Getting Your Product on the Market: Premarket Approval is Only the Beginning

Moderator: Adam Saltman – Medical Officer, OPEQ IO CSP, CDRH/FDA
Jim Prodafikas - Worldwide Director Market Access and Reimbursement Diabetes Care, BD
Ken Skodacek - Ombudsman, CDRH/FDA
Chuck Stemple - Vice President, Health Guidance Organization, Humana
Amanda Klingler - Partner, FDA and Life Sciences Practice, King & Spalding
Why Are We Talking About Reimbursement?

It’s Not Just About You and FDA

Hopefully not too much of this!
Why Are We Talking About Reimbursement?

It’s Not Just About You and FDA

And more of this!
Why Are We Talking About Reimbursement?

It’s Because TPLC Doesn’t End With Packaging
Why Are We Talking About Reimbursement?

Somewhere in Here: Between Marketing and Commercial Use
Somebody Has To Pay!
Agenda

• Talk about really closing the cycle in TPLC
• Once your product is “OK’ed” for market
  • How will you get paid for it?
  • Who will pay for it?
  • Why should they pay for it?
  • And where does all this stuff go???
• Perspectives from industry, FDA, payors, and legal advisors
• Panel discussion and audience questions
Speakers

• Jim Prodafikas
  • Roche – Primary Care Medical Science Liaison
  • Novartis – US and Global Medical Affairs
  • AstraZeneca – National Clinical Account Manager
  • Merck – Global Market Access lead for Hospital/Acute Care
  • Becton Dickinson – Worldwide Director of Market Access and Reimbursement for Diabetes Care
Speakers

• Ken Skodacek
  • Medical device industry (1991)
    • CPI/Guidant – design engineering, clinical engineering
    • Biotronik – clinical engineering, regulatory, marketing, heart failure portfolio lead
    • Impulse Dynamics – clinical engineering
  • FDA/CDRH (2008)
    • Pre-market (lead reviewer)
    • Compliance (manufacturing and BIMO)
    • Clinical trials program
    • CDRH Deputy Ombudsman
    • CDRH Payor Communications Task Force
Speakers

• Chuck Stemple
  • MBA Xavier 1987
  • Emergency Medicine physician
  • Cross-cutting expertise
    • Genetic testing, integration of clinical, pharmaceutical and operational activities across the health plan
    • Medicare claims, policy, ICD-10 coding, and regulatory/compliance
    • Utilization, cost trend drivers, coding, reimbursement, and disease management programs
    • National medical director for bariatric and transplant services for commercial and Medicare lines of business
    • Value-based outcome contracting, hospital contracting and provider-based initiatives
  • ChoiceCare – Medical Director, Utilization Management
  • UnitedHealthCare – Medical Director, Director of Clinical Operations
  • Humana – Vice President, Health Guidance Organization
    • Chairman of national medical technology assessment committee
    • Chairman of medical pipeline committee
    • Co-chair of the pharmacy and therapeutics committee
Speakers

• Amanda Klingler
  • Partner in King & Spalding’s FDA and Life Sciences Practice Group in the Washington, D.C. and Chicago offices.
  • Represents medical device, pharmaceutical, and pharmacy clients in a wide range of FDA regulatory matters, enforcement actions, civil litigation, internal investigations, and compliance counseling.
  • Counsels on premarket submissions, adverse event reporting, quality system and manufacturing practices for drugs and devices, factory inspections, recalls, and product labeling.
  • Represents medical device, pharmaceutical, and other life sciences companies relating to FDA issues in products liability litigation.
Planning for Successful Medical Device Market Access and Reimbursement

Jim Prodafikas, PhD
Worldwide Lead Market Access and Reimbursement
Diabetes Care - Becton Dickinson
“If you build it, they will pay....”
Reality

• The cost of not proactively developing economic data can be high. Payer decisions have a significant impact on clinical adoption rates and profitability.

• With increasing focus on cost containment, even some legacy products have been met with a demand for compelling economic data.

• Understanding and incorporating the payer perspective and data requirements early in product development is essential in this environment.

• The payer perspective is just as crucial to success as regulatory agency input and approval. Essential to proactively seek payer input, listen closely and incorporate expectations.

