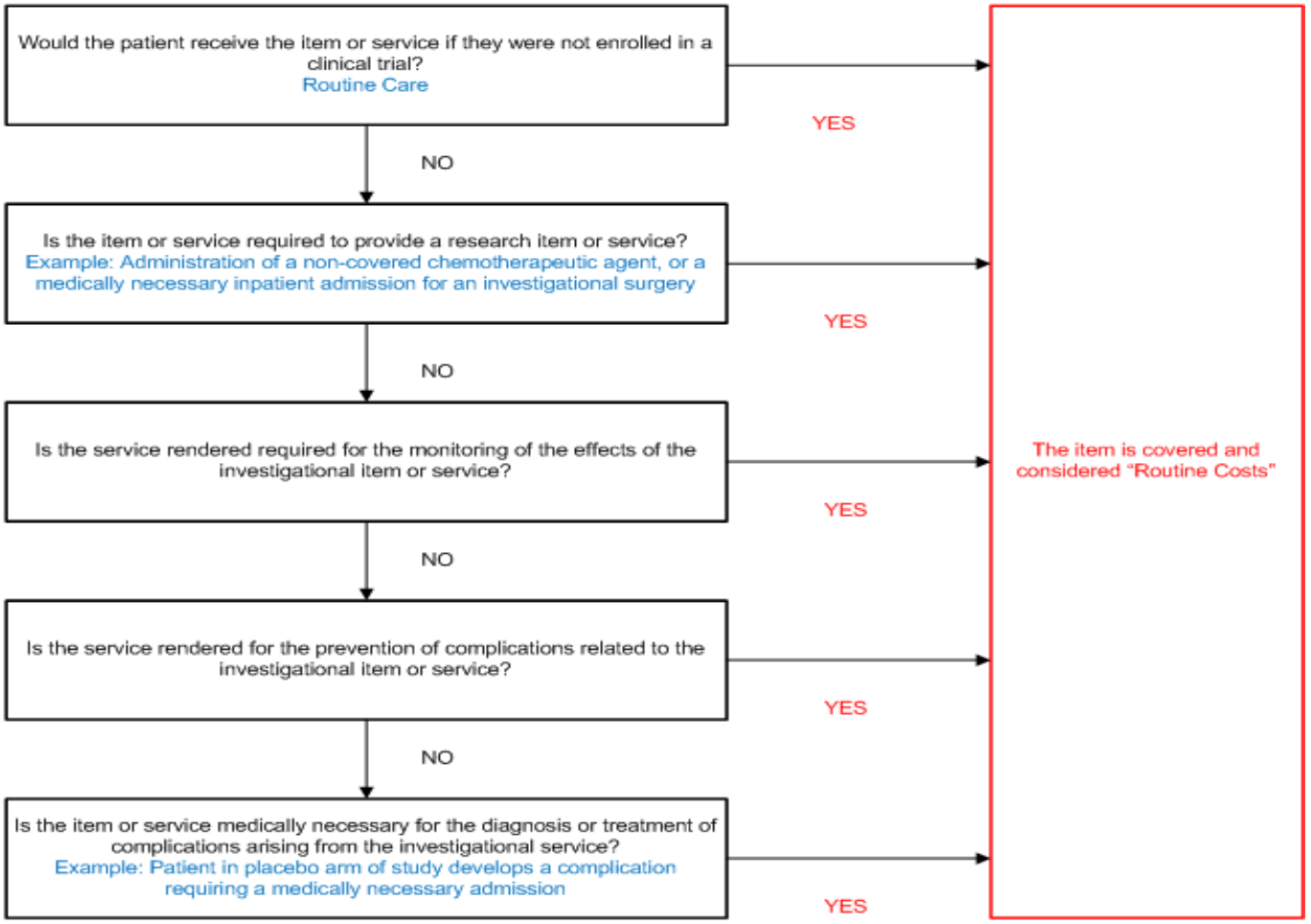
  Illness or injury

Clinical Research Routine Costs

CMS considers "routine costs" to be:

- Items or services that are typically provided absent a clinical trial
- Items and services that are medically necessary for the diagnosis and treatment of complications arising from the provision of an investigational item or service
- Items or services required for the provision of the investigational item or service
- Items and services required for the clinically appropriate monitoring of the effects of the item or service and prevention of complications

Routine Care Decision Tree



Separation of Allowable Costs

- Note all services that are already paid by the sponsor
- Identify remaining line items as administrative, routine clinical services or investigational clinical services.
- Consider all line items identified as administrative to be paid by the sponsor:

  -Non-clinical, investigator salaries, protocol development, recruitment, data QA, statistical analyses, dissemination of findings and study management

  -Clinical services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient

Separation of Allowable Costs (cont.)

- Identify “routine costs” that are payable by the patient and/or third party payor

  -Sponsors may indicate in a CTA or budget that some services are “SOC” – “Standard of care” for research billing purposes is not a recognized term and does not always equate to a billable service based on CMS criteria for research claims submissions.
- If the sponsor indicates that an item or service is standard of care and they are not paying for it, are the services billable?

Separation of Allowable Costs (cont.)

