The FDA Breakthrough Device Program:

Regulatory and Reimbursement Insights and Key Considerations

MCRA Presenters

John Doucet Ph.D.
Tonya Dowd MPH
John McDermott MBA

info@mcra.com

MCRA Presenters

John Doucet, Ph.D.

Sr. Director, Neurology Regulatory Affairs

Former FDA Policy Lead, Breakthrough Device Program

Additional prior roles at FDA include: Acting Director of IDE Program, Acting Branch Chief of Neurostimulation Devices Psychiatry Branch

Highlights:

- 10+ years of FDA and neurology devices experience
- Expertise in neurology devices covering psychiatric disorders & acute/chronic pain
- Expertise in regulatory submissions including 510(k), IDE, PMA, HDE, 513(g), Q-Submissions, & De Novo
- 13+ years as NIH-funded neuroscientist at John Hopkins University (5+ million dollars in awarded grants)

Tonya Dowd, MPH

Vice President, Reimbursement, Health Economics & Market Access

Former Global Franchise Director of Healthcare Economics and Market Access within Johnson & Johnson's medical device division

Highlights:

- 30+ years of reimbursement, health economics & market access experience
- Disease and life sciences experience: medical devices, molecular dx, biologics, cardiovascular, GI, ophthalmology, orthopedic, urology
- Expert in upstream product plan development and downstream execution of reimbursement strategies

John McDermott, MBA

Sr. Director, Reimbursement Strategy

Former Vice President of Covance Market Access. Former Director of DK Pierce Market Access Strategy

Highlights:

- 30+ years of industry experience spanning market access, reimbursement, coverage access programs, and health economics and outcomes research (HEOR)
- Deep experience engaging drug and medical device industries evaluating a wide variety of therapeutic areas including cardiology, urology, oncology, rare diseases, and diagnostic imaging

Learning Objectives

I **Understand the purpose and benefits of the breakthrough device program and how FDA reviews designation requests.**

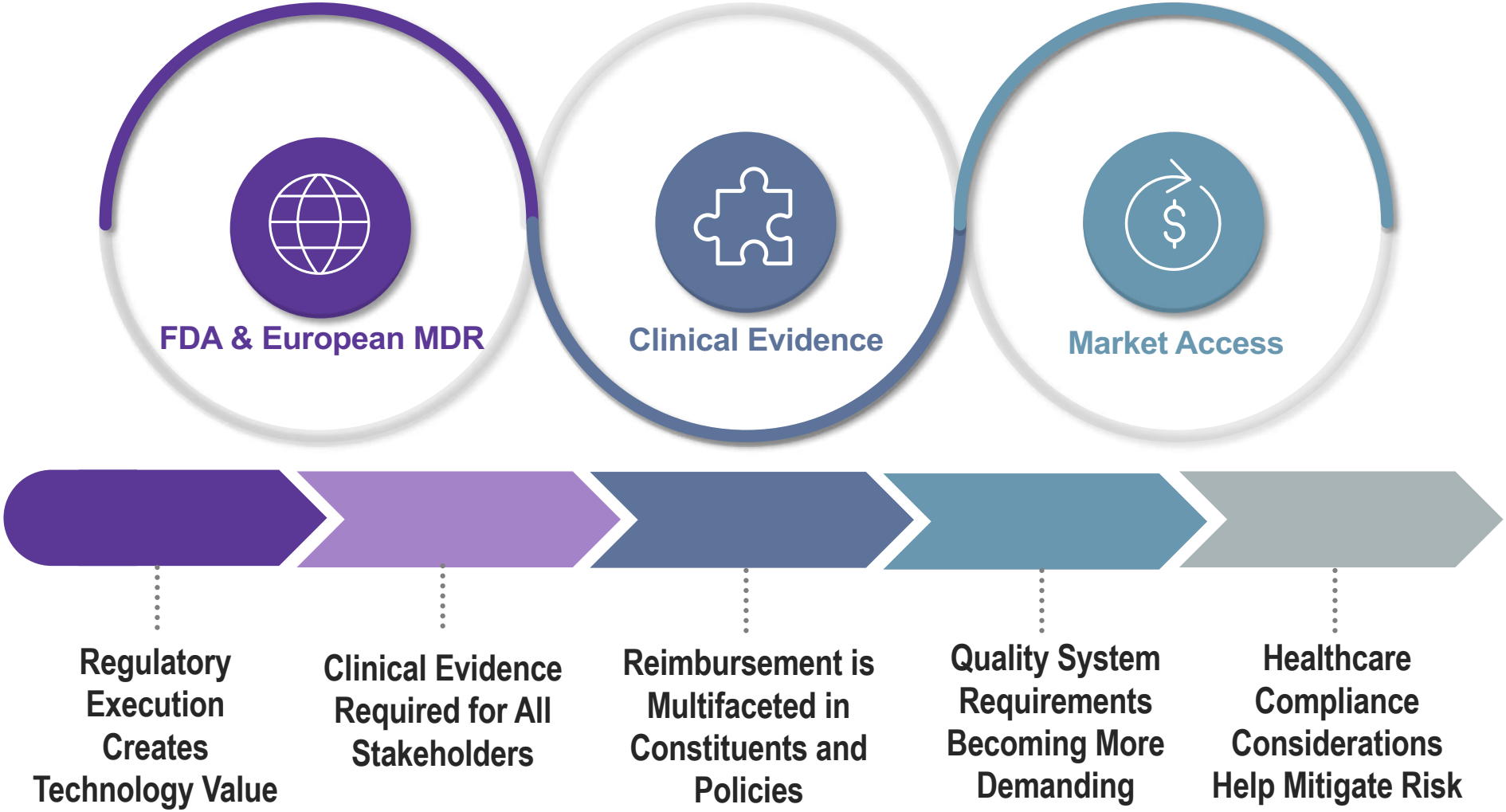
II **Understand how breakthrough designation impacts reimbursement, specifically, with coding, coverage and payment with CMS/Medicare**

III **Dialogue with the experts- discussion of FAQs**

MCRA

Would you ever start training for a marathon 5 days before race day?

