Breakthrough Device Designation & Its Impact on Reimbursement

Presented by
Greenlight Guru; Acknowledge Regulatory; JD Lymon

Breakthrough Device Designation and Reimbursement

What you need to know today, tomorrow, and how to prepare for the uncertain future.

Today's Presenters:

Connor Remaley
Greenlight Guru

Allison Komiyama
AcKnowledge Regulatory

Mark Domyahn
JD Lymon

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ABOUT THE PRESENTERS

Allison Komiyama, PhD, RAC

Owner and Principal Consultant at AcKnowledge Regulatory Strategies

- 15+ years in life sciences industry
- Supports both small start-ups and large companies with their regulatory submissions
- Main submission types include 510(k)s, Pre-submissions, De Novos, IDEs, Breakthrough Designations and STeP Entrance Requests.

AcKnowledge Regulatory Strategies specializes in Regulatory Affairs (RA) consulting exclusively for the medical device industry. The team focuses primarily on US FDA submissions.

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ABOUT THE PRESENTERS

Mark Domyahn, MBA

Partner at JD Lymon

- 25+ year career in the healthcare industry
- Focused on medical technology, provider reimbursement and health economics
- Founded Pursuance Consulting, a reimbursement and health economics consulting practice

JD Lymon is a Minneapolis, based market access and health economics consulting firm providing strategic market access consulting solutions that address the complex relationships between evidence, coding, coverage policy, payment and health care decision makers

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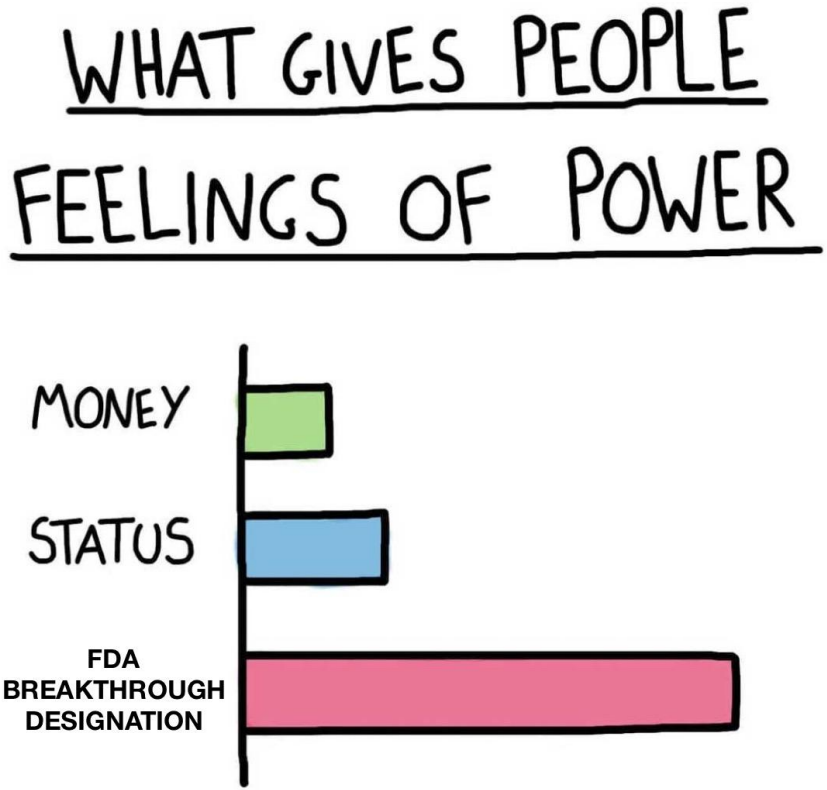
Agenda

- Breakthrough Device Designation Overview
- Realistic Expectations
- Evaluating Reimbursement Impact of BD

I HAVE A BREAKTHROUGH!

I HAVE A BREAKTHROUGH!



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Criterion (1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions;

and at least one of the following from:

Criterion (2)

(A) that represent breakthrough technologies;

(B) for which no approved or cleared alternatives exist;