- Refer to the Medicare NCDs and local contractor policies for coverage and NON-coverage statements
- Refer to the Investigator Brochure and Professional Practice Guidelines

Study Title: Randomized Phase II Study to Evaluate STUDY DRUG Treatment versus Placebo in Patient Population
Study Sponsor: SPONSOR, INC
Protocol Number: IURX1234
Principle Investigator:
Study Coordiantor: June Smith
Sponsor Contact: Joe Smith
COMPANY ABC
(123) 456-7890; joe.smith@abc.com
Location of Study:
Planned Enrollment: 5

Clinical Trial Billing Grid	Baseline	Treatment				Follow Up	
		Week 1	Week 2	Week 3	Week 4	Month 2	Month 4
Procedures							
Informed Consent	SPONSOR						
Concominant Medications	SPONSOR						
Medical History	SPONSOR						
Physical Exam	RC				RC	RC	RC
Vital Signs	RC	SPONSOR	SPONSOR	SPONSOR	RC	RC	RC
ECG	SPONSOR						
Serum Preg. Test (HCG)	SPONSOR						
Complete CBC / Auto	RC				SPONSOR	RC	RC
Creatinine	RC				SPONSOR	RC	RC
AST/ALT	RC				SPONSOR	RC	RC
Alkaline Phosphatase	RC				SPONSOR	RC	RC
LDH	SPONSOR				SPONSOR	SPONSOR	SPONSOR
Sodium	RC				SPONSOR	RC	RC
Magnesium	SPONSOR				SPONSOR	SPONSOR	SPONSOR
PK	SPONSOR				SPONSOR	SPONSOR	SPONSOR
	RC					RC	
Dose Administration		SPONSOR	SPONSOR	SPONSOR	SPONSOR		
SAE Reporting	SPONSOR	SPONSOR	SPONSOR	SPONSOR	SPONSOR	SPONSOR	SPONSOR
CRF Completion	SPONSOR	SPONSOR	SPONSOR	SPONSOR	SPONSOR	SPONSOR	SPONSOR
Other							
Misc. Admin	SPONSOR						

RC (Routine Care) - Billed to Patient's Insurance
SPONSOR - Billed to Research Grant & Paid by the Sponsor

Consistency in Study Documents

Assure consistency in all of the final study documents:

- CTA
- Budget
- Protocol
- Schedule of Events
- Informed Consent
- Separation of Allowable Costs

Documentation Requirements for Items and Services

Medicare Claims Processing Manual, Chapter 32,

§ 69.6: Requirements for Billing Routine Costs of Clinical Trials

(Rev. 1723, Issued: 05-01-09, Effective: 10-01-09, Implementation: 10-05-09) *(Notice first issued in Medicare Program Memorandum dated September 19, 2000.)*

Routine Costs Submitted by Practitioners/Suppliers

Claims with dates of service before January 1, 2008:

- HCPCS modifier 'QV'
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis

Claims with dates of service on or after January 1, 2008:

- HCPCS modifier 'Q1' (numeral 1 instead of the letter i) affixed to each service; and
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis

If the QV or Q1 modifier is billed and diagnosis code V70.7 is submitted by practitioners as a secondary rather than the primary diagnosis, do not consider the service as having been furnished to a diagnostic trial volunteer. Instead, process the service as a therapeutic clinical trial service.

Effective for claims processed after September 28, 2009, with dates of service on or after January 1, 2008: Claims submitted with either the modifier QV or the modifier Q1 shall be returned as unprocessable if the diagnosis code V70.7 is not submitted on the claim.

Documentation Requirements for the medical record

Medicare Claims Processing Manual, Chapter 32,

§ 69.3 - Medical Records Documentation Requirements

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

The billing provider must include in the beneficiary's medical record the following information:

- trial name,
- sponsor, and
- sponsor-assigned protocol number.

This information does not need to be submitted with the claim but must be provided if requested for medical review.

Research Billing Responsibility

- Harmonization of all study documents for financial responsibility
- Determine if it is a Qualifying Trial for reimbursement of routine care costs by Medicare
- Separation of Allowable Costs Coverage Analysis
- Medical record documentation that services/procedures are related to clinical trial
- V 70.7: Diagnosis Code for research; “examination of participant in clinical trial”
- Q0: Modifier; Investigational clinical service provided in a clinical research study that is an approved clinical research study
- Q1: Modifier; Routine clinical service provided in a clinical research study that is an approved clinical research study

What Can You do to make sure you are in Compliance?

- Determine whether your trial qualifies for Medicare coverage for routine care costs associated with the trial
- Ensure consistency of payment terms across study documents
- Complete the Separation of Allowable Costs
- Ensure that there is documentation to support each service billed and that the cost allocation is appropriate

Questions?

How should we bill for adverse events?

If a subject is regularly seen in the office as part of routine care, does the diagnosis code still need to be added?

What if a sponsor agrees to cover costs for subjects without insurance? Or costs that insurance denies?

Contact

- Chartley McMaster Bondurant, CHRC
  Compliance Projects Manager
  cmbondur@iupui.edu
  278-1882

- Resource:

http://researchadmin.iu.edu/

http://researchadmin.iu.edu/CT/ct_allowablecosts.html