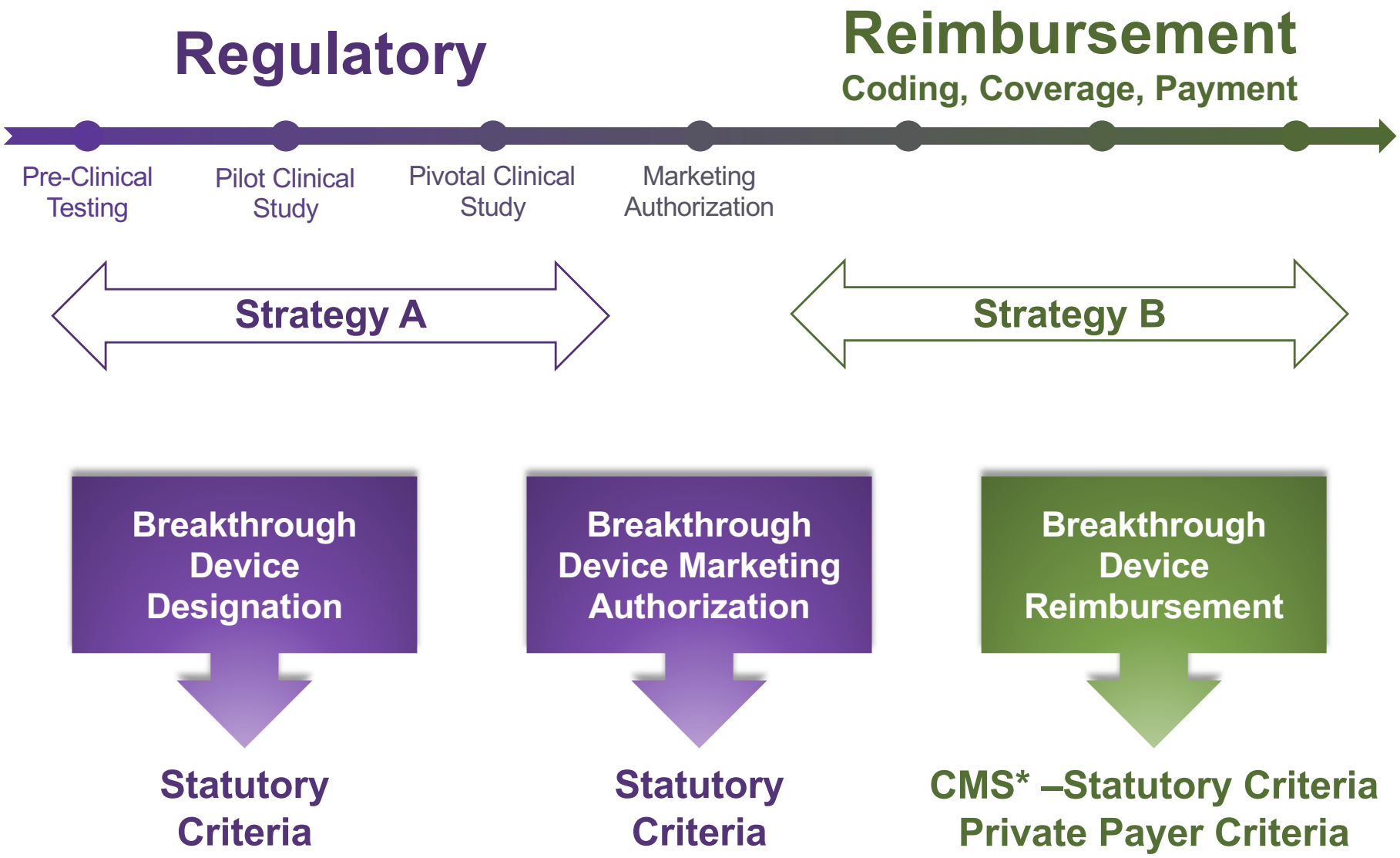
The MCRA Model
Integrated Development and Commercialization Strategy



Clinical Evidence Generation with World Class Regulatory and Reimbursement Integration Creates Long Term Value

