Coverage with Evidence Development (CED)

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What do we know about CED?

- CMS Guidance Document, April 7, 2005
- CMS clarification issued, July 12, 2005
- Revised draft guidance document still “pending”
What CED Appears to be

- Covers services with insufficient evidence to permit NCD
- Will rely primarily on registry data, rather than clinical trial evidence
- Will not generally result in final coverage decision
- Data will generally be evaluated by non-CMS folks
What CED is not

- Is not “coverage in exchange for data”
- Is not a decision that service should be covered in a limited manner
- Is not an attempt to develop evidence that will result in Medicare restrictions
- Is not a CMS coverage review and decision process
Positive Points of CED

- Offers coverage otherwise denied
- Offers early opportunity for beneficiaries to receive service
- Offers source of funds for cash-strapped sponsors
- Offers source of income for malpractice attorneys
Negative Points of CED

• Publicly identifies service as not proven
• Registry data seldom justifies expansion of coverage
• Claims process unforgiving
•Freezes consideration of service, can slow adoption
• Potentially damaging information public
Service Less than Adequate

- Will only be offered to services with insufficient evidence for coverage
- MD’s and patients may think service is useless or harmful
- Can be cited as “proof” service does not meet “reasonable & necessary” test
- Service may appear on injuryboard.com
Registries Have Limitations

• Registries usually only confirm service is performing as clinical trial suggested
• Registries more likely to spot anomalies that call service into question
• Registries generally only show trends
• “Renegade” use of service can result in spike of unfavorable data
Claims Process Unforgiving

- CMS limited by claims process
- Medicare contractors must process claims quickly due to high volume
- No time for reconciling bad data
- Data collection requires much cooperation and clearance--uncertain that can be done in reasonable time
Freezes Consideration of Service

• CMS unlikely to reconsider service while CED in place
• New entries to market may be discouraged by limited coverage
• Coverage not stable, may scare investors
• Economic projections suspect
Potentially Damaging Information Public

- CMS will make data public, relying upon private researchers for analysis
- Sponsor has no influence over how data is collected, reviewed or evaluated
- CMS plans to publicize unfavorable results for MD’s and patients to consider
- Potential for bad publicity for a long time
Is it Worth it?

• High “hassle factor” for MD’s and hospitals
• May offer cash flow for service with difficulty meeting CMS coverage rules
• Must be balanced against possible continuing long-term damage from adverse data (or interpretations of data)
Can you Avoid it?

- CMS gives no indication applicant for NCD can avoid CED
- CMS coverage decisions generic--competitors may force you into CED
- CMS appears to favor leaving issue in CED status an for extended time--may discourage entry into market
Summary

• CED appears to offer some minimal benefit, but with serious risks
• Considerable reputation and financial risks for companies involved in CED
• No indication by CMS that CED can be avoided, either by individual companies or industry as a whole