


HORIZONS

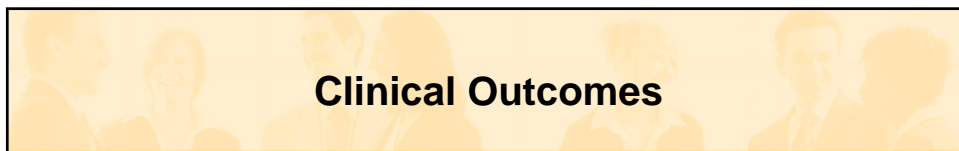
Think. Challenge. Excel.

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26-28 March 2008 • San Francisco • The Fairmont

Utilizing Clinical Trials to Foster Payer Adoption




RAPS REGULATORY AFFAIRS
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Making better healthcare products possible



Clinical Outcomes

- Use clinical trials as much as possible to meet both regulatory and reimbursement requirements
- Meet with payers to discuss most appropriate patient selection and outcomes before trials
- Include patients as dictated by payer mix
- Develop inclusion and exclusion criteria for clinical studies with payer medical policies in mind



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Clinical Outcomes

- Key to successful coverage is controlled, long-term, published data
- CMS (Medicare) has signaled a move toward cost effectiveness (CE) for coverage decisions
- Clinical trials provide good vehicle for collecting economic and quality of life outcomes
- Recommend publishing on both clinical and CE outcomes as possible (i.e., power study for both)

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Clinical Outcomes

- Clinical outcomes for regulatory approval may be different from those important to payers, e.g.,
 - Physiologic measures of improvement
 - Function
- Payers will require education if quality of life is more relevant or clinically important than physiologic changes
 - Publish clinical papers

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Clinical Outcomes

- Important clinical data to collect as it relates to health outcomes/coverage/payment:
 - Complications and co-morbidities
 - Severity of the condition
 - Previous treatments
- Important long-term resource-use data to collect as possible/relevant:
 - Hospitalizations outside of protocol
 - Physician/other provider visits outside of protocol
 - Change in medication use
 - Return to work

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Seeking Reimbursement in Trial

- Trials automatically approved for reimbursement in clinical trials under Medicare CRP NCD:
 - Trials funded by or supported by centers that are funded by federal programs
 - Most drug trials
- Includes coverage of routine costs only:
 - Services provided outside of a clinical trial for the patient population
 - Services required for the provision of investigational service, monitoring of effects of the service, or prevention of complications
 - Services for diagnosis or treatment of complications in trial (controversial)

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Clinical Trial Reimbursement

- CMS issued a Final Rule in 1995 to enable coverage of IDE-approved medical devices categorized by the FDA as Category B “non-experimental” or “evolutionary changes in proven technology”
 - Updated in 2003 to include some Category A routine care coverage for life-threatening illnesses
- Only Aetna has officially followed among private payers
- Does not guarantee coverage but enables Medicare contractors to evaluate for coverage

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Clinical Trial Reimbursement

- Final Rule allows trial sites to seek coverage for the device and all services associated with it
 - Services required solely to satisfy clinical study requirements not eligible (e.g., data collection, administration)
 - Device payment – Medicare will pay up to what it currently pays for a similar device

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Clinical Trial Reimbursement

- Process requires negotiating with Medicare contractors post-IRB approval
- Many have approved; however:
 - Some contractors requiring published human data for approval
 - Many contractors don't understand difference between IDE and CRP reimbursement
- Claim forms must identify that patient in a clinical trial with –QA modifier for IDE reimbursement (check with contractor)

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Clinical Trial Reimbursement

- Advantages of IDE billing:
 - Revenue / cost recovery
 - Educate payers early in product lifecycle
 - Ascertain possible issues post-launch

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Clinical Trial Reimbursement

- Challenges associated with IDE billing:
 - Resource-intensive for company with regard to site support and Medicare interactions
 - Resource-intensive for study coordinator and hospital billing personnel
 - Commercial payer coverage variable
 - Potential contract/budget delays (many sites not familiar with clinical trial reimbursement)
 - Impact on patient re: co-insurance

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Clinical Trial Reimbursement

- Resources required:
 - Budget and contract to negotiate with sites
 - Trial agreement and patient consent form that address billing implications
 - Payer dossier with clinical, economic, coding reference information
 - Submission letters for the sites (pre-authorization, appeal, etc.)
 - Reimbursement support line (as needed)
 - Personnel to negotiate with Medicare contractors

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Clinical Trial Reimbursement

- Before you start:
 - Discuss plans with 2-3 sites and 1-2 Medicare contractors to assess reception
 - Determine cost/benefit of proceeding based on percentage of Medicare versus private pay patients
 - Determine risk of slow enrollment due to co-insurance concerns versus benefits of cost offsets
 - Budget and staff appropriately for process and follow-up

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Q&A

Thank you

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