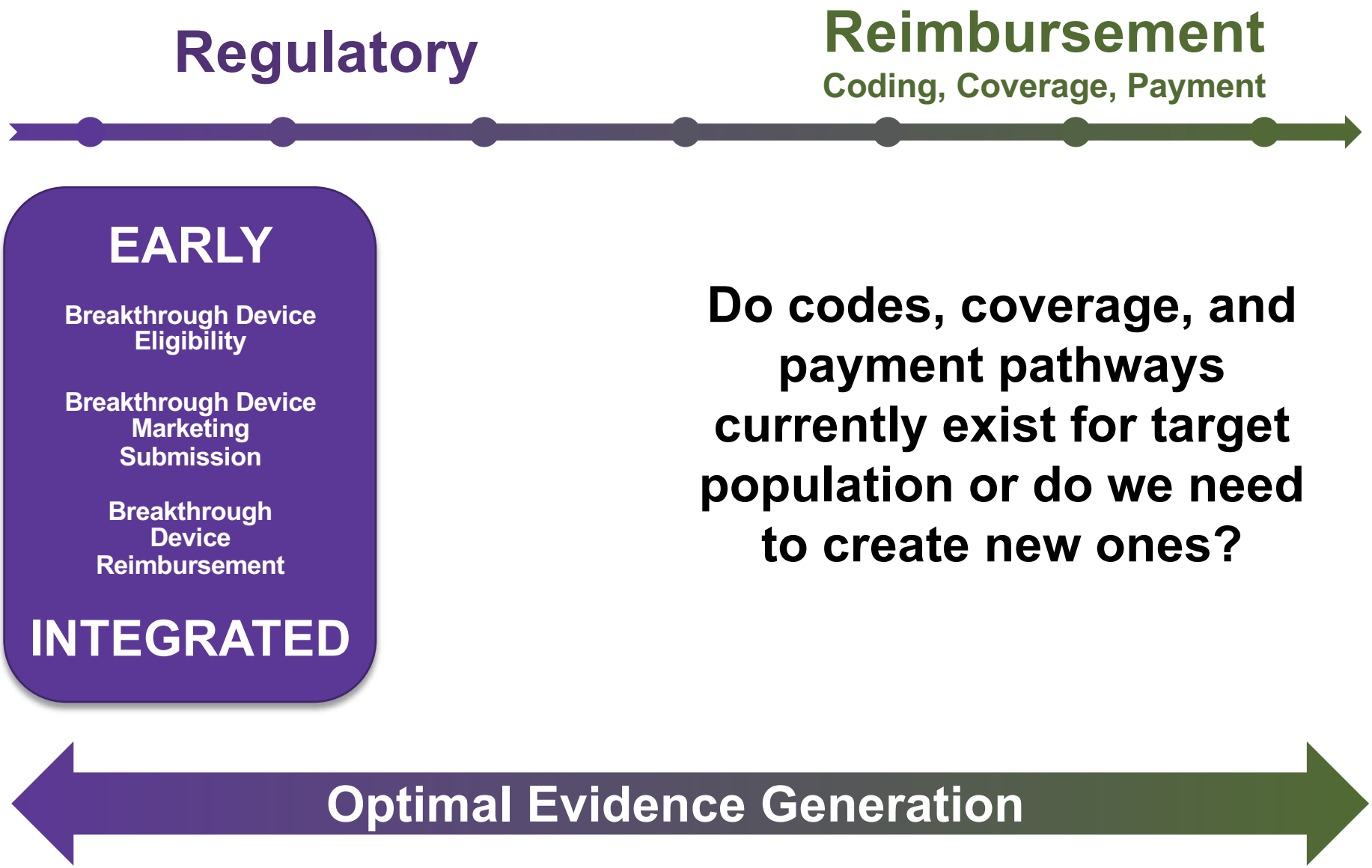
MCRA

Sequential Strategy is High-Risk (and common)



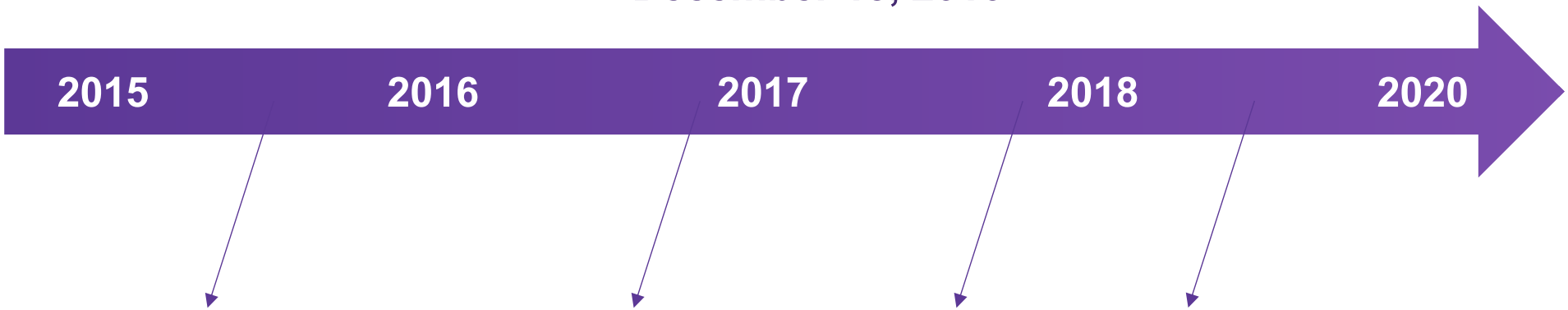
* *Centers for Medicare and Medicaid Services*

Integrated Strategy is Optimal



Breakthrough Program: Origin and Evolution

21st Century Cures Act
December 13, 2016



SEC. 515B. [21 U.S.C. 360e–3] B

(a) PURPOSE.—The pur
Secretary, and provide the
apply efficient and flexible
of, and prioritize the Food
vices that represent breakt

D

Irreversibly Debilitating Diseas
Conditions

Guidance for Industry and Food and Drug Administration Staff

Document issued on April 13, 2015.

Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 18, 2018.

600+ Breakthrough Designation Requests

100s of Breakthrough Device Interactions

MCRA

Breakthrough Program Purpose

*"This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health."**

Focus FDA on Breakthrough Devices

Promote Collaboration

* *Breakthrough Devices Program – Guidance for Industry and Food and Drug Administration Staff*

FDA Interaction Mechanisms

Standard Interaction Mechanisms:

513(G) Request for Information
Informational Meeting
Study Risk Determination
Pre-Submission
Submission Issue Request
Agreement and Determination Meeting
PMA Day 100 Meeting
Accessory Classification Request

510(k)

De Novo

PMA

Breakthrough Device Designation Request → **Breakthrough Interaction Mechanisms**

MCRA

Breakthrough Interaction Mechanisms

Breakthrough Device Designation Request

Breakthrough Interaction Mechanisms

510(k)

De Novo

PMA

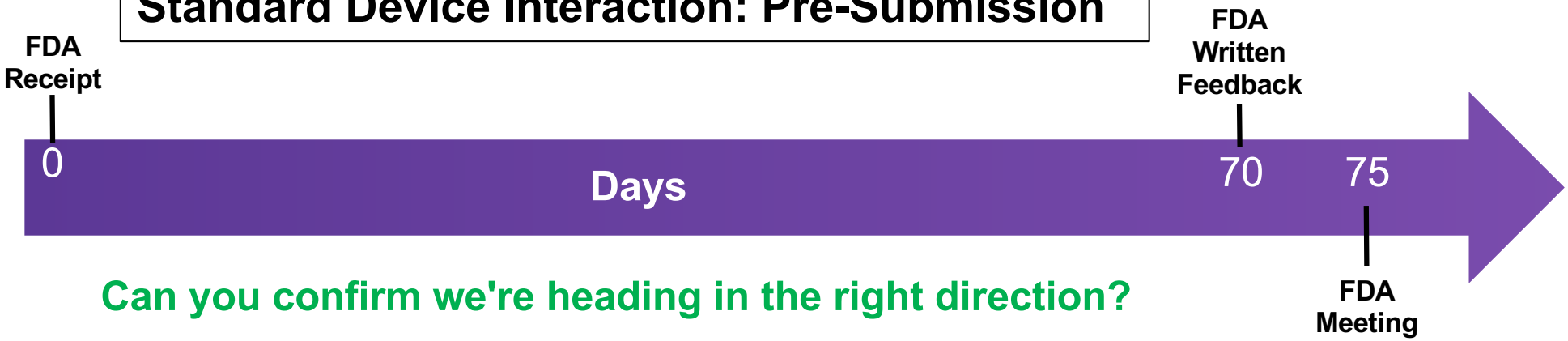
Data Development Plan (DDP)
Sprint
Clinical Protocol Agreement
Pre-submission

