Coverage, Coding and Payment—Collaboration between FDA and CMS

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Objectives


Learn the basics of Medicare reimbursement
Explore strategies to maximize reimbursement in certain key areas
Appreciate the differences between CMS's mission and FDA's mission
Recognize that an early reimbursement strategy is essential for successful product development!

Agenda

Medicare Reimbursement Basics: Coverage, Coding and Payment

Reimbursement Strategies in Key Areas

- NCD vs. LCD
- The Future of MCIT…TCET?
- Coding Considerations
- New Technology Payments

CMS and FDA

- FDA-CMS Program Coordination
- Medicare Coverage of IDE Clinical Trials

Tips for New Product Development

The Basics of Reimbursement

Coverage
- Is the item or service eligible for payment?

Coding
- How is the item or service identified?

Payment
- What are the payment methodologies and amounts?

Overview of Medicare Coverage

Must fall within a defined benefit category

Must not be excluded

Must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"

- Social Security Act §1862(a)(1)(A)

Definition of "Reasonable and Necessary"

Safe and effective

Not experimental or investigational

- Exception for Clinical Trials NCD

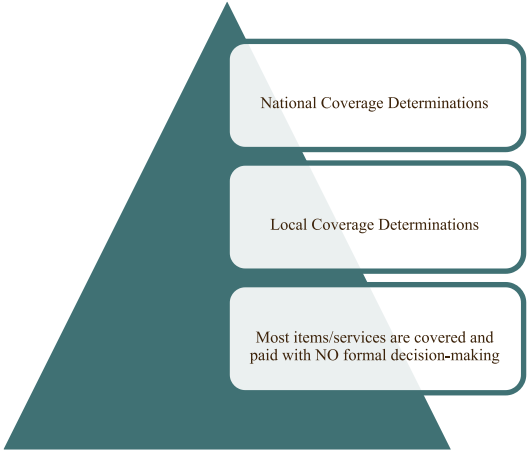
Appropriate for Medicare patients, including duration and frequency, considering:

- Furnished in accordance with accepted standards of medical practice
- Furnished in a setting appropriate to the patient's medical needs and condition
- Ordered and furnished by qualified personnel
- Meets, but does not exceed, the patient's medical need
- At least as beneficial as an existing and available medically appropriate alternative

This definition is in CMS guidance only.
The Trump Administration attempted to codify this definition into regulation, but the Biden Administration withdrew the rule.

Who Makes Medicare Coverage Decisions?

- Determinations by CMS and its contractors
  - National Coverage Determinations (NCDs)
  - Local Coverage Determinations (LCDs)
  - Individual Consideration



Overview of NCDs

National and binding coverage decision by CMS Coverage and Analysis Group (CAG)

May be initiated internally by CMS or externally by formal request from an outside party

May include certain conditions for coverage

- Device covered only for patients with specific clinical or demographic characteristics
- Device covered only when provided by physicians and/or facilities that meet specific criteria
- Coverage with Evidence Development

