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Session Topic

This talk will cover the lessons being learned in commercialising L-Dex® diagnostic tool used in early detection and prevention of lymphoedema

Issues or experiences that could be explored in this session include:

What is the target market for ImpediMed, and how has this been ascertained?

Does Cat I reimbursement guarantee success for medical device companies in the US, if not, why not, and what are examples of companies that have been successful and those that have not, and why?

How important is it to reassess a company’s corporate and marketing strategy and how has ImpediMed done this?

What is the benefit of adopting trial sites and what is being learnt from these trial sites?

When will ImpediMed ramp up its sales and marketing efforts and what should investors expectations be and when, and what should investors be monitoring with ImpediMed over the next 12-24 months?

The spirit of the Mike Hirshorn Address is that the speaker talks about successes, failures and lessons learned from the world of medical product development or financing. So we would like you to integrate your recent lessons learnt at ImpediMed with your training and work at P&G and Medtronic, or even from situations that predated your time spent in those two organisations.
# Our Journey

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT® Category III to a Category I Code</td>
<td>1 year early</td>
</tr>
<tr>
<td>Effective Jan 2015</td>
<td>Nov 2013</td>
</tr>
<tr>
<td>Breast Cancer Related Lymphoedema to All Cancer Related Lymphoedema</td>
<td>2 years early</td>
</tr>
<tr>
<td></td>
<td>Sept 2014</td>
</tr>
<tr>
<td>NCCN Guidelines</td>
<td>1 year early</td>
</tr>
<tr>
<td></td>
<td>Apr 2015</td>
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</tbody>
</table>
Getting to CPT I
2014 Bioshares Biotech Summit

Rick Carreon
July 2014

CPT Process

Specialty Society
Industry

AMA Staff Review
CPT Advisors
CPT Panel

Society Comments

Table Proposal
New or Revised CPT Code
Reject Proposal

Take Nothing for Granted

35
A zero sum game
183 - 17 - 6 and it's not over
Piggyback 44
A draw is worth the effort
Does Cat I reimbursement guarantee success for medical device companies in the US?

NO!

There is always risk with the commercialisation phase of any medical device.
Let's stick with a Cat I for a moment…

\[10 = 8\]

10 Medicare Jurisdictions that are managed by 8 Medicare Administrative Contractors

8 decisions impact 10 jurisdictions

These decisions can change at any time for a number of reasons

CPT I Code allows a physician to “seek reimbursement” it does not guarantee payment

Get use to constant change, it's the normal part of doing business in the US Healthcare market
835 Health Insurance Companies registered in the US

835 Decisions… Maybe

And the reimbursement landscape is becoming even more volatile

4 + 5 = 2

aetna #4 Humana #5 #2

For how long?
The Evolving US Healthcare System

Mergers and Acquisitions
Insurance Companies
Medicare Administrative Contractors
Hospitals
Physician Practices

Payment Schedules
Transitioning from fee-for-service
to value-based medicine
### Level of Evidence Table

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of evidence (based on AHCPR 1992)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia</td>
<td>Evidence obtained from meta-analysis of randomized controlled trials</td>
</tr>
<tr>
<td>Ib</td>
<td>Evidence obtained from at least one randomized controlled trial</td>
</tr>
<tr>
<td>IIa</td>
<td>Evidence obtained from at least one well-designed controlled study without randomization</td>
</tr>
<tr>
<td>IIb</td>
<td>Evidence obtained from at least one other type of well-designed quasi-experimental study</td>
</tr>
<tr>
<td>III</td>
<td>Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities</td>
</tr>
<tr>
<td>V</td>
<td>Evidence obtained from case reports or case series</td>
</tr>
</tbody>
</table>
Clinical Evidence Secures Your Future

Level 1b trial
n=1100

VANDERBILT-INGRAM CANCER CENTER

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

MAYO CLINIC

MACQUARIE UNIVERSITY

MASSEY CANCER CENTER

THE UNIVERSITY OF KANSAS CANCER CENTER
What is the target market for ImpediMed, and how has this been ascertained?

How important is it to reassess a company’s corporate and marketing strategy and how has ImpediMed done this?