Priority Review

MCRA

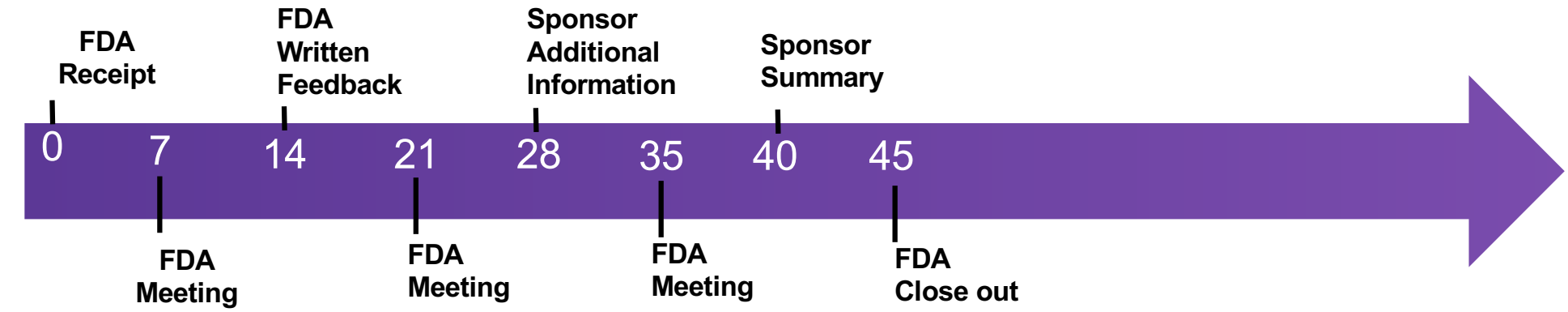
Breakthrough Interaction Mechanism: Benefits

Standard Device Interaction: Pre-Submission



Can you confirm we're heading in the right direction?

Breakthrough Device Interaction: Sprint or DDP



Let's collaborate and identify the right direction together.

MCRA

Breakthrough Device Criteria

Criterion 1:

"provide for more effective treatment or diagnosis of life threatening or irreversibly debilitating human disease or conditions; AND

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."

MCRA

Reference: Section 515(b) of Food, Drug and Cosmetic Act

How do you meet Criterion 1?

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

CONGRESS

FDA believes it is appropriate to consider whether there is a reasonable expectation that a device could provide for more effective treatment or diagnosis **relative to the current standard of care (SOC) in the U.S.**

FDA*

* *For all recommendations, see Breakthrough Devices Program – Guidance for Industry and Food and Drug Administration Staff*

How do you meet Criterion 1?

Your Device

Standard of Care

Received marketing authorization for the indication being considered

Currently marketed in the U.S. and is a relevant option for patients with the identified disease or condition

MCRA

How do you meet Criterion 1?

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

CONGRESS

FDA believes it is appropriate to consider whether there is a reasonable expectation that a device could provide for **more effective** treatment or diagnosis relative to the current standard of care (SOC) in the U.S

FDA*

* *For all recommendations, see Breakthrough Devices Program – Guidance for Industry and Food and Drug Administration Staff*

How do you meet Criterion 1?

SOC

Your Device

How do you meet Criterion 1?

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

CONGRESS

…likelihood of death is high unless the course of the disease is interrupted in a population or subpopulation.

...based on its impact on such factors as survival, day-to-day functioning, and the likelihood that the disease or condition, if left untreated, will progress to a more serious disease or condition.

FDA*

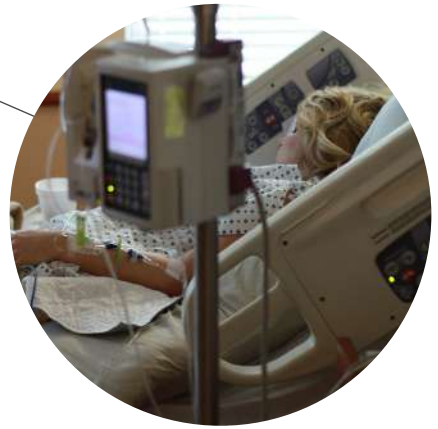
* *For all recommendations, see Breakthrough Devices Program – Guidance for Industry and Food and Drug Administration Staff*

