

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- Revised draft guidance document still “pending”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