What is the benefit of adopting trial sites and what is being learnt from these trial sites?
Technology Adoption Curve

Crossing the Chasm
Market Development Phase

Early Market

Innovators
Early Adopters

Growth Market
Early Majority
Late Majority

Mainstream Market

Late Market
Laggards
Market Development Roadmap

Foundational Requirements

Positioning
Training
Clinical Evidence
Reimbursement

Early Adopters
Stage I
Targeted Launch
Stage II
National Launch
Stage III
Expanded Indications
Stage IV

MARKETING
• Conduct Primary Market Research
• Develop Strategy

EDUCATION
• Develop Training Strategies

REIMBURSEMENT
• Identify Society to Champion CPT Application
• CPT I Submission
• AMA Level of Evidence

MARKETING
• Product and Procedure Protocols
• Journal Article Strategy
• Patient Advocacy Groups
• Evaluate Customer Targets

EDUCATION
• Implement product training for:
  • Customers & Sales
  • Patients
  • Payors

  Podium Strategy

REIMBURSEMENT
• CPT I Code
• MAC/CAC Specific Strategy
• MAC Education Material
• Update Proof Points
• Customer Education
• Appeal Support

MARKETING
• Confirm Target Markets
• Stratify Target Customers
• Patient Awareness Campaigns
• Customer Awareness Campaigns
• Patient Advocacy Groups
• Expand Journal Articles
• Social Media Strategy

EDUCATION
• Training of:
  • New Customers
  • Referral Audience
  • Support Personnel

  Training on Expanded Indications for:
  • Distribution
  • Current Customers
  • New Customers
  • Referral Base

REIMBURSEMENT
• Expand Coverage
• Expand Level of Payment
• Expand MAC/CAC Training
• Expanded Indication(s) Training
• Expanded Appeal Support for New Ind.

MARKETING
• Expanded Indication(s) material
• Expand Promotional Activities
• New Customer Targets
• Referral Focus
• Patient Advocacy Expansion
• Expand Social Media
• Patient Outreach Programs

EDUCATION
• Training on Expanded Indications for:
  • Distribution

REIMBURSEMENT
• Journal Articles recognised by Payors
• MAC/CAC Training
• National Payor Strategy
• Regional Payor Strategy
• Case by Case Reimbursement Training
• Expanded Appeal Support
• Reimbursement Training for Distribution

For personal use only
5 Year Value of Acquired Customers  
- Example -

Critical Questions
Scalability?  
Long-term growth?  
Who not to call on?

Reference Sites  
High Potential Customers

Threshold

Early Adopters

Innovators
Customer Strategy

Tier III Targets
Multidisciplinary Centres conducting 300-499 more new breast cancer cases per year
• NAPBC, NCI centres, ACO
• Follow NCCN Guidelines

Tier IV Targets
Multidisciplinary Centres conducting 299 or less new breast cancer cases per year
• NAPBC, NCI centres, ACO
• Follow NCCN Guidelines

Evaluation Targets
Top 10 Community Oncology Centres and Key Physical Therapy Centres
Requires Authorisation from The Leadership Team

Reference Sites
NCCN Member Institutions
Designated Team

Tier I Targets
Multidisciplinary Centres conducting 1,000 or more new breast cancer cases per year
• NAPBC, NCI centres, ACO
• Follow NCCN Guidelines

Tier II Targets
Multidisciplinary Centres conducting 500-999 new breast cancer cases per year
• NAPBC, NCI centres, ACO
• Follow NCCN Guidelines

Note: Potential customers not listed above must have authorisation from The Leadership Team prior to beginning the sales process

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Targeted Launch

1 Year Early
Breast Cancer Related Lymphoedema

2 Years Early
All Cancer Related Lymphoedema

1 Year Early
NCCN Guidelines

Breast Surgeon

Oncology Centres

Multidisciplinary Integrated Systems
Take Nothing for granted (Part 2)

- The day you obtain your CPT I Code is the day you begin to defend it (carryover from last year)
- High level clinical evidence secures your future (high number of patients at recognised institutions)
- Your early adopters may not be your ultimate target market
- What is your plan B?
Thank You