Breakthrough Designation = Device + Indications for Use

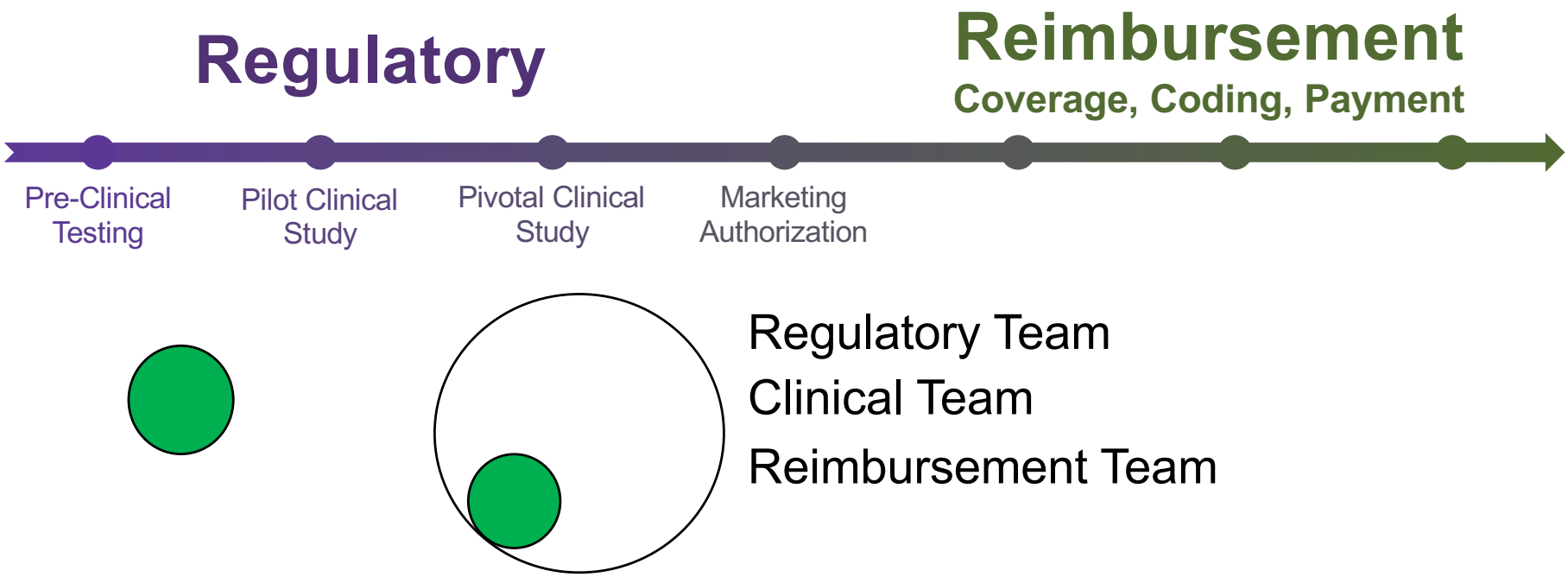
Device

Breakthrough Designation

Indication for Use



Breakthrough Device – Pivotal Study Design



Breakthrough Device Designation

Statutory Criteria

Breakthrough Device Marketing Authorization

Statutory Criteria

Breakthrough Device Reimbursement

CMS –Statutory Criteria
Private Payer Criteria

MCRA

Integrated Strategy is Optimal

Regulatory

Reimbursement

Coding, Coverage, Payment

EARLY

Breakthrough Device Eligibility

Breakthrough Device Marketing Submission

Breakthrough Device Reimbursement

INTEGRATED

Early questions that promote integrated strategy:

1. What is the patient demographic for the device? Does indicated population include patients who are 65 (Medicare) and older?

2. What percentage of pivotal study subjects should be from the "Breakthrough Population" vs. "non-Breakthrough Population"?

3. Do coding, coverage, and payment pathways exist today for my new Breakthrough treatment or diagnostic device? If not, what is required to establish new pathways?

4. What is the plan for evidence generation that will resonate with all the relevant stakeholders- FDA, hospital buyer, commercial and public payers?

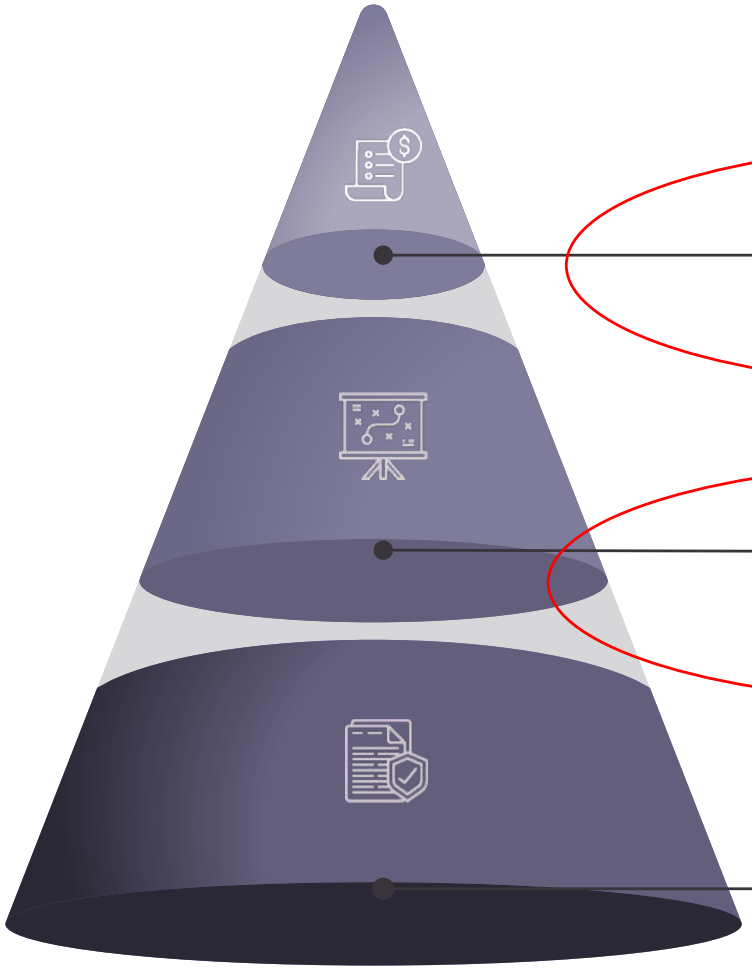
Optimal Evidence Generation


Breakthrough Designation &
Reimbursement Considerations

Regulatory, reimbursement, and market access processes are not linear…

…however, those with breakthrough status benefit from temporary reimbursement policies.