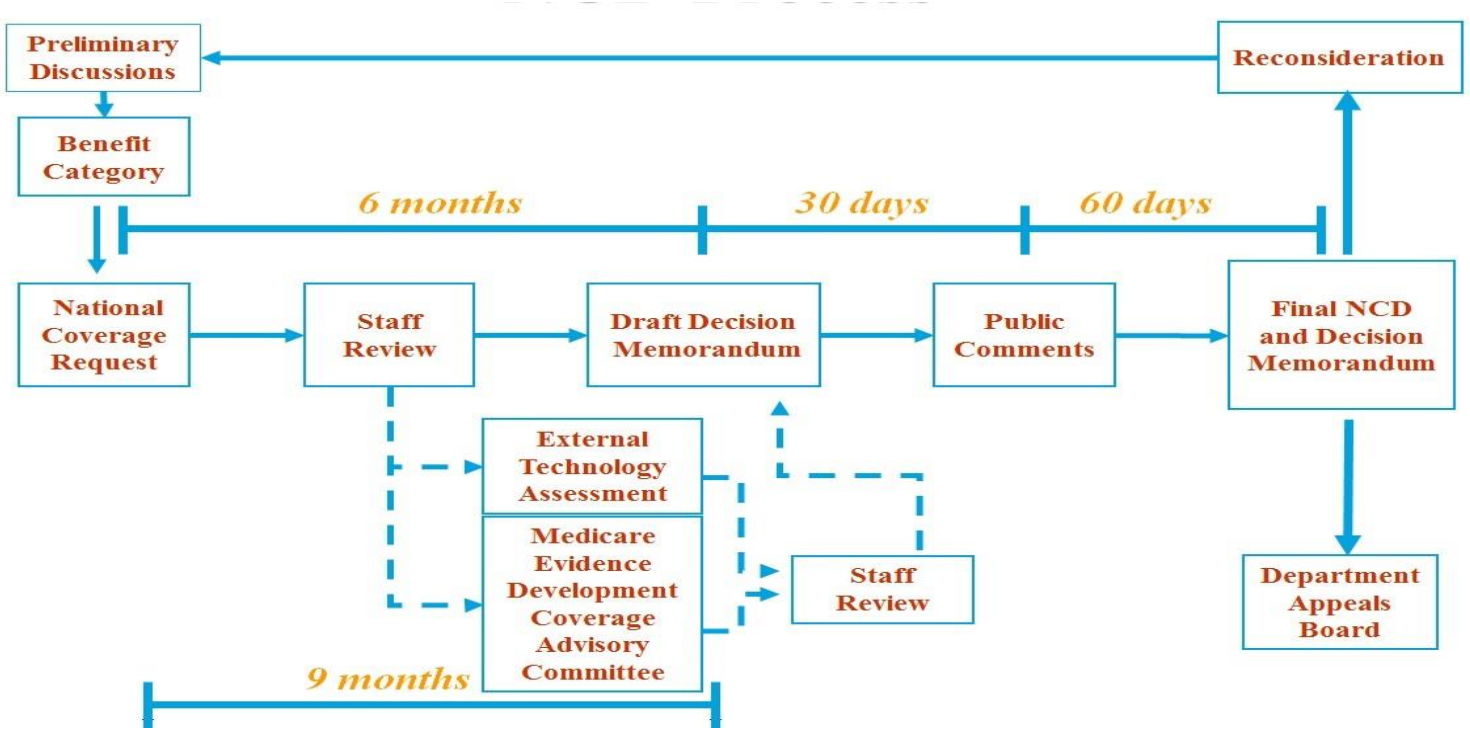
Coverage with Evidence Development

Evidence-based coverage paradigm that permits CMS to develop coverage policies for certain items and services that are likely to show health benefits to Medicare beneficiaries but for which the available evidence base is not yet sufficiently developed

Two Types of CED

- SSA §1862(a)(1)(A): Medical evidence is adequate to conclude that an item or service is reasonable and necessary for certain beneficiaries in certain circumstances, but additional data is required to demonstrate that the item or service is furnished as specified in the NCD (e.g., data registries)
- SSA §1862(a)(1)(E): Medical evidence is not adequate to conclude that an item or service is reasonable and necessary, but coverage would be provided if the beneficiary were enrolled in a clinical study designed to provide additional medical evidence regarding the health risks and benefits of using the item or service

NCD Process


Preliminary Discussions
Benefit Category
Reconsideration
6 months
30 days
60 days
National Coverage Request
Staff Review
Draft Decision Memorandum
Public Comments
Final NCD and Decision Memorandum
External Technology Assessment
Medicare Evidence Development Coverage Advisory Committee
Staff Review
Department Appeals Board
9 months

Components of a Formal NCD Request

Written letter of request for NCD

Full and complete description of item/service

- Design
- Method of use
- Target Medicare population
- Medical indication(s) for which it can be used
- Whether it is intended for use by providers or beneficiaries
- Relevance, usefulness or medical benefits of the item or service to the Medicare population

Scientific evidence supporting the clinical indication(s) for the item/service

Medicare Part A or Part B benefit category or categories in which the requester believes the item/service falls

Components of a Formal NCD Request

The "integrated summary of safety data" and "integrated summary of effectiveness data" of the combined "summary of safety and effectiveness data" portions of the FDA application

For 510(k) devices, identification of the predicate devices to which the item/service is claimed to be substantially equivalent

Status of current FDA regulatory review of the item/service at the time the formal request is submitted

Labeling submitted to FDA or approved by FDA for the item/service, indicating whether the item or service for which review is being requested is covered under the labeled indications