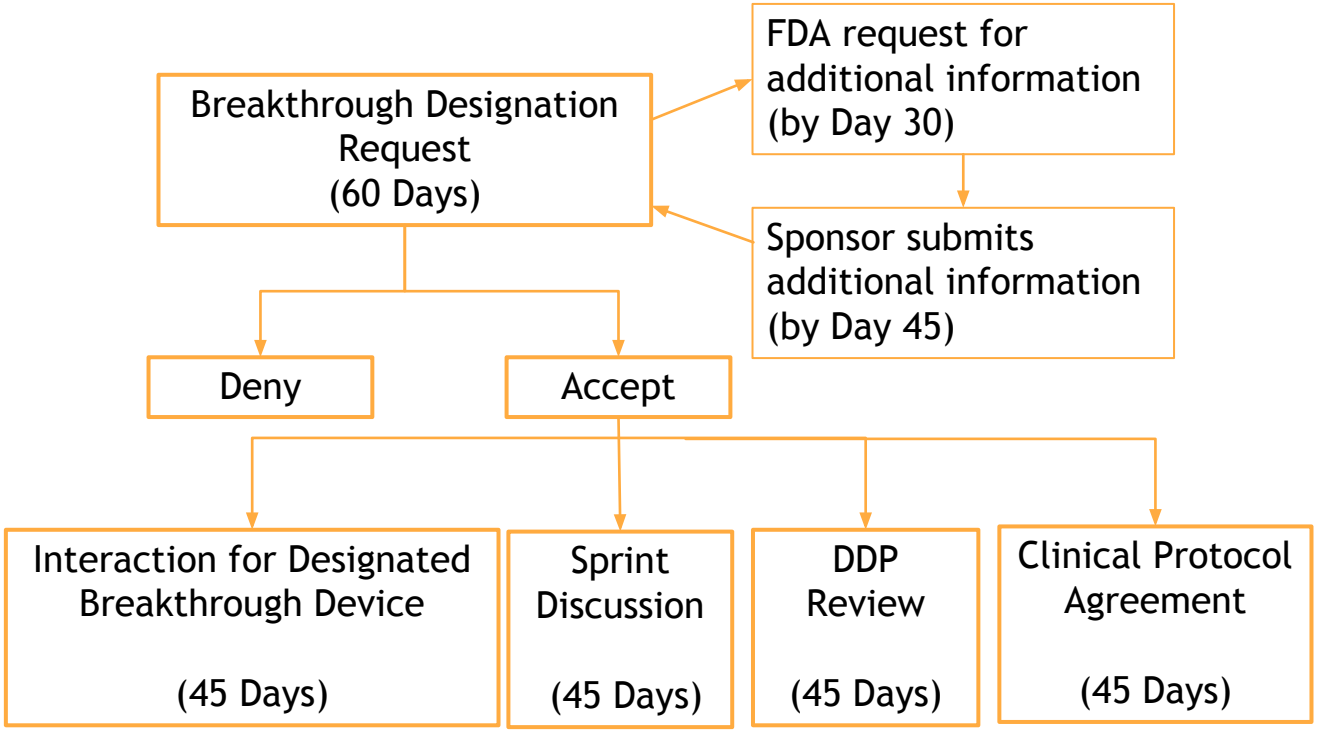
(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

(D) the availability of which is in the best interest of patients.

Breakthrough Device Designation Request (Pre-submission)

- Cover Letter
- Device Description
- Indications for Use
- Regulatory History
- Planned regulatory pathway - 510(k), De Novo, PMA
- Overview of Product Development
- Justification for Meeting Designation Criteria

BD Reviews and Timelines



What FDA says you get vs. what you get

- Interactive and Timely Communication
  - Sprint Discussion
  - Data Development Plan Review
  - Clinical Protocol Agreement
- Priority Review
- Review Team Support
- Senior Management Engagement
- Efficient and Flexible Clinical Study Design
- Pre/Postmarket Balance of Data Collection
- Manufacturing Considerations for PMA Submissions