• Adding early payer input evidence generation strategies requires a fundamental shift in how organizations think about market strategy and product development.

• Companies that are able to adapt to a value-based marketplace will be positioned to succeed in this changing environment.
Reimbursement: Coverage, Coding and Payment

• A detailed analysis of the current reimbursement landscape in country/region is imperative
• Need to develop a strategy for how product will be paid for (very dependent on product and setting of use)
• Coverage
  – Coverage via a National Coverage Decision (NCD) or local coverage decision (LCD) applies to new medical procedures and technologies not currently defined in the regulations. CMS generally focuses on superiority of a product relative to gold standard
• Coding
  – Coding translates to payment. There are numerous types of codes depending on where a procedure is performed, who is performing procedure and what equipment is involved
  – Determining how and where product fits into coding landscape can be complicated and requires thorough analysis. Utilize existing code or create new code?
  – Creating new code generally requires a good body of data
• Payment
  – After coverage determination and coding hurdles have been crossed, the amount a hospital or physician practice will get paid directly determines sales success
  – Success is not just determined by reimbursement its also driven by a well defined value proposition focusing on all key stakeholders
Pillars of Reimbursement Landscape Assessment

- **Coverage status** – How are payers such as CMS, private payers, Medicaid, etc. looking at the device?
- What is the **setting of use** and **realistic target patient profile**?
- **Current coding** – What codes are physicians, facilities (hospitals, outpatient, ASCs), homecare, etc. using?
- **Payment** – How does reimbursement compare to charges?
- **Competing/Proposed Technologies** – Are there similar products? How are they paid for and reimbursed?
- **Status of evidentiary needs** – Does the technology improve health outcomes and is it cost effective?
- **Findings and recommendations for strategic plan** – What does the assessment tell you about strategic planning needs?
Demonstrating Value – A broad set of stakeholders

**Payers**
- Focused on reducing cost of care
- Interested in identifying the least expensive approach that fixes the problem
- Interested in innovation that helps them reduce costs, including improved patient compliance and chronic disease management
- Interested in preventing future costly complications

**Employers**
- Focused on reducing cost of care and healthcare insurance expenses
- Interested in improved employee productivity and presenteeism, reduced absenteeism
- Prevent future costly complications

**Providers**
- Interested in products that help them reduce costs and meet quality metrics
- Interested in products and services that help them improve consistency in care delivery and meet clinical quality standards, increase safety, effectiveness, lowers outcome variability, reduces length of stay/readmission rates and improved patient experience

**Patients**
- Want improved quality of life
- Prefer interventions that are easier to use and regimens that are easier to stick to
### Activity
- Reimbursement Landscape
- Reimbursement Planning
- Implementation

### Description
- Money flows and financial incentives
- Reimbursement mechanisms
- Decision makers and strategy
- Value story
- Economic model
- Support of clinical data
- Feedback from decision makers
- Billing guide/dossier
- Support of medical community
- Pilot projects with individual payers
- New Reimbursement mechanisms

### Phase
- R&D
- Pre-Clinical/Clinical
- Pre-Sales/Launch

### Potential Impact
- Features and applications
- Predicate device/intended use
- Price
- Market size
- Price
- Clinical study protocol
- Time to market
- Revenue
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FDA/Xavier MedCon Conference

Ken Skodacek
FDA/CDRH
May 1, 2019
The Long Journey

Patients that need your device

You with your medical device
Your Questions

What is FDA doing to address this challenge?

Why is FDA talking about reimbursement?
Why FDA? Three Critical Facts

- FDA interacts with medical device manufacturers early in the process
- FDA approval ≠ patient access
- Obtaining reimbursement is a significant obstacle especially for innovative medical devices

https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm621681.htm
FDA’s Activities: 2010 - Present

• FDA/CMS Memorandum of Understanding
• FDA/CMS Parallel Review
• CDRH 2013 Strategic Priorities
• Entrepreneurs in Residence Program
• **Payor Communication Task Force**
• Private Payor Engagement
• Payor Communication Guidance
Challenges: Internal

Regulatory Language

Reimbursement Language

Regulatory
Clinical
Reimbursement
Marketing
Sales
Challenges: External

How do I external stakeholders to understand what they need?
Value of Early Communication

Pre-Submission (IDE)

