CSRC and MDEpiNet Thinktank

"The role of Endpoint Adjudication in Medical Device Clinical Trials"

Efficient use of premarket data sets to meet both FDA & CMS requirements: Engagement with CMS and FDA – What is it and what is its current status in device trials or:

Promoting Better Collaboration between Regulatory and Reimbursement: CDRH Perspective

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It's About the Patients

And ACCESS to Safe and Effective Medical Devices

Keys to Patient Access

Evidence

Market Value

Patient Value

Reimbursement

Why is FDA Talking About Coverage and Reimbursement?

"Winning coverage and payment has become a steeper challenge than gaining FDA approval for small device firms in recent years" ***Mike Carusi on behalf of NVCA, AdvaMed and MDMA***

The success or failure of an innovative technology should be based on whether that technology works and fulfills a clinical need. However, the reality is that many other issues may cause the technology to fail, and two of those issues are coverage and reimbursement.

What are we talking about?

FDA is not talking about coverage or payment but rather about communication of the evidentiary requirements from 3rd party payers to sponsors.

Designed for Patient Access

What is the Issue we are Trying to Address?

- Device Innovators assume that FDA clearance/approval results in CMS coverage
- Statutory requirements are different
- End-point requirements are different
- Can result in needing additional trials ($ - time)
- Can result in delay patient access

Statutory Authorities
FDA vs. CMS

CDRH approves/clears devices that "provide a reasonable assurance of … safety and effectiveness…." *See* Federal Food, Drug & Cosmetic Act Section 513, (21 USC 360c).

CMS covers devices that are "reasonable and necessary for the diagnosis or treatment of illness or injury …." *See* Social Security Act Section 1862(a)(1)(A), 42 USC 1395y(a)(1)(A).

What Works Well Today

- FDA pre-submission program
  - Robust approach to obtaining input from FDA on clinical trial design for end-point adjudication
- Independent communications with CMS
  - Can also provide input for end-point adjudication but often under utilized
- Most coverage determinations made by MACs (local coverage decisions)

Parallel Review Program

Purpose: Reduce the time between FDA marketing approval and a CMS national coverage determination (NCD)

First announced: 75 Fed. Reg. 57045 (Sept. 17, 2010)

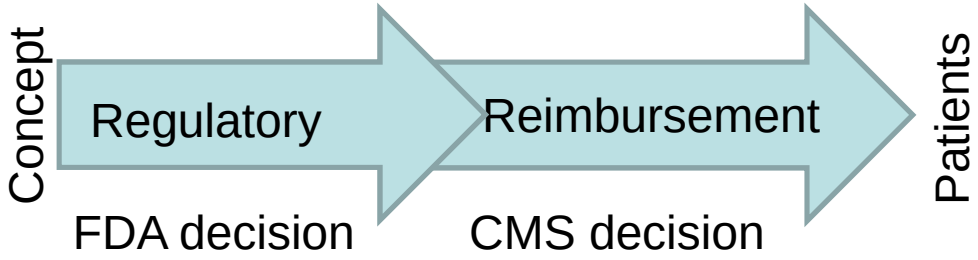
Described: 76 Fed. Reg. 62808 (Oct. 11, 2011)

Extended: 78 Fed. Reg. 76628 (Dec. 18, 2013)

Concept of Parallel Review

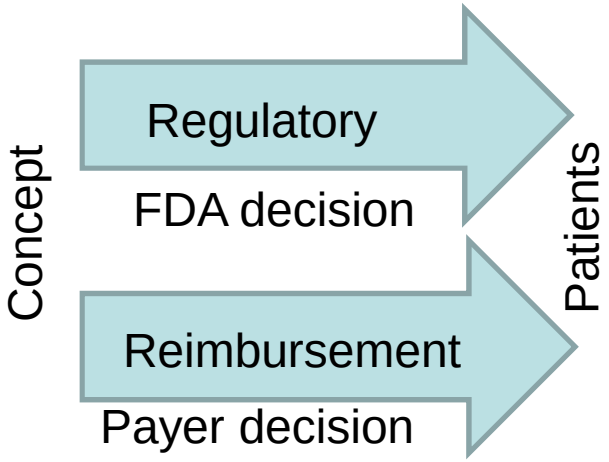
Before PR

- Steps in series
- Coverage/Reimbursement considered late
- Long gap between FDA decision and patient access



With PR

- Steps in parallel or simultaneous
- Coverage/Reimbursement considered early
- Shorter gap between FDA decision and patient access



Pilot Projects

- **Exact Sciences: Cologuard** – Colon cancer screening diagnostic device
  - August 11, 2014:
    - FDA approves Cologuard
    - CMS issues its proposed NCD
  - October 9, 2014: CMS issued its final NCD

- **Medtronic: Symplicity** – Renal Denervation device
  - Ongoing

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm255678.htm

What's broken

- Developer/payer (coverage organization) communications
- Under utilization of Parallel Review
- Under utilization of CED
- Lack of robust data repositories and methodologies to efficiently evaluate real-world clinical experience with medical devices post-approval

Highest Priorities: Short term

- Expand scope of Parallel Review
- Develop earlier communication between developers and payers to determine and adjudicate end-points
- Include private 3rd party payers
- Pilots for development of National Medical Device Evaluation System

Medical Device Payer Communication Task Force

Mission

Streamline the pathway from regulatory clearance or approval to reimbursement to support access to innovative medical devices

Plan

Develop a voluntary process that facilitates earlier interactions with payers, including private 3rd party payers about evidence to support coverage and reimbursement

Staff

OCD / ODE / OIR with support from CMS

What are we proposing?

FDA Review Team

Manufacturer

Payer

Provide a process to enable manufacturers to include and engage payers during meetings with FDA using the Pre-Submission program.

What is FDA not doing?

- Being coverage or payment experts
- Promoting specific devices or manufacturers
- Promoting specific payers or specific codes
- Considering payment or costs for approvals
- Modifying FDA review or decision processes
- Suggesting that payers use FDA's evidentiary requirements or alter anyone's standards

Important Clarifications

- FDA evaluates safety and effectiveness in the same way using the same methods
- FDA's communication facilitation will be done through FDA's established Pre-Submission process
- Manufacturers will opt-in
- Manufacturers will invite payers/providers

Value to Stakeholders

Patient

- Earlier access to innovative technologies

Payer

- Learn more about new technologies beyond current horizon scanning
- Provide suggestions about what data and analyses would be useful for evaluation
- Learn more about FDA review process

Manufacturer

- Engage payers earlier in discussion about evidentiary needs
- Consider and address coverage-related issues earlier in the process
- Potential for earlier payment through earlier engagement

FDA

- Improve public health by shortening the time for patients to access innovative medical devices

Highest Priorities: Long Term

- Improved communications for sponsors with regulators and payers early during development
- Post market device evaluation system for:
  - Surveillance
  - Payers (coverage determinations)
  - Regulatory decision-making
  - Robust feedback on data regarding function of devices in the real world
- Approaches to focus development of devices (combination devices) to address unmet needs, such as bio-artificial kidney

More Information

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Internet Information:

1) FDA/CDRH Innovation:

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm2024881.htm

2) Payer Communication Task Force and Parallel Review:

http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhinnovation/ucm456149.htm

3) Pre-Submission Program Guidance:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm

Thank You