



EFS Site Best Practices Workshop

Event Materials

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**MDIC Offices
1501 Wilson Blvd.
Arlington, VA 22209**

Coverage Determinations & Site Budgets

Jill Trekell
Senior Director, Clinical Affairs
Edwards Lifesciences

jill_trekell@edwards.com



Edwards

Trial Reimbursement

- **Category A**
 - CMS will pay for standard of care / routine procedures, and the implant procedure, but NOT the Device
- **Category B**
 - CMS will pay for standard of care / routine procedures, the implant procedure, and the Device
- **No Reimbursement**
 - Sponsor pays for everything, including the device and does not charge for the Device



Developing EFS Budgets

- Start with the protocol and determine what procedures are required by the protocol and which are standard of care (SOC)
- Establish Fair Market Value (FMV) for study procedure costs, SOC vs non-SOC items
 - FMV calculators – Grant Plan, Grant Manager, etc.
 - Establish FMV range from low to high

Procedures (24)		United States	Sub-Study: All Budgets			
Code	Procedure	Qty	Low	Med	High	
T9209	IQVIA Code: Medical History with Informed Consent (Formerly IQVIA code 99209)	8	181	219	268	
S0074	New York Heart Association Functional Classification (NYHA); 8 clinician- or researcher-administered	8	39	44	48	
99214	Detailed office or other outpatient examination: Includes at least two of these three components - a detailed medical history, a detailed physical examination including vital signs, medical decision making of moderate complexity. Typically, 25 minutes are spent performing or supervising these services; visit (formerly code 92120, 92130)	9	188	202	212	



FMV Rates per Procedure

Procedure Cost Estimation (non-CMS reimbursed)

- If sponsor *doesn't* have CMS approval, Sponsor will pay for all procedures required by the protocol & hospitalization
 - To obtain implant procedure estimate, pull hospital data for CMS reimbursement for similar procedure and provides estimate and rationale
 - Fee is a one-time fixed payment which will cover everything during hospitalization
- Budget sent to site includes implant and hospitalization fee plus other FMV data required at study intervals
- Goal: Find middle ground with clinical sites within FMV range

Procedure Cost Estimation (non-CMS reimbursed)

- Find appropriate similar procedure DRG
- Estimate the occurrence of major cardiovascular complications and weighted average between reimbursement with or without MCCs
- Compare national average and local hospital reimbursement
- Add any additional costs
 - Hospital component: inpatient reimbursement
 - Physician component: payment for first/second device placement, TEE, etc.
- Medicare reimbursement assumes payment for device; deduct as applicable
- Resulting fee is basis for negotiation with hospital

Challenges with Negotiating Budgets Before CMS Determination

- Clinical sites want higher fees for the implant & hospitalization than what is considered FMV
 - Sites are unsure of the “unknowns” that may occur & don’t want to be left with a large bill
 - Sponsor can only pay within FMV due to kick-back concerns & the payment has to be fixed vs. open ended
- Budget negotiations without CMS determination can take 2x or 3x longer



Budget Negotiations



“Okay, so what number can we both be happy with?”

Common Challenges with MCTAs & CTAs

- Most disputed issues:
 - Who pays in the event of an injury?
 - Breach of confidentiality and damages – LOL Section
 - Indemnification
 - Will we indemnify both the PI and his or her employer that hasn't entered into the contract?
 - Publication on clinical trials.gov and other disclosure requirements

**IT TAKES TIME & ONE ISSUE
ALONE CAN CAUSE DELAYS THAT LAST MONTHS!**

Case Scenario A

- Hospital is a university hospital ultimately governed by state policies and regulations
- Hospital claimed that under their university/state policies they may have to disclose all trials they were working on – no secrets as a public institution
- Some EFS trials can be *highly* confidential & sponsor doesn't always want to disclose trial information
- Site insisted that it could not keep any information secret due to public disclosure requirement
 - Site refused to take the risk of breaching confidentiality provisions
- Impasse lasted months and several rounds of negotiation calls

- In addition ...
 - Required external review of SOW; >1 year delay (MDIC site)

Case Scenario B

- Hospital is a university hospital
- EFS program without CMS reimbursement where sponsor proposed FMV budget
- Hospital initially agreed to proposed FMV budget and signed statement of work, site activated to enroll
- Prior to first patient enrolled, site balked and requested increase in procedure cost reimbursement to 3x FMV rate
- Sponsor could not justify 3x FMV from a compliance perspective
 - It's not always about the actual money, but about the risk sponsors run if they pay over FMV
- EFS was not able to move forward at this site unless the trial received CMS reimbursement