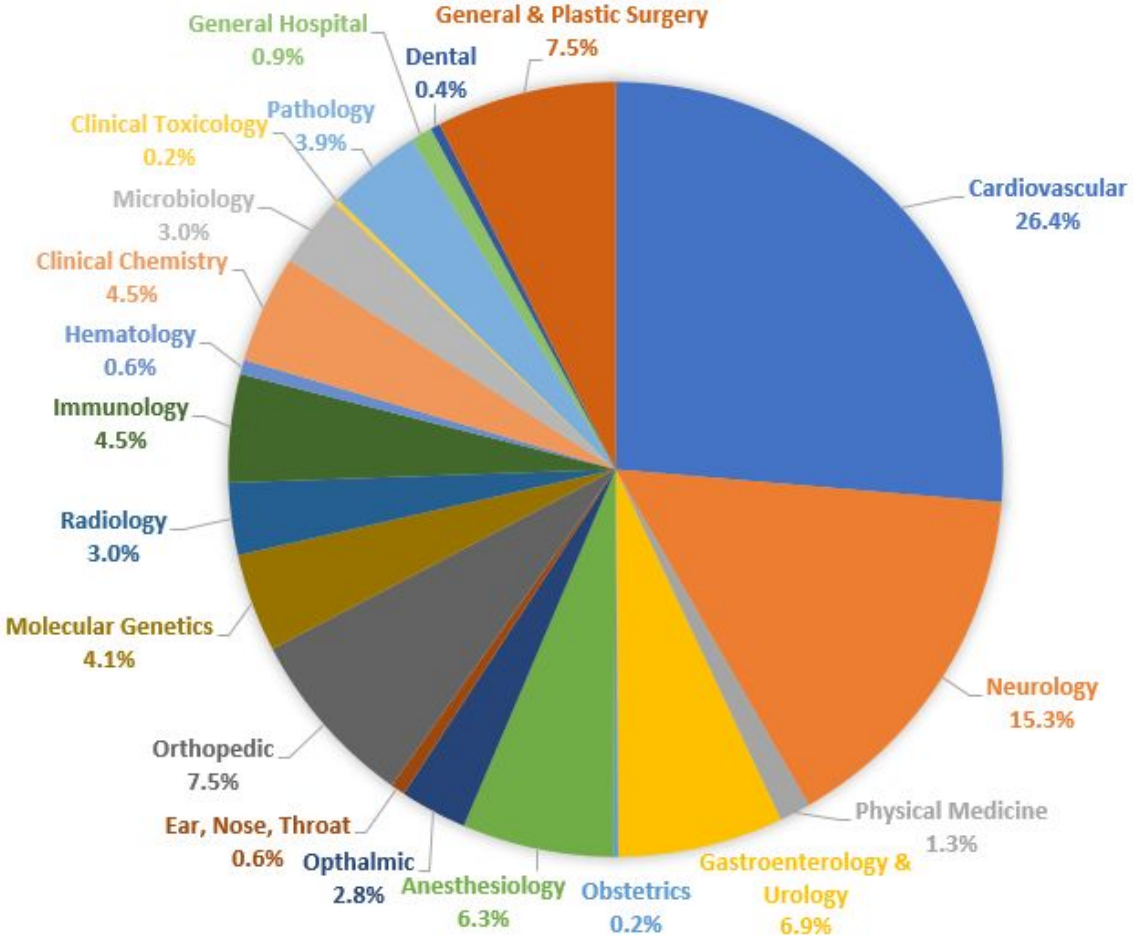
As of October 1, 2021*, CDRH has:

- Designated 561 Breakthrough Devices
- 32 Breakthrough Devices have received marketing authorization
  - 13 PMAs
  - 8 510(k)s
  - 11 De Novos

Year	2016	2017	2018	2019	2020	2021
Number Granted	11	19	55	136	193	147

* Information from FDA (DCEA1: Division of Clinical Science and Quality | OCEA: Office of Clinical Evidence & Analysis)

Breakthrough Breakdown



Modified from FDA presentation, M. Dreher May 2021

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REIMBURSEMENT IMPACT OF BREAKTHROUGH DEVICE DESIGNATION (BDD)

CMS REIMBURSEMENT IMPACT FROM BDD

Reimbursement Element	Provider	Impact of BDD	
		Program	Description
Coverage	All	MCIT	Potential automatic Medicare coverage for 4 years
Coding	Physician	N/A	Does not impact CPT coding
	Hospital	NTAP & TPT	New codes can be created if required due to NTAP and TPT (see below)
Payment	Physician	N/A	Does not influence physician payment
	Hospital	NTAP	Probability of securing increases dramatically
		TPT	Probability of securing increases

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Hospital New Technology Payment Mechanisms

- **Medicare hospital payment rates are based on historical hospital claims data from two years prior (e.g., 2021 rates are based on 2019 claims)**
  - By definition, the cost of new technology cannot be reflected in current payment rates
- **CMS provides an opportunity for select technologies to receive temporary incremental payment while claims data are collected**
  - Hospital Inpatient – New Technology Add-On Payment (NTAP)
    - Lasts 2-3 years
    - Effective each October 1
  - Hospital Outpatient – Transitional Pass-Through (TPT) Payment Status
    - Lasts 3 years
    - Effective each January 1
- **Applies only to Medicare fee-for-service patients**
  - Other payers set their own payment rates
- **FDA approval is required for both NTAP and TPT**