Key Reimbursement Fundamentals



PAYMENT

Establish the payment methodology

CODING

Determine the coding pathways available and implications for each

COVERAGE

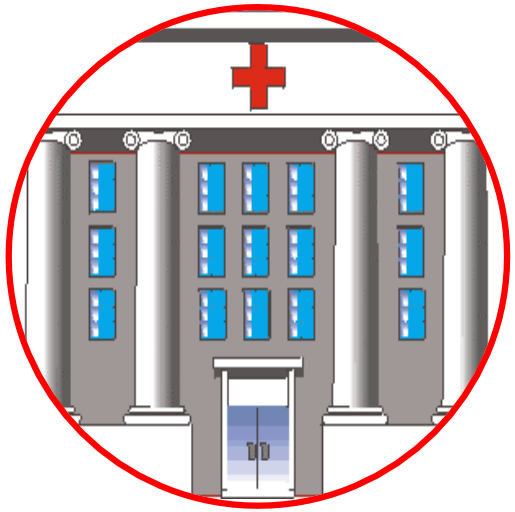
Build up evidence and patient demand to establish or optimize payer coverage

Interrelated*, but not *interdependent

MCRA

Medicare Fee for Service (FFS) Payment Methods

Physician Payment
“Professional Component”



Hospital or ASC Payment
“Facility Component”

Medicare Fee for Service (FFS) Payment Methods – based on setting of care

Hospital Inpatient

- **Payment System:** Inpatient Prospective Payment System (IPPS)
- **Method:** Medicare Severity-Diagnosis Related Groups (MS-DRGs)
- **Coding:** ICD-10-CM diagnosis and ICD-10-PCS procedure codes

Hospital Outpatient or ASC

- **Payment System:** Outpatient Prospective Payment System (OPPS)
- **Method:** Ambulatory Payment Classifications (APC)
- **Coding:** CPT, HCPCS, and ICD-10-CM diagnosis codes

MCRA

The Problem with New Technology in Medicare

It takes at least two years for the costs of new technologies to be incorporated into updated payments.

Medicare's new-technology payments accelerate the availability of updated payment rates.

- **Medicare Hospital Inpatient Prospective Payment System**
  Can save up to 21 months
- **Medicare Hospital Outpatient Prospective Payment System**
  Can save up to 20 months

MCRA

CMS temporary add-on payment pathways *for new technology*

Hospital INPATIENT - DRG

New Technology Add-on Payment (NTAP)

- Must meet newness criteria
- Must meet substantial clinical improvement criteria
- Must meet cost criteria

Hospital OUTPATIENT - APC

Transitional Pass-Through Payment for New Category of Device

- Must meet newness criteria
- Must meet substantial clinical improvement criteria
- Must meet cost criteria

To learn more: https://www.odtmag.com/issues/2020-03-01/view_columns/the-abcs-of-reimbursement-for-breakthrough-devices

MCRA

CMS temporary add-on payment pathways *for new technology with breakthrough status*

Hospital INPATIENT - DRG

New Technology Add-on Payment (NTAP)

- Already meets newness criteria
- Already meets substantial clinical improvement criteria
- Must meet cost criteria

Hospital OUTPATIENT - APC

Transitional Pass-Through Payment for New Category of Device

- Must meet newness criteria
- Already meets substantial clinical improvement criteria
- Must meet cost criteria

To learn more: https://www.odtmag.com/issues/2020-03-01/view_columns/the-abcs-of-reimbursement-for-breakthrough-devices

MCRA

Hospital Inpatient

A deeper dive into
New Technology Add-On Payment (NTAP)
for breakthrough devices

NTAP Criteria

Hospital Inpatient

Newness

- FDA approval or clearance
- Not currently reflected in MS-DRG weights
- Not substantially similar to an existing technology

Breakthrough Devices are Exempt

Substantial Clinical Improvement

- Serves untreated population
- Significantly improves clinical outcomes compared to current treatments

Breakthrough Devices are Exempt

Cost

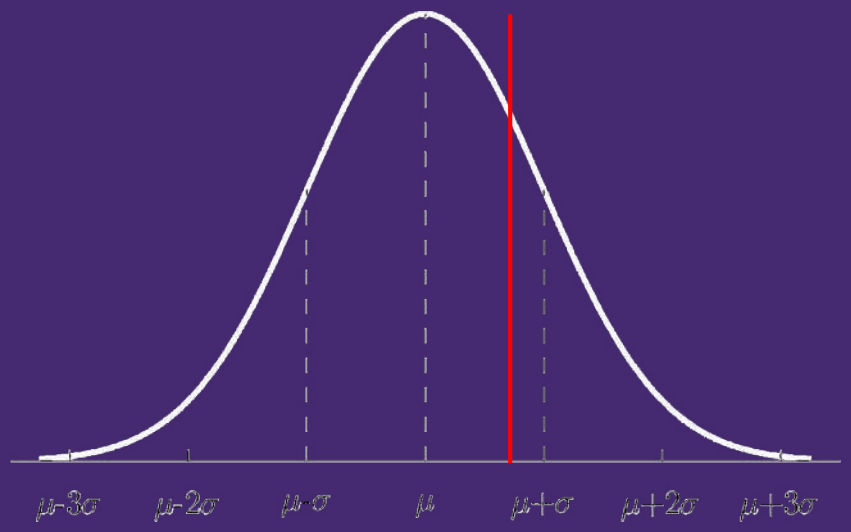
- Payment must be inadequate
- Average charge per case must exceed published thresholds

MCRA

NTAP Cost Criteria

Hospital Inpatient

The charge threshold is set at 75% of 1 standard deviation higher than the mean charge within an MS-DRG



To test for meeting the cost criterion:

- Start with charge data for the target patient population from MedPAR claims
- Subtract the charges of prior technologies being replaced
- Add in charges for the new technology
- Compare average charge per case to published threshold for MS-DRG

MCRA

New Technology Add On Payment

Hospital Inpatient

NTAP Payment Calculation

- For a case to qualify for NTAP, the costs of the stay must exceed the MS-DRG payment.
- The NTAP payment is calculated on a case-by-case basis and is capped at 65% of the cost of the new technology.

25,000 – 22,000 = **$3,000**

MS-DRG Payment	Hospital Cost	No NTAP Payment

25,000 – 35,000 = **-$10,000**

MS-DRG Payment	Hospital Cost	Qualifies for NTAP

NT Cost = **$20,000**

Payment = 65% * $10,000
= **$6,500**

Maximum= 65% * $20,000
= **$13,000**

MCRA

New Technology Add On Payment

Hospital Inpatient

NTAP Expiration

- NTAP is valid for a period of 2-3 years after the technology becomes available on the market.
- The cost of the technology will be captured in the Medicare claims data after 2-3 years will be reflected in the relative weights for the relevant MS-DRGs.