IDE Application

Pre-Submission (PMA)

Marketing Application
FDA/CMS Parallel Review

Parallel Review → Parallel Planning
Voluntary Engagement Opportunity

Pre-Submission Meeting

FDA Review Team  Manufacturer  Payor

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

- BlueCross BlueShield Association
- CareFirst BlueCross BlueShield
- Center for Medicare & Medicaid Services (CMS)
- Cigna
- Duke Evidence Synthesis Group
- ECRI Institute
- Humana
- Kaiser Permanente
- National Institute for Health and Care Excellence
- United Health Group
Example: Strategic Planning

Regulatory pathway and reimbursement may depend on more than just the medical device:

- Indications for Use (IFU)
- Prescription vs. OTC
- Inpatient vs. outpatient
- Physician specialty considerations
- Specific labeling claims (vs. tool claims)
Example: Increasing ROI

Evidence Collection

Evidence Utilization
Payor Engagement Specials

- Pre-Submission with Payor/HTA
- Pre-Submission with CMS
- Formal FDA/CMS Parallel Review

Other Selections

- Bring reimbursement staff into FDA discussions
- Engage reimbursement experts
- Engage payor without FDA
Our Goal & Potential Impact
CDRH Payor Communication Task Force

CDRHPayorCommunications@fda.hhs.gov

FDA/CMS Parallel Review

Parallel-Review@fda.hhs.gov
Payor Communication Task Force

Mission
Facilitate earlier communication between device manufacturers and payers to potentially shorten the time between FDA approval or clearance and coverage decisions

Goal
Develop voluntary processes that facilitate earlier interactions with Payors about evidence to support 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
Reference Links

CDRH’s Payor Communication Task Force
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm456149.htm

FDA Voices: New Program with Payors Aims to Accelerate Patient Access to Medical Devices
https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm621681.htm

FDA-CMS Parallel Review Federal Register Notice

Coverage Organizations Interested in Providing Input Regarding Private Payer Coverage
https://www.federalregister.gov/documents/2016/02/24/2016-03909/request-for-expressions-of-interest-from-coverage-organizations-coverage-organizations-interested-in

FDA-CMS Memorandum of Understanding
http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm217585.htm

Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities - Questions and Answers (Guidance, June 2018)
Clinical Policy
Agenda

- Medical Pipeline Committee
  - Technology Assessment Forum (TAF)
  - Policy Development Process
  - Post TAF Implementation
  - Adhoc Medical Research
  - Questions
Medical Pipeline Committee

• Led by CMO
• Members include:
  – Clinical Policy
  – Product Development
  – Healthcare Economics
  – Chronic Care Strategies
• Identify and research new and emerging medical technologies, including medical devices, diagnostics, laboratory tests, professional society recommendations, CMS coverage decisions, etc. to determine financial impact and inform other departments in an effort to proactively develop strategies around these technologies
• Meets on a bimonthly basis
• Update distributed monthly
• Refer Information to:
  – TAF
  – Trend
  – Product Development
  – Provider Contracting
  – Claims
  – Healthcare Economics
  – Chronic Care Strategies
  – Vendors (e.g., HealthHelp)
Technology Assessment Forum (TAF)

- Led by Medical Director
- Members include, but are not limited to:
  - Clinical policy
  - Claims process organization
  - Commercial and Medicare medical directors
  - Legal
  - Product development
  - Provider contracting
  - Clinical review areas
- Provide consistent, efficient systematic process for assessment of new technologies and a mechanism for annual review of existing technologies
- Committee meets monthly

- 200+ Medical Coverage Policies (MCPs) that cover a broad spectrum of topics
- MCPs are utilized for Commercial reviews and are used for Medicare if there are no applicable NCDs, LCDs, etc.
- All MCPs are reviewed at a minimum of annually
Post TAF Implementation

• Review of codes from each policy
• Determination of what codes should pay, pend or deny and which should be on the Reviewed Services List (RSL)
• 90 day provider notification required for adverse changes
• Internal communication regarding policy changes distributed monthly
• Provider notification is managed via quarterly Humana Your Practice publication and code editing provider notifications
Medical Coverage Policy Website