Overview of LCDs

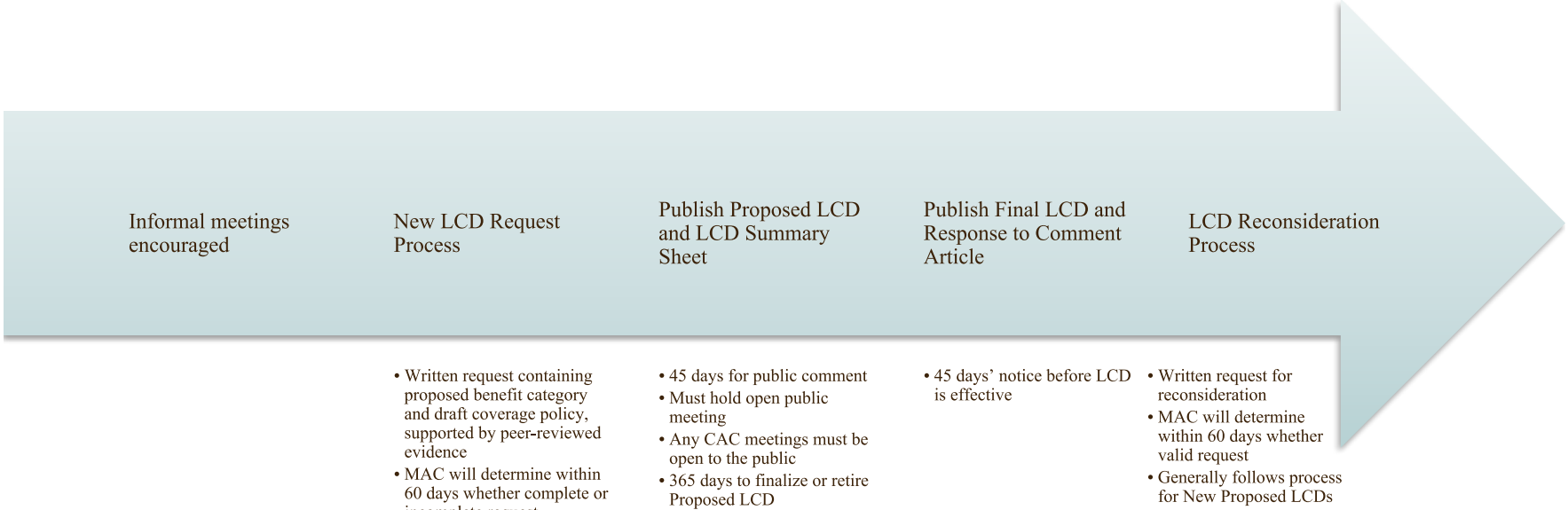
Issued by Medicare Administrative Contractors (MACs)

Historically, no formal process to request LCDs – process was driven by contractor Medical Directors

- Publish a draft LCD based on review of medical literature and contractor's understanding of local practice
- Public meetings
- Contractor Advisory Committee (CAC) review
- Comment and notice periods (for all new LCDs and revisions that restrict existing LCDs) – minimum 45 days each

Limited to particular MAC jurisdiction

LCD Process


Informal meetings encouraged
New LCD Request Process
• Written request containing proposed benefit category and draft coverage policy, supported by peer-reviewed evidence
• MAC will determine within 60 days whether complete or incomplete request
Publish Proposed LCD and LCD Summary Sheet
• 45 days for public comment
• Must hold open public meeting
• Any CAC meetings must be open to the public
• 365 days to finalize or retire Proposed LCD
Publish Final LCD and Response to Comment Article
• 45 days' notice before LCD is effective
LCD Reconsideration Process
• Written request for reconsideration
• MAC will determine within 60 days whether valid request
• Generally follows process for New Proposed LCDs

Components of a LCD Request

NCD vs. LCD?

NCD

- National decision that is binding on all MACs ("all or nothing")
- Possibility of CED
- Defined process once accepted for review

LCD

- Limited to particular jurisdiction ("multiple bites at the apple")
- Process historically driven by MAC Medical Director – how has this changed?

The Future of MCIT…TCET?

"Medicare Coverage of Innovative Technology" Final Rule withdrawn by Biden Administration

- FDA-designated breakthrough devices authorized on or after March 15, 2019 are eligible for 4 years of Medicare coverage
- Voluntary coverage (must make request to CMS within 2 years of FDA market authorization)
- Must not be the subject of an NCD
- Must fall within a Medicare benefit category

New Biden Administration initiative— "Transitional Coverage of Emerging Technology"

- Two CMS listening sessions
- Potential rulemaking this year?
- Congress may act first in CURES 2.0 legislation

Overview of Coding

Coding is the language of reimbursement

Coding operationally links coverage and payment

Having a code does not guarantee reimbursement!

Types of Codes

Type of Code	Coding System	Who Sets Code?	Who Uses Code?
Diagnosis	ICD-10-CM, Diagnoses, Vols. 1 & 2	WHO and NCHS	All Providers
Procedure or Service	ICD-10-CM, Procedures, Vol. 3	WHO and CMS	Hospital Inpatient
Procedure or Service	CPT-4	AMA	Physicians, Hospital Outpatient, Clinical Labs, etc.
Products and Certain Services	HCPCS	CMS	Physicians, Hospital Outpatient, DMEPOS Suppliers, etc.
Drugs	NDC	FDA	Pharmacies, etc.

ICD-10-CM: International Classification of Diseases, 10th Edition, Clinical Modification
CPT-4: Current Procedural Terminology, 4th Edition
HCPCS: Healthcare Common Procedure Coding System
NDC: National Drug Code

WHO: World Health Organization
NCHS: National Center for Health Statistics at the Centers for Disease Control and Prevention
AMA: American Medical Association

DMEPOS: Durable medical equipment, prosthetics, orthotics and supplies

Overview of CPT Codes

Maintained by the AMA CPT Editorial Panel, with recommendations from the CPT Advisory Committee

Identify medical services furnished by physicians and other health care professionals