Coding

- An ICD-10-PCS procedure code is required to identify the use of NTAP technologies on inpatient claims
- NTAP applicants must apply for an ICD-10-PCS procedure code as it is not included in the NTAP application

- Timeline:
  - December deadline
  - March public meeting
  - October 1 implementation
  - June deadline
  - September public meeting
  - April 1 implementation

MCRA

Hospital Outpatient

A deeper dive into Transitional Pass Through Payment (TPT) for breakthrough devices

Transitional Pass-Through Payment Criteria

Hospital Outpatient

Newness

- Must apply within 3 years of FDA approval or clearance
- Not appropriately described in current or expired device category
- Not substantially similar to an existing technology

Substantial Clinical Improvement

- Will substantially improve diagnosis or treatment of illness or injury compared to available treatments

Cost

- Cost is not insignificant
- Passes 3 cost tests

Breakthrough Devices are Exempt

MCRA

Transitional Pass-Through Payment Cost Criteria

Hospital Outpatient

HCPCS	Descriptor	APC	APC Payment	Device Offset %	Device Offset Amount
2988	Knee arthroscopy/ surgery	5114	$5,981	36.51%	$2,184

The Cost of the Device Is Not Insignificant

1. The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices. **NT Cost: $3,000** **$3,000 > ($5,981 * 25% = $1,495)**

2. The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent. **$3,000 > ($2,184 * 25% = $546)**

3. The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service. **($3,000 - $2,184 = $816) > ($5,981 * 10% = $598)**

MCRA

Transitional Pass-Through Payment

Hospital Outpatient

Transitional Pass-Through Payment Calculation

- Transitional Pass-Through Payment is calculated on a case-by-case basis.
- The payment is the cost of the new technology minus the amount specified for devices already included in the APC payment (called the "device offset").

  $3,000 - $2,184 = $816

Transitional Pass-Through Payment Expiration

- Transitional Pass-Through Payment is valid for a period of 2-3 years after the technology becomes available on the market.
- The cost of the technology will be captured in the Medicare claims data after 2-3 years will be reflected in the relative weights for the relevant APCs.

MCRA

Transitional Pass-Through Payment

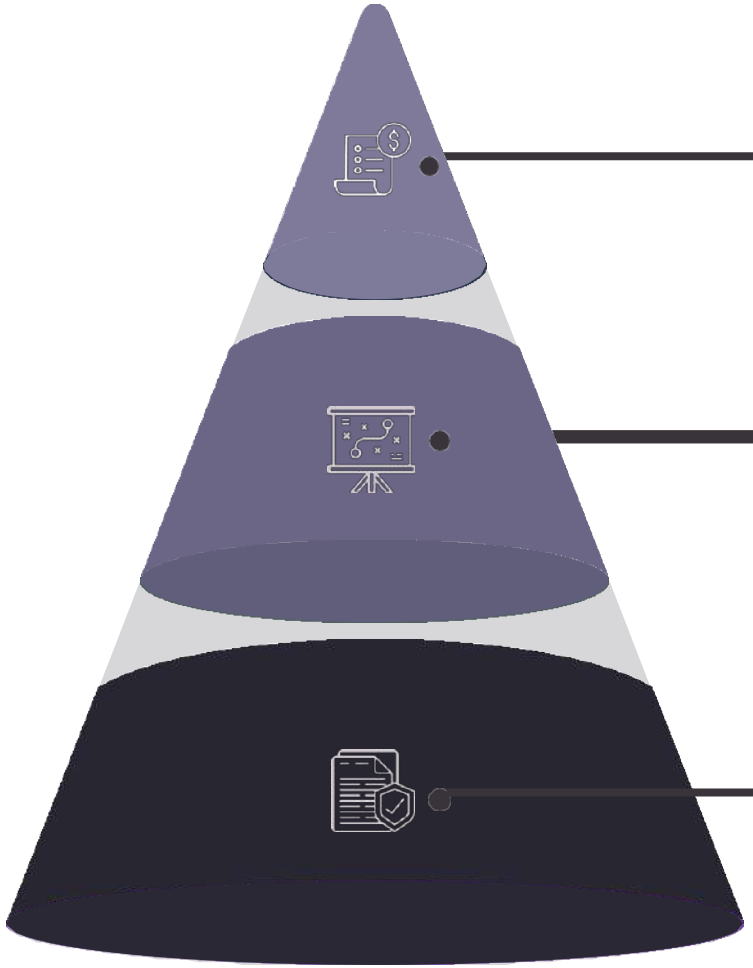
Hospital Outpatient

Coding

- Unlike NTAP, coding is included in the Transitional Pass-Through Payment application.
- If the application is successful, CMS will issue a code.
  - Healthcare Common Procedure Coding System (HCPCS) level II code
  - Alphanumeric “C” code: C123
  - Required to be billed on claim to trigger pass-through payment

Key Reimbursement Fundamentals

Interrelated, but not *interdependent*



PAYMENT

Payment methods based on setting of care and paye and provider contracts.

CODING

Identifes what procedure was performed and its diagnosis, submitted on a claim for reimbursement.

COVERAGE

Payer determination under what conditions a technology is deemed "medically necessary"

Establishing coverage, coding, and payment for new technology is an *evidence-based process*

MCRA

Medicare Formal Coverage Mechanisms

CMS Coverage

- **NCD- National Coverage Decision through CMS**
  - **Coverage is granted to procedures and technologies when they meet the definition of "reasonable and necessary"**
  - **Often under a Coverage with** Evidence Development (CED) protocol
- Reserved for high profile, high impact, controversial technology
- Medicare national decisions, binding on all MACs
- Typically 9-12 months to establish

- **Local Coverage Decisions (LCD) through Medicare Administrative Contractors (MAC)**
- MACs establish LCDs for selected services with criteria outlining under what conditions a technology is "reasonable and necessary"
- MACs may or may not have formal published LCDs
- LCDs can differ across MAC jurisdictions – inconsistent coverage

In the absence of a formal NCD or LCD, the technology is covered on a case-by-case basis, if it meets the "reasonable and necessary" criteria

MCRA

CMS Recently Issued a Proposed Rule to Expedite Coverage for Breakthrough Devices

CMS Coverage

Medicare Coverage of Innovative Technology (MCIT) highlights

Publication Date: August 31, 2020.

