CRRC: CLINICAL RESEARCH REVENUE CYCLE MANAGEMENT: AVOIDING THE PITFALLS

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Objectives

- Evaluate leading practices for establishing a clinical research revenue cycle (CRRC)
- Distinguish pitfalls and techniques for managing regulatory risks throughout the revenue cycle
- Construct the high-level framework for effective and complaint CRRC management

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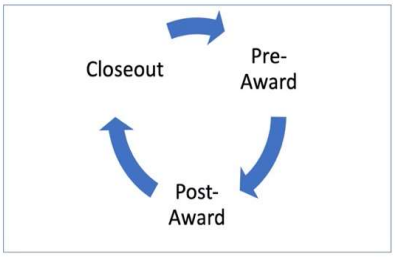
Clinical Research Revenue Cycle

- Reconciliation

- Research vs. Non-Research Charge Capture
- Billing & Coding
- Claims Editing
- Invoicing & Claims
- Collection



- Coverage Analysis
- Budgeting & Contracting
- Research Order Sets

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CRRC Risks & Mitigation

Focus Area	Sub Area	Regulatory Agency	Risk Description	Proposed Approach
Billing Compliance	Coverage Analysis	CMS	Without a documented coverage analysis, the institution is at risk of potentially billing Medicare for non-qualifying clinical trials and/or potentially inaccurate clinical research billing. In addition, this step is key to the successful execution of the remaining steps in the billing compliance continuum. The institution may also be losing revenue due to billing denials by third party for services billable to a sponsor.	The following controls should be incorporated into operational procedures: • Consolidate coverage analysis, oversight and enforcement into a central office • A documented coverage analysis should be used for all the current clinical research studies (with billable procedures)
Billing Compliance	Patient Tracking / Enrollment Registration	CMS	Without a centralized location for recording all enrolled clinical research participants, registration and scheduling of these participants is difficult and could lead to errors.	• A central database for patient billing compliance should be used that identifies all clinical research participants, and which has mechanisms for recording whether an individual procedure charge is considered Standard of Care (SOC) or Research related (RS).
Billing Compliance	Coding and Billing	CMS	Without appropriate routing of SOC vs. RS charges, the institution is at risk for: • Improper billing • Loss of revenue due to denials • Non-compliance with Medicare clinical research coding and billing regulations	The following controls should be incorporated into operational procedures: • Standardized coverage analysis billing grids should be used • Billing grids should be centrally available and shared with coding and billing teams within each ancillary department.

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CRRC Risks & Mitigation

Focus Area	Sub Area	Regulatory Agency	Risk Description	Proposed Approach
Billing Compliance	Reconciliation	CMS	Without a periodic reconciliation process, there is a risk of: • Loss of revenue • Not remediating improper billing in a timely manner	• A centralized, single source of clinical research billing data should be used (SOC and RS charges). • The centralized clinical trials office staff should generate monthly or quarterly reconciliation report utilizing this data.
Financial Management	Sponsor Invoicing		An inconsistent invoicing and tracking process may result in unbilled invoices and loss of potential revenue.	• A centralized AR invoice tracking system should be used for sponsor invoices. Alternatively, an enterprise-wide clinical research management system (CTMS) could be used.

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Defining the regulatory landscape & impact

Although the regulatory landscape for research remains relatively constant, determining the institutional risk impact is challenging.