Typically consist of 5-digit numeric codes

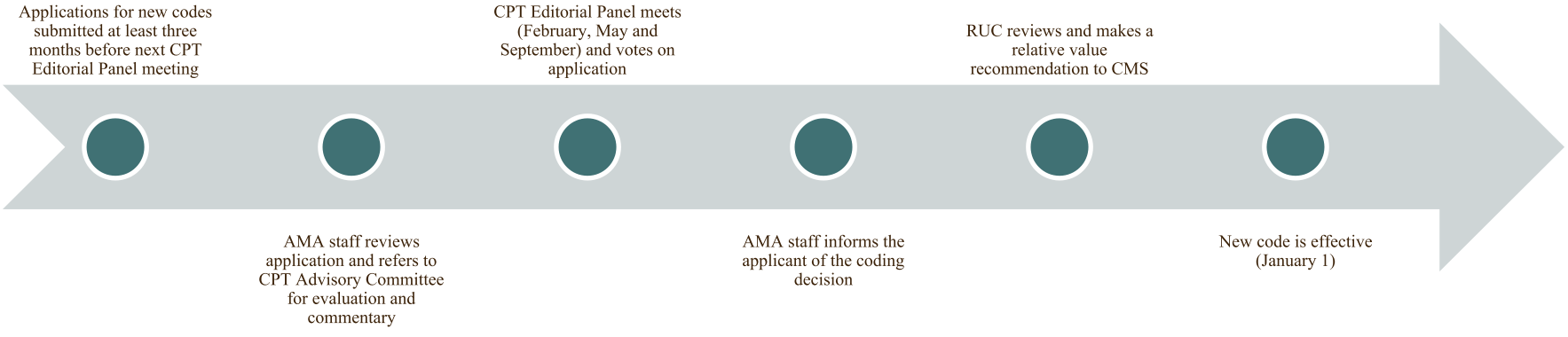
Descriptors are generic and do not identify specific products or brand names

- *CPT 33533: Coronary artery bypass, using arterial graft(s); single arterial graft*

Three types of CPT codes

- Category I CPT codes
- Category II CPT codes (optional performance tracking codes - ####F)
- Category III CPT codes (emerging technology codes - ####T)

Process for Obtaining a CPT Code



The deadline for applications for the 2023 CPT codeset has passed. June 15, 2022 (for the September 2022 CPT Editorial Panel meeting) is the deadline for applications for the 2024 CPT codeset.

Category III codes are released on January 1 and July 1 and are effective six months later.

Criteria for Obtaining a Category I CPT Code

- Unique and well-defined procedure that (1) is distinguishable from other procedures, (2) is not a fragmentation of an existing procedure, (3) is not currently reportable as a complete service by one or more codes, and (4) is not a means to report extraordinary circumstances related to the performance of a procedure already described in the codeset
- Descriptor accurately reflects the procedure as typically performed
- All devices and drugs used are FDA approved or cleared
- Procedure is performed by many physicians across the U.S. with frequency consistent with the intended clinical use, and consistent with current medical practice
- Clinical efficacy is documented in published literature

CPT Application Literature Requirements

- Up to 5 published references must be listed
- At least 1 must report the procedure/service in a U.S. patient population, and at least 2 references must report different patient populations or have different authors (no overlapping patient populations or no overlapping authors
- For new technology (e.g., PMA device), at least one reference must have minimum Level of Evidence IIa
- For existing or non-contributory technology (e.g., 510(k) device), at least one reference must have minimum Level of Evidence IIIa/IIIb
- Different requirements for technology that is limited, specialized, or has humanitarian utilization

LEVELS OF EVIDENCE
Level Ia – Evidence obtained from systematic review of randomized controlled trials
Level Ib – Evidence obtained from an individual randomized controlled trial
Level IIa – Evidence obtained from systematic review of cohort studies
Level IIb – Evidence obtained from an individual cohort study
Level IIIa – Evidence obtained from systematic review of case control studies
Level IIIb – Evidence obtained from a case control study
Level IV – Evidence obtained from case series
Level V – Evidence obtained from expert opinion without explicit critical appraisal

Criteria for Obtaining a Category III CPT Code

- Unique and well-defined procedure that (1) is distinguishable from other procedures, (2) is not a fragmentation of an existing procedure, (3) is not currently reportable as a complete service by one or more codes, and (4) is not a means to report extraordinary circumstances related to the performance of a procedure already described in the codeset
- Descriptor accurately reflects the procedure as typically performed
- The procedure or service is currently or recently performed in humans
- (1) The application is supported by at least one CPT or HCPAC advisor representing practitioners who would use this procedure or service ~~OR~~ (2) The actual or potential clinical efficacy of the specific procedure or service is supported by peer reviewed literature which is available in English OR (3) There is at least one IRB-approved protocol of a study of the procedure or service, a description of a current and ongoing U.S. trial outlining the efficacy of the procedure or service, or other evidence of evolving clinical utilization