CMS' INCREMENTAL HOSPITAL PAYMENT MECHANISMS FOR SELECT NEW TECHNOLOGY

Traditional Pathway	Hospital Inpatient	Hospital Outpatient
	New Technology Add-On Payment (NTAP)	Transitional Pass-Through (TPT)
Requirements	• Must be "New" based on indication and FDA approval • Not substantially similar to existing technologies	• Must apply within three years of FDA approval • No previous/current APC category for the device
	• Meet a MS-DRG charge threshold based on total case charges	• Meet three cost criteria on cost of new technology
	• Provide a substantial clinical improvement (SCI) over current therapies	
Approval Timeline	Annual – effective October 1	Annual – effective January 1
Duration	2-3 years maximum	3 years
Payment	65% of incremental cost of case over MS-DRG, capped at 65% of device price (+ MS-DRG)	100% of incremental cost of device over device portion of APC (+ APC)

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CMS' INCREMENTAL HOSPITAL PAYMENT MECHANISMS FOR BDD TECHNOLOGIES

Alternative Pathway (with BDD)	Hospital Inpatient	Hospital Outpatient
	New Technology Add-On Payment (NTAP)	Transitional Pass-Through (TPT)
Requirements	• Must be "New" based on indication and FDA approval • Not substantially similar to existing technologies	• Must apply within three years of FDA approval • No previous/current APC category for the device
	Meet a MS-DRG charge threshold based on total case charges	Meet three cost criteria on cost of new technology
	Provide a substantial clinical improvement (SCI) over current therapies	
Approval Timeline	Annual – effective October 1	• Annual – effective January 1 • Quarterly for Breakthrough Devices
Duration	2-3 years maximum	3 years
Payment	65% of incremental cost of case over MS-DRG, capped at 65% of device price (+ MS-DRG)	100% of incremental cost of device over device portion of APC (+ APC)

Criteria automatically met for devices with Breakthrough Device Designation (BDD)

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Breakthrough Device Designation Timeline and Impact

- **Hospital Inpatient – NTAP**
  - Effective October 1, 2019, CMS implemented an Alternative Pathway for NTAP for devices with BDD

Device	Traditional			Alternative (BDD)		
Fiscal Year	Approvals	Denials	Total	Approvals	Denials	Total
2020	0	4	4	NA	NA	NA
2021	4	3	7	2	0	2
2022	1	6	7	7	2*	9

* One technology was FDA approved on 9/20/2018 (outside the NTAP eligibility period) and the other technology was all capital costs, which are not eligible for NTAP

- **Hospital Outpatient – TPT**
  - Effective January 1, 2020, CMS implemented an Alternative Pathway for TPT for devices with BDD

Device	Traditional			Alternative (BDD)		
Calendar Year	Approvals	Denials	Total	Approvals	Denials	Total
2019	1	6	7	NA	NA	NA
2020	3	3	6	2	0	2
2021	2	0	2	2	0	2
2022	1	5	6	2	0	2

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Hospital Payment Impact of BDD

BDD increases the probability of securing NTAP and/or TPT significantly

- **Hospital Inpatient – NTAP**
  - Eliminates the two hardest criteria to qualify – “Newness” and SCI
  - Only two devices with BDD have been denied NTAP, but one was out of the NTAP eligibility period and one technology was strictly capital (not eligible for NTAP)
- **Hospital Outpatient – TPT**
  - Eliminates the hardest criterion to qualify – SCI
  - However, the other criteria can be problematic and need to be considered carefully
    - Newness – do existing/previous device categories describe the new technology?
    - Cost Threshold – device must cost enough, and this can be an issue if multiple devices are required to perform the procedure and the new technology only replaces a portion of those devices

Medicare Coverage of Innovative Technology (MCIT)

TIMELINE

Date	Description
August 31, 2020	• Medicare proposes MCIT rule • Provides 4 years of automatic coverage for CMS with no data collection requirements and minimal registration efforts
January 12, 2021	Medicare finalizes MCIT rule, with an effective date of March 15, 2021
March 12, 2021	Medicare postpones MCIT effective date to December 15, 2021
September 13, 2021	Medicare proposes to fully repeal MCIT
October 28, 2021	• Final rule for appeal is posted at OMB • Pending publication of the final rule for MCIT repeal

Medicare Coverage of Innovative Technology (MCIT)

Deep Thoughts / Next Steps

- **Need CMS to publish the final repeal of MCIT so the process can restart**
- **There were legitimate concerns in regards the implementation of MCIT as proposed**
  - Data collection
  - Impact on the Medicare patient population
  - Benefit category of the device
  - Logistics in terms of coding, billing instructions, etc.
- **From what we've heard, CMS is still interested in considering coverage under a revised MCIT to address many of these concerns**
  - This will require going through the CMS rulemaking cycle – proposed rule, comments, final rule
  - The sooner this can start, the sooner we hopefully end up with some form of Medicare coverage for devices with BDD

QUESTIONS?

Thanks for Joining!

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