IMPACT

SCORE	RATING	FINANCIAL	OPERATIONS	GOVERNANCE	EXTERNAL	PEOPLE
5	Catastrophic	Greater than 20% increase in costs	Talent loss that is not easily replaced (scale of loss, degree of talent) so severe to shut down operations	Criminal sanctions, penalties/sanctions /performance guarantees with loss of >$1M Loss of government contract, licensure, or accreditation	Serious damage by media exposure (breadth and length of negative coverage) - irreparable loss of member confidence Broad implications for patient, employee health and safety	Requires senior management and/or BOD oversight There is a leadership vacuum so severe would require fundamental, large scale changes
4	Significant	Greater than 10% increase in costs	Loss of confidence in the function/area to deliver its business objectives	Sanctions $500K up to $1M	Broad and extended negative media coverage Implications for patient, employee health and safety	Requires high level of senior management attention May involve changes to management team
3	Moderate	Greater than 5% increase in costs	Future composition of the service, activity, production, function in question Known risks identified in monitoring, audit, testing, assessments or investigations	Sanctions $100K to $500k Moderate impact to government contract or accreditation	Negative press/social media mentions limited in duration/audience Potential implications for patient, employee health and safety	Requires management team focus with some senior management oversight
2	Limited	Greater than 2% increase in costs	Routine operations would be able to cope with these issues Indication of risk identified in monitoring, audit, testing, assessments or investigations	Regulatory warning or nominal sanctions Government contract or accreditation requires corrective action plans	Negative press/social media mentions confined to one story or local coverage only No indication of risk to patient, employee health and safety	Limited management team time is required, generally only periodic briefings to oversee resolution
1	Minimal	Less than 2% increase in costs	Routine operations would be able to cope with these issues. No indication of risk identified in monitoring, audit, testing, assessments, or investigations	No regulatory sanctions or fines Business objectives being met	No negative press/social media mentions No indication of risk to patient, employee health and safety	Minimal, if any, management team time is required

A risk may be assigned a rating of 1-5 by meeting one or more of the criteria associated to that rating; it is not necessary to meet all associated criteria for a given rating.

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Slide 6

VL1 Erika - i would like to talk about this slide. need to fully understand it. how can we make it easier to read?
Veazie,Mary L, 5/15/2020

Prioritizing CRRC risks

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RISK MITIGATION STEPS

Understanding the Regulations

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Understanding the Regulations

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."

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Understanding the Regulation (cont.)

In response to the Presidential order the Center for Medicare and Medicaid Services (CMS) issued the clinical trial policy national coverage determination (NCD)

- NCD 310.1 Routine Costs in Clinical Trials
  - *(CMS Internet Only Manual (IOM) Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Section 310.1 "Routine Costs in Clinical Trials")*
- Effective September 19, 2000
- Revised July 9, 2007

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Understanding the Regulations

Patient Protection and Affordable Care Act (PPACA) became 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 & services furnished in connection with participation in the trial; and
- Discriminate against the individual based on their participation

For this act, 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

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Local Regulations

Medicare Administrative Contractors works on behalf of Medicare to manage and process claims and implement state/regional coverage rules called:

- Local Coverage Determinations (LCD)

LCDs detail requirements necessary for reimbursement for certain services including

- Applicability, frequency, and exceptions
- Off-Label Drug Use in Clinical Trials
- Reimbursement requirements for IDE (investigational device exemptions)

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RESOURCE TOOLS USED TO DETERMINE ROUTINE CARE

- Centers for Medicare and Medicaid Services (CMS) **www.cms.hhs.gov**
- Novitas (LCD) – Texas

  www.novitas-solutions.com

For oncology:

- National Comprehensive Cancer Network (NCCN)

Other disease groups:

- Utilize the national compendia applicable for the disease being investigated
- Review of coverage policies of common insurance carriers (Blue Cross, Aetna, Cigna, and United Healthcare)

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RISK MITIGATION STEPS

The Medicare Coverage Analysis – a Multiuse Document

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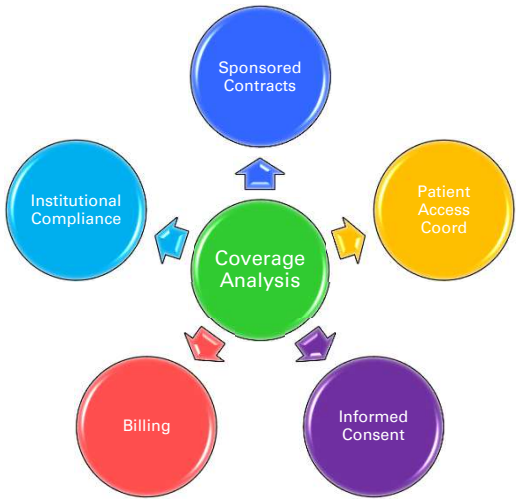
Cross functional & multi-purpose



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Clinical Trial Routine Cost Coverage

CMS has specific rules that must be met to qualify for coverage of the Routine Costs associated with the trial

Cannot bill for Routine Services if the trial fails to meet CMS criteria

- Some items/services never can qualify to bill to CMS

Items that cannot be billed must be covered by the trial funding source such as the sponsor

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NCD 310.1 - Routine Costs for Clinical Trials

National Coverage Determination 310.1 explains that specific requirements must be met in order to:

- Qualify for coverage
- Submit a claim properly and
- Receive reimbursement for claims submitted

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Qualifying for Coverage

Three (3) Mandatory Requirements:

1. Trial must:
   - Evaluate an item or service within a benefit category and
   - Not be statutorily excluded from coverage

   Example: What Meets this Criteria?
   - Diagnostic tests, drugs, & biologics
     - Yes!
   - Hearing aids, cosmetic surgery, dental exams
     - No!