Key Components of a CPT Code Application

- Complete description of the procedure or service (e.g., describe in detail the skill and time involved)
- Clinical vignette, which describes the typical patient and work provided by the physician
- Copies of peer-reviewed articles indicating the safety and effectiveness of the procedure
- Diagnosis of patients for whom the procedure/service is performed, prevalence of the disease/condition, sites of service where performed and physician specialties who perform it
- Volume, frequency and length of time the procedure is/has been performed
- Copies of additional published literature related to the request, and any practice parameters/guidelines or policy statements on the procedure/service
- Evidence of FDA approval of the drug or device used in the procedure/service
- Rationale why existing codes are not adequate, list of codes that would be an inherent/integral part of the requested code, and other codes that would be reported on the same day as new code

Overview of HCPCS Codes

Maintained by the CMS HCPCS Workgroup

Identify items and services not described by CPT codes

Consist of 5-digit alphanumeric codes

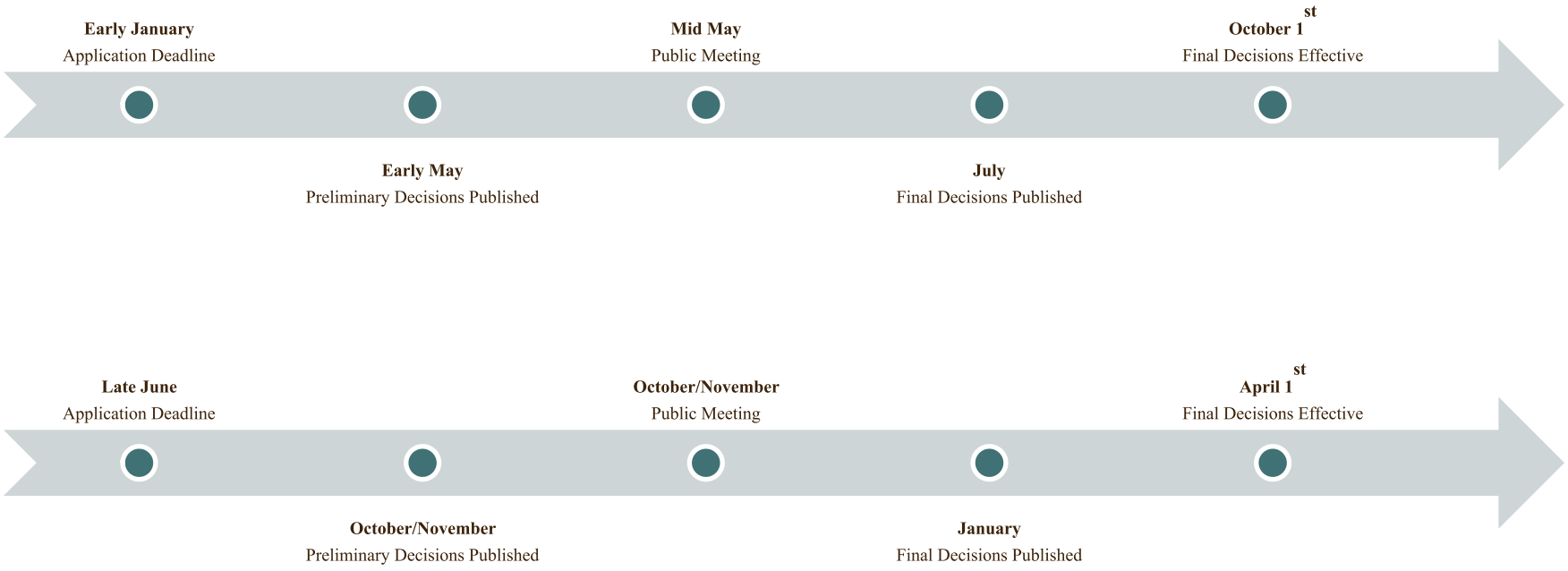
Product descriptions are generic, to cover more than one brand of product

- *E2402: Negative pressure wound therapy electrical pump, stationary or portable*

Three types of HCPCS codes

- Permanent HCPCS codes
- Temporary HCPCS codes ("Q codes")
- Miscellaneous/Not Otherwise Classified HCPCS codes (*E1399: Durable medical equipment, miscellaneous*)

Semi-Annual Process for HCPCS Codes for Devices



The HCPCS process for drugs is quarterly, with no public meetings.

Criteria for Obtaining a Permanent HCPCS Code

- There is no existing code that adequately describes the product, or there are therapeutic distinctions between the product and other products described by existing codes
- The product is not used only in the inpatient setting
- The product serves a diagnostic or therapeutic purpose
- The product must be authorized for marketing by FDA (or exempt from FDA marketing authorization)
- The product must be marketed in the U.S.
- There is a national program operating need for the code, or the code is required by statute

Overview of Medicare Payment

How much will Medicare pay for the item or service?

What is the payment methodology?