What is the proposal

- The proposed rule seeks to codify three requirements to meet the definition of **"Reasonable and Necessary"** for coverage determinations, as well as add commercial coverage of a device in lieu of one of the requirements.
- The rule also seeks to **fast track coverage**, through the MCIT pathway, for devices that have already secured FDA Breakthrough Device status and received FDA market authorization.

Timeframe

- CMS proposes an immediate coverage pathway for any FDA market authorized breakthrough device if criteria is met.
- Coverage granted for a 4 – year period through a National Coverage Determination (NCD).

What happens when coverage ends?

- The breakthrough device would be subject to one of the following:
  - Affirmative NCD coverage
  - Non NCD coverage; or
  - MAC discretion (claim by claim adjudication)

MCRA

Consideration for Manufacturers

CMS Coverage

FDA marketing authorization must be established	• **Breakthrough device must be used for the FDA approved or cleared indication(s) for use.**
Voluntary	• **Initiated when a manufacturer notifies CMS of its intention to utilize the MCIT pathway.** • **Manufactures should notify CMS of their intention to elect MCIT within 2 weeks of receiving breakthrough designation.**
Evidence Generation	• **Manufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during coverage under MCIT.** • **CMS is seeking comments whether manufacturers should provide data on outcomes or should be obligated to enter into a clinical study similar to the CMS "Coverage with Evidence Development (CED)" protocol.**

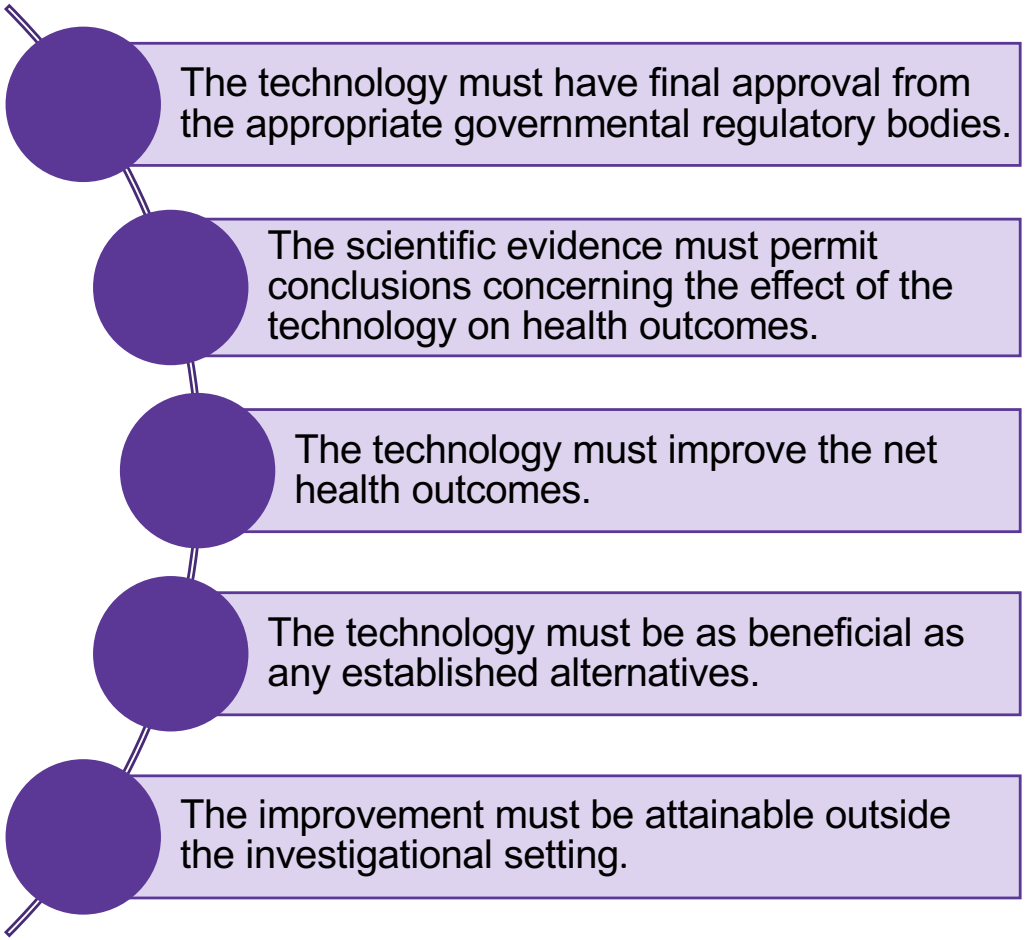
Comments are due to CMS on November 2, 2020

https://www.federalregister.gov/documents/2020/09/01/2020-19289/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and

MCRA

Technology Evaluation Criteria for Coverage

Common Commercial Payer Technology Evaluation Criteria



MCRA

Key Takeaways

New-technology payment under Medicare is not a reward or an entitlement for innovators – it is a stop-loss payment for hospitals.

Breakthrough devices must still qualify for payment but have the benefit of being exempt from *newness* and/or *substantial clinical improvement.*

Having higher costs, compared to the rest of the cases within the MS-DRG or the rest of the devices within the APC, is key to meeting cost criteria.

MCIT is in a proposed state, and comments to CMS from interested stakeholders is imperative.

Coverage through MCIT is temporary and will not guarantee coverage with commercial payers, nor will continued coverage with CMS be guaranteed.

MCRA

Breakthrough Device Benefits and Challenges

Agencies	Benefits	Challenges
Regulatory (FDA)	Label Collaboration Speed Focus	Novelty
Reimbursement (CMS)	NTAP TPT MCIT	Assumptions

MCRA

Frequently Asked Questions

1. *Does the chosen approval route (510k, PMA), in combination with FDA Breakthrough Device Designation have implications on the request for NTAP or TPT and what are the considerations for coverage?*

2. *Does the FDA Breakthrough Device Designation influence the assignment of category A or B to IDE upcoming studies?*

3. *How can a device cleared under a 510k be considered "breakthrough"? This seems counterintuitive.*


Questions?
1050 K Street NW
Suite 1000
Washington, DC 20001
(202) 552-5800
info@mcra.com
MCRA