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Qualifying for Coverage

2. The Trial must:
   - Not be designed exclusively to
     - Test toxicity or
     - Disease pathophysiology
   - Have therapeutic intent

Example: What Meets this Criteria?

- Phase 2 clinical trial testing FDA investigational new drug
  - Yes!
- Prospective lab trial to test tumor signal pathways
  - No!

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Qualifying for Coverage

3. Trials of therapeutic interventions must:
   - Enroll patients with diagnosed disease rather than healthy volunteers
   - Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group

Example: What Meets this Criteria?

- Phase 2, two-arm comparison trial testing use of endoscopy dye to detect colon polyps. Will enroll participants with known polyp hx scheduled for follow-up colonoscopy, and pts with no known colon hx scheduled for initial colon screening.
  - Yes!
- Phase 1 study of the general population testing new cholesterol lowering medicine. Will enroll healthy volunteers ages 40-65.
  - No!

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Qualifying for Coverage

3 Requirements Are Not Enough

Trial **Must ALSO** meet 7 characteristics (synopsis)

- potentially improves health outcomes
- well-supported by scientific & medical information
- does not unjustifiably duplicate existing studies
- is appropriate to answer the research question
- sponsored by a credible organization
- in compliance with Federal regulations
- conducted with scientific integrity

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Qualifying for Coverage

Some trials will meet the 7 characteristics automatically if:

- Funded by NIH, CDC, AHRQ, CMS, DOD and VA;
- FDA IND & IRB Deem IND Exempt Drug Trials: or
- Supported by Centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA

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Qualifying Clinical Trial

If the trial:

- Meets all 3 mandatory criteria **and**
- The 7 desirable characteristics (synopsis)

Then the trial is considered to be a

- Qualifying Clinical Trial
- Thereby meets the requirements for coverage of Routine Costs

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Covered Services/Routine Costs

- What Does CMS consider to be Routine Costs?
- Routine costs of a qualifying clinical trial is defined as:
  - Reasonable & necessary items and services used to diagnose and treat complications
  - All other Medicare rules apply
  - All items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial
  - Items or services that are typically provided absent a clinical trial

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Routine Costs (cont.)

- Items or services required solely for:
  - The provision of the investigational item or service
    - Covers the administration of an investigational product
  - Clinically appropriate monitoring of the effects of the item or service, or
  - Clinically appropriate monitoring for the prevention of complications
- Items or services needed for reasonable and necessary care for the diagnosis and/or treatment of complications.

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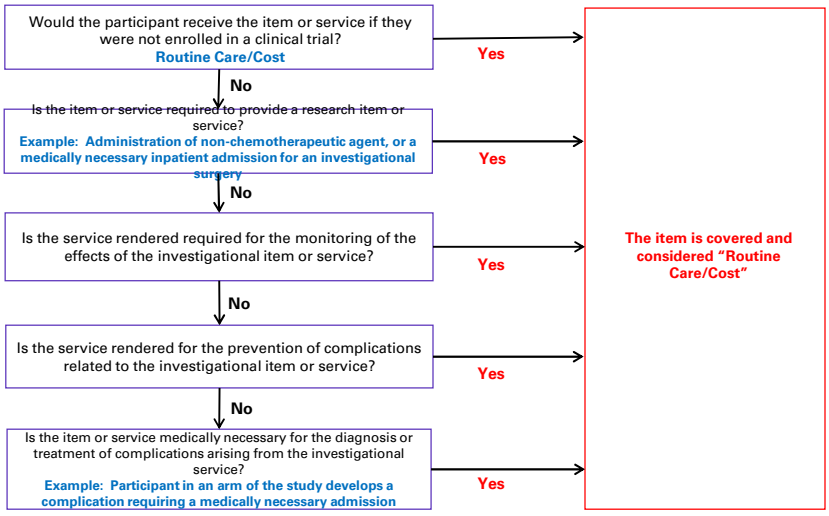
Routine Care/Cost Decision Tree



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CMS Defined Research Costs

What does CMS consider to be Research?

The investigational item or service itself

- Unless otherwise covered outside of the clinical trial
  - Example: Some items or services are covered but are also part of the trial investigation
    - Off-Label Use of approved drugs
      - Provided these meet CMS criteria usage requirements

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Research Costs Include

- Items and services provided solely to:
  - Satisfy data collection and analysis needs
  - Services not used in the direct clinical management of the patient
    - Example: Monthly CT Scans for a condition usually requiring only a single scan
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial
  - If sponsor covers the cost of the service, CMS cannot be billed

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What To Bill?

Covered

- Administration of drug
- Labs to monitor effects of drug
- Complications
- All items and services are subject to LCDs and NCDs.

Non-covered

- Satisfy data collection
- Absent a clinical trial the service or item that provided solely for the purpose of the study.

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What Does This Mean?

For each item or service, ask the question, why is this being done?

What is the reason / diagnosis for this service?

- Assign the diagnosis and determine if it is covered under the terms of an LCD or NCD.

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Facts

The billing mechanics are easy
Communication is key
The hard part is:

Getting the right information to the billing department!

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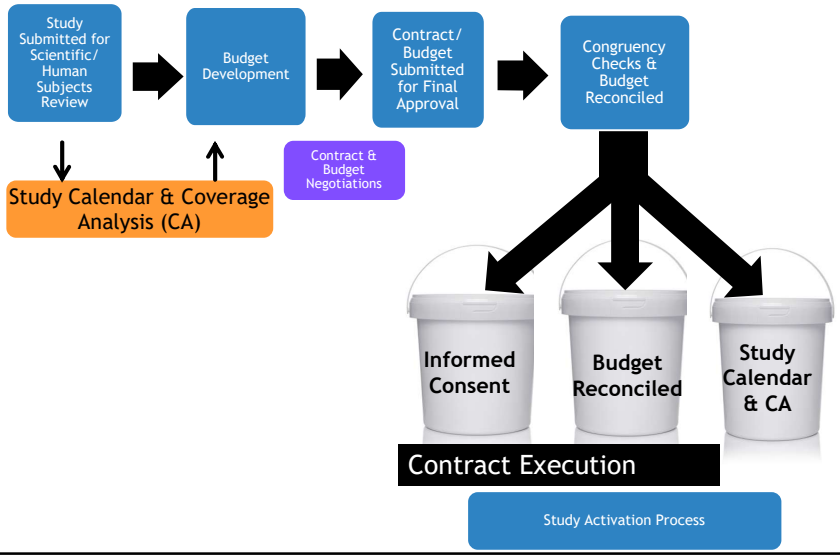
Financial Life Cycle of Clinical Research Study - CTMS



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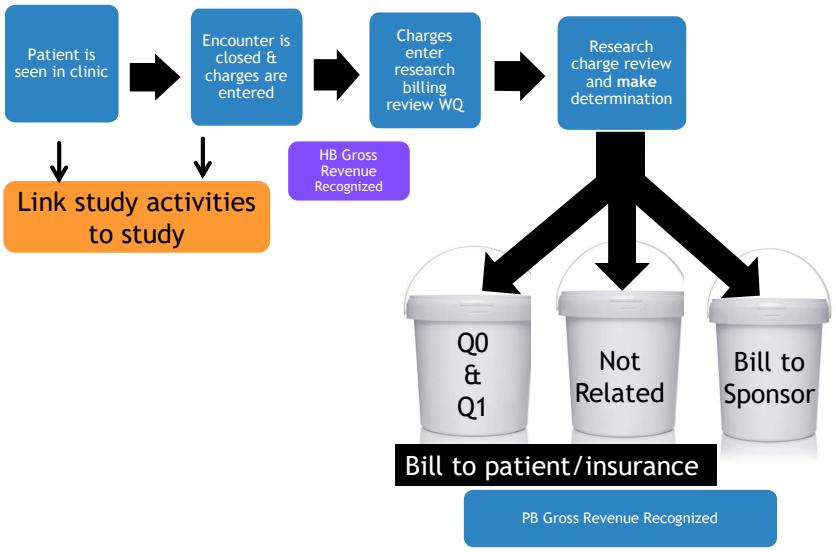
Clinical Research Billing (CRB)
Research Charge Review Process - EHR