Depends on the site of service and provider/supplier types

- Prospective Payment System (PPS)
- Fee Schedule
- Competitive Bidding/Acquisition

Key Medicare Payment Systems

Site of Service	Type of Payment Methodology	Codes Claimed to Generate Payment Amount	New Technology Payment Program
Hospital Inpatient	IPPS MS-DRG Bundle (per discharge) (Medicare Part A)	ICD-10 Diagnosis Codes, ICD-10 Procedure Codes	New Technology Add-On Payment (NTAP)
Hospital Outpatient	OPPS APC Package (per procedure) (Medicare Part B)	ICD-10 Diagnosis Codes, CPT Codes, HCPCS Codes	Pass-Through Status New Technology APC
Physician	Physician Fee Schedule (Medicare Part B)	ICD-10 Diagnosis Codes, CPT Codes, HCPCS Codes	
DMEPOS	DMEPOS Fee Schedule or Competitive Bidding (Medicare Part B)	ICD-10 Diagnosis Codes, HCPCS Codes	
Clinical Laboratory Tests	Clinical Laboratory Fee Schedule (Medicare Part B)	ICD-10 Diagnosis Codes, CPT Codes	ADLT

IPPS: Inpatient Prospective Payment System
MS-DRG: Medicare Severity Diagnosis Related Group
OPPS: Outpatient Prospective Payment System
APC: Ambulatory Payment Classification
ADLT: Advanced Diagnostic Laboratory Test

Payments for New Technology

"It's the latest technology.
A Pacemaker/MP3 Player. That's where
you plug in your earbuds."

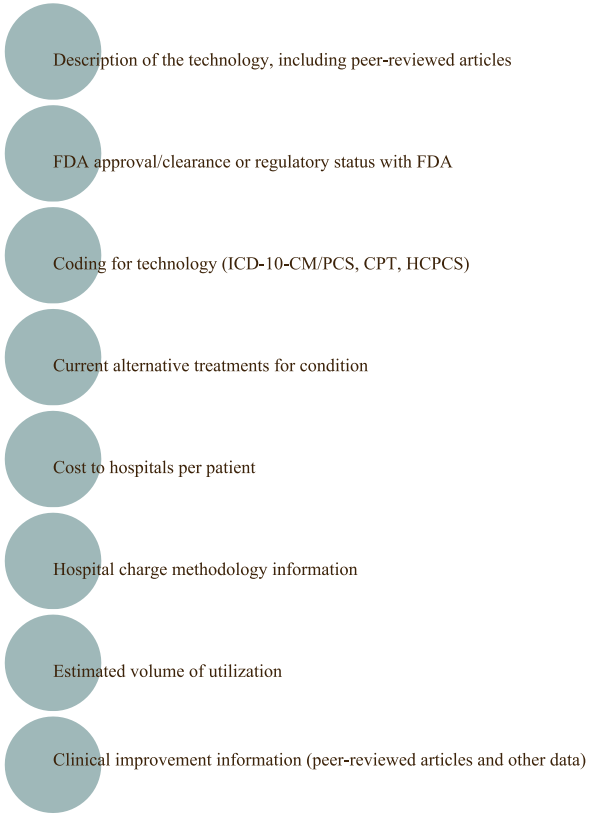
Inpatient Add-On Payment (NTAP): Criteria

"Substantially similar" means that (1) a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) a product is assigned to the same MS-DRG; and (3) the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population.

The MS-DRG payment is inadequate for a new technology if the charges for cases involving the new technology exceed certain threshold amounts.

"Substantial clinical improvement" criterion is evaluated using a number of factors, including whether other treatments are available for the patient population, whether the device enables earlier diagnosis and treatment, and whether clinical outcomes are improved.

Inpatient Add-On Payment (NTAP): Application



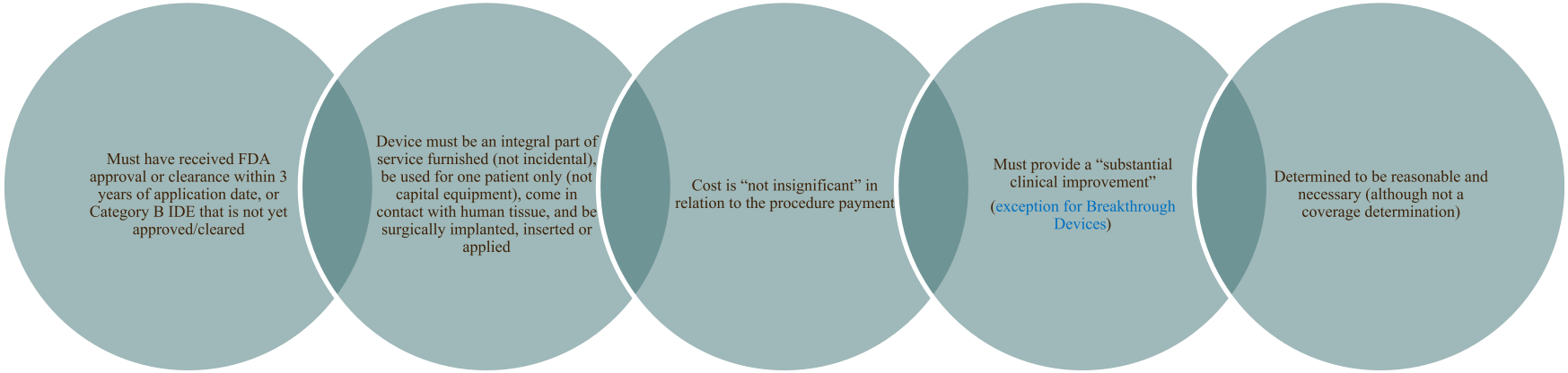
Applications are evaluated through the IPPS annual rulemaking process. For FY 2023, the application deadline was October 8, 2021.