- Average 85,000 hits per month (pharmacy and medical combined)
- Members and providers access via Humana.com
- Search by provider claims code or keyword across pharmacy and medical policies
- Pharmacy and medical coverage policies indexes can be viewed separately and both can be displayed “alphabetically” or by “reviewed date” or by “effective date”
- Policies with adverse changes can be posted with a “future effective date”
Internal support provided for individual **case reviews** where there is no MCP and a question whether a service is “standard of care”

- Submitted via link from MCP website
- Average 20 questions/month (combined commercial and Medicare)
- Research current for 90 days from date of initial research
- “Mini” policy reviews – many of same sites searched as for policy reviews
QUESTIONS?
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Amanda Klingler
Partner
“It is a riddle wrapped in a mystery inside an enigma.”

-Winston Churchill
The Basics of Reimbursement

Coverage
• Is this item or service eligible for payment?

Coding
• How is the item or service identified?

Payment
• What are the payment methodologies and amounts?
Product Considerations

- Market
- Development
- Product
- Commercial Opportunity
CMS vs. FDA: Regulatory Expectations

CMS
• “reasonable and necessary” standard (clinical benefit)
• Social Security Act
• Purchaser of medical products

FDA
• “reasonable assurance of the safety and effectiveness of the device” (risk-based classification)
• Food, Drug and Cosmetic Act
• Regulator of medical products
CMS vs. FDA: Decisions

CMS
- Coverage, Coding and Payment
- Not limited to indications and uses in the labeling

FDA
- PMA, 510(k), etc.
- Indication for use
CMS vs. FDA: Information Considered

CMS
- Clinical evidence (including FDA submissions)
- External technology assessments
- Advisory committee recommendations
- Position statements by relevant groups
- Expert opinion
- Public comments
- Economic and other cost-effectiveness data
- Other informal opinion

FDA
- “Well-controlled” clinical investigation data
- Non-clinical laboratory studies
- Quality system controls
- Labeling
- Post-market controls
- Advisory Committee recommendations
- Published and unpublished literature
Tips for New Product Development

- Bring the entire team together early in the product development process to discuss goals and objectives
  - Clinical, Regulatory, Reimbursement, Marketing, R&D

- Consider the intended patient population and the payer mix for the product
  - In what settings of care will be device be used?
  - Are there special payer rules that will be applicable?
  - Will device labeling be consistent with reimbursement strategy?
Tips for New Product Development

Clinical trials should be structured to maximize reimbursement objectives

- Comparative effectiveness studies important to demonstrate value proposition
- Medicare requires its beneficiaries to be part of study population
- Must demonstrate an improvement in overall outcomes (safe and effective is not enough)
- Quality of life, reduced medications, return to activities of daily living, reduction in follow up procedures and medical services, faster recovery
- Payers are increasingly looking to evidence of cost savings to justify coverage, particularly for expensive treatments
Tips for New Product Development

The FDA regulatory pathway can affect coverage, coding and payment

- 510(k) may make it difficult to persuade CMS that a device needs a new code and new payment amount
- PMA may make it difficult to use an existing code and payment amount
- 510(k) submission may not provide the clinical outcome data required by payers
Tips for New Product Development

Build physician society and patient group support for the product

- Can influence payer coverage, coding and payment

Consider the changing payer landscape

- Fee for service is being replaced by bundled/packaged payments, transfer of risk, value-based payments
Key Takeaway

It is never too early to plan your reimbursement strategy!
Audience Question 1

- What entity covers most of your devices?
  1. CMS
  2. Private payors and payor-provider organizations
  3. Evenly split CMS-private
  4. Foreign healthcare systems
  5. Other
Audience Question 2

• Do you use reimbursement specialists?
  1. Yes, in-house
  2. Yes, by contract
  3. No
  4. Other
Audience Question 3

- When do you introduce reimbursement considerations in the product lifecycle?

1. Early - when developing a regulatory strategy with FDA
2. In the middle - before submission requesting clearance/approval
3. Late - after submission but before FDA grants clearance/approval
4. Very late - after FDA grants clearance/approval
5. Not at all - throw it over the wall between different parts of the organization
Audience Question 4

• What much do you know about the CDRH’s payor engagement program?
  1. Nothing
  2. A little bit
  3. Have engaged – had value
  4. Have engaged – not found much value