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RISK MITIGATION STEPS

Building Controls in Systems

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Building Controls in Systems

- Centralize the study calendar & coverage analysis (CA)
  - Drives standards
  - Ensures compliance with CMS billing guidelines
  - Validate build with PI and/or designee
    - Provides assurances build matches IRB approved study
    - Obtain signature and date
- Electronically transfer coverage analysis to EHR
  - Becomes billing grid in EHR
  - Drives research billing process
- Create study note templates in EHR
  - Include study number; date of service; cycle & day; treatment provided; adverse events, if any
  - Drives standardization
  - Aid with research billing review

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Building Controls in Systems

- Consent patient
  - Electronically transmit the consent date to CTMS and/or EHR
    - Associates the patient to the study
  - Central office creates initial patient timeline
- Associate to treatment plan and link encounters
  - PI and/or designee associates patient to treatment plan & timeline
    - Adjust as needed; based on patient
  - Generated research orders
    - Link encounters, as needed
- Patient treatment occurs
  - PI and/or designee ensure encounter is linked appropriately
  - Document study notes in patient's chart
    - Include cycle and day; treatment; adverse event, if any

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Building Controls in Systems

- Study Revisions
  - Revise the CA
    - Validate with PI and/or designee (obtain signature & date)
  - Migrate revised CA to EHR
    - Revise billing grid at study level
  - PI and/or designee re-associate patient treatment plan and timelines, as needed

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Building Controls in Systems

- Research Billing Review
  - Centralized process
  - Utilize the CA in CTMS to aid with determination of appropriate charge routing
  - Monthly reconciliation of sponsor paid charges
    - Validation process between central office and department personnel
      - Utilize work queues in EHR to drive process
    - Post charges to general ledger within 30 days of month end
    - Mitigates risk of inappropriate billing
- Clear Effective Communication

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RISK MITIGATION STEPS

Checks and Balances

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Checks & Balances

- Reports
  - Research patient appointment report (linked encounters)
  - Patient timelines in CTMS vs. linked encounters in EHR
  - Patients with missing timelines & treatment plans report
  - Copy forward report (Beacon treatment plans)
  - Productivity reports:
    - Research billing review productivity report
    - Research reconciliation productivity report
  - Research billing reports
    - Study charges by department

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Checks & Balances

- Monitoring
  - Monthly review of reports
    - Run queries to perform reasonableness checks
  - Review patient timeline in CTMS vs. linked encounters
  - Reconciliation process
    - Validate centralized charge review
    - Shared learning – central office and department personnel
  - Milestone achievements
    - Timely sponsor invoicing
  - Close out process
    - Review research billing
      - Ensures appropriate billing prior to closing
    - Reasonableness checks for other budget categories

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BEST PRACTICES

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Best Practices

Differentiate covered services from non-covered (research related) services for major payers.

Creation of Coverage Analysis utilizing CMS guidelines

Once study is approved, enroll study www.ClinicalTrials.gov and obtain 8 digit number.

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Best Practices

Define how study enrollees will be identified on the front end.

Determine if internal systems can "talk" to one another for data transmission purposes.

- Study number
- Coverage by service
- Diagnosis codes

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Best Practices

At enrollment, informed consent should list out services that are non-covered.

At time of registration, obtain ABN for non-covered services.

- Work with finance dept to inform patient of financial responsibilities associated with the trial.

If patient receives services at another institution, facility or entity that does their own billing, ensure that the services are identified appropriately. (i.e. national lab)

Conduct audits after the first 10-20 group of enrollees meet their first benchmark to ensure process is working correctly.

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Best Practices

If problems are identified, fix it before it becomes out of hand.

End of trial procedures:

- Perform post-study audit to ensure funds have been invoices, received and appropriated correctly.
- Determine cause of credit balance
- Review contract to determine what happens to excess funds.

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Questions

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Contact Information

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