Inpatient Add-On Payment (NTAP): Payment

Payment rate is equal to the lesser of (1) 65% of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare's payment); or (2) 65% of the difference between the full MS-DRG payment and the hospital's estimated cost for the case

NTAP is effective for at least two years but no more than three years

Outpatient Pass-Through Status: Criteria



"Not insignificant" criterion requires a three-part test: (1) the estimated average reasonable cost of devices in the category exceeds 25% of the applicable APC payment amount for the service associated with the category of devices; (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 service associated with the category of devices by at least 25%; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determine to be associated with the device in the associated APC exceeds 10% of the total APC payment.

"Substantial clinical improvement" criterion is evaluated using a number of factors, including whether other treatments are available for the patient population, whether the device enables earlier diagnosis and treatment, and whether clinical outcomes are improved.

Outpatient Pass-Through Status: Application

- Clinical use of device, clinical characteristics, how it is different from or improves upon other devices
- List of all established pass-through categories that describe related or similar products
- List of codes for procedures in which device is used
- Discussion how device meets substantial clinical improvement criterion (peer-reviewed clinical trials preferred)
- Sales and marketing information (date of first sale, number sold, annual utilization, etc.)
- Actual cost of device to hospitals
- FDA approval/clearance or IDE documentation

Applications are considered on a quarterly basis, but are then finalized or discontinued in the annual OPPS annual rulemaking process

Complete application submitted by first business date in:	Earliest effective date for pass-through status:
March	July 1
June	October 1
September	January 1
December	April 1

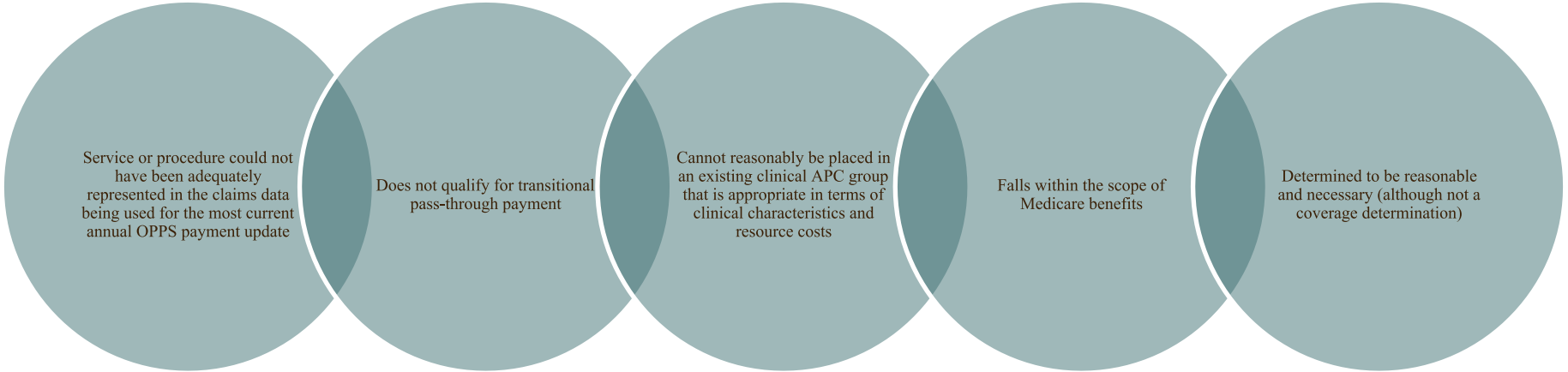
Outpatient Pass-Through Status: Payment

Payment rate is based on the charge on the individual bill, converted to cost by application of a hospital-specific cost-to-charge ratio (average CCR for its outpatient departments) and subject to a reduction that offsets the cost of similar devices already included in the APC payment rate for the associated procedure

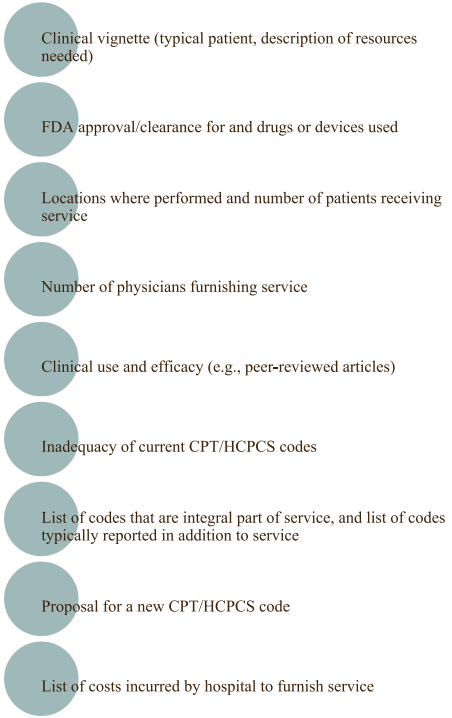
Device is assigned a HCPCS C code

Pass-through status is effective for three years

Outpatient New Technology APC: Criteria



Outpatient New Technology APC: Application



Applications are considered on a quarterly basis

Complete application submitted by first business date in:	Earliest effective date for New Tech APC:
March	July 1
June	October 1
September	January 1
December	April 1

Outpatient New Technology APC: Payment

Payment rate is based on the midpoint of a range of costs, and not on a relative payment weight

Procedure is assigned to one of 52 New Tech APCs (APC 1491 through APC 1908)

- APC 1491 (New Technology – Level 1A) - $0-$10 (Payment is $5.00)
- APC 1908 (New Technology – Level 52) - $145,001 - $160,000 (Payment is $152,500.50)

New Tech APCs have one of two status indicators:

- S (not subject to the multiple procedure payment reduction)
- T (discounted when furnished with other procedures or services that are also subject to discounting)

Procedure is assigned to a New Tech APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms (approximately 2-3 years from the time a new HCPCS/CPT code becomes effective)

Payment for Clinical Lab Tests

Historic Fee Schedule

- Adopted in 1984 based on charge data
- Updated annually for inflation
- Payment for new tests based on crosswalking or gapfilling

Fee Schedule Effective January 1, 2018

- Payment based on weighted median private payer rates paid to applicable laboratories reported to CMS
- If no information reported to CMS, payment for test based on crosswalking or gapfilling

Rates Through CY2023 Based on:
Data Collection Period: January – June 2016
Data Reporting Period: January – May 2017

Rates in CY2024 Based on:
Data Collection Period: January – June 2019
Data Reporting Period: January – March 2023

Advanced Diagnostic Laboratory Tests (ADLTs)

Clinical diagnostic laboratory test covered under Medicare Part B

Offered and furnished by a single laboratory

For use only by original developing laboratory (or successor owner)

Meets one of the following criteria:

- (1) The test is an analysis of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result
  - The test must include an empirically derived algorithm that yields a result that predicts the probability a specific patient will develop a certain condition or respond to a particular therapy
  - The test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests
- (2) The test is cleared or approved by FDA

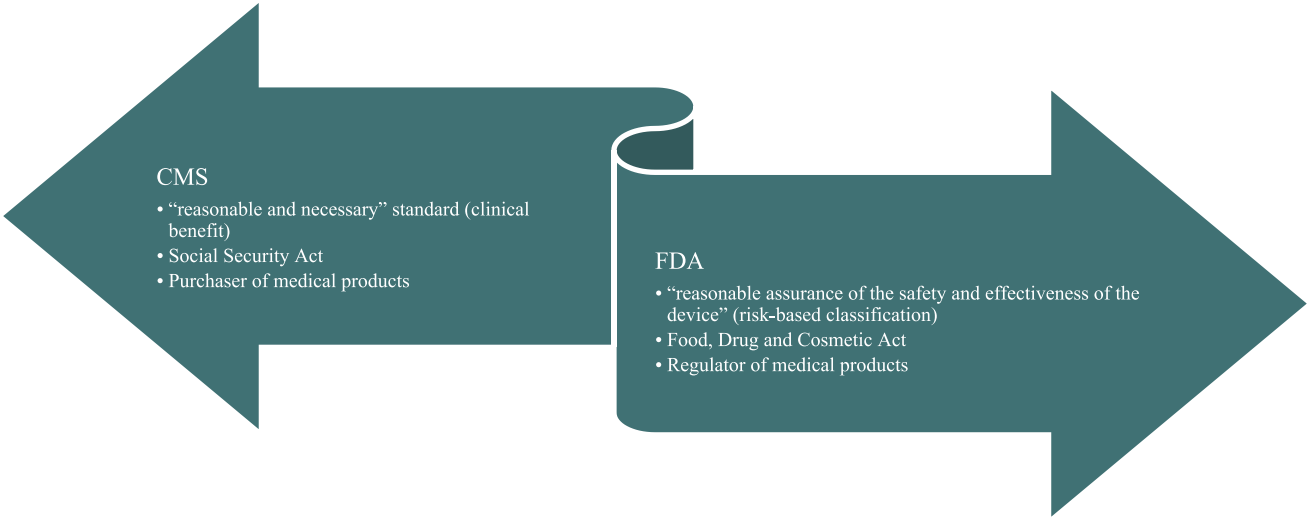
Payment for ADLTs

New ADLTs are paid using the "actual list charge" amount during an initial period of three quarters (which begins on the first day of the full calendar quarter following the later of the date a Medicare Part B coverage decision for the test is made or the date ADLT status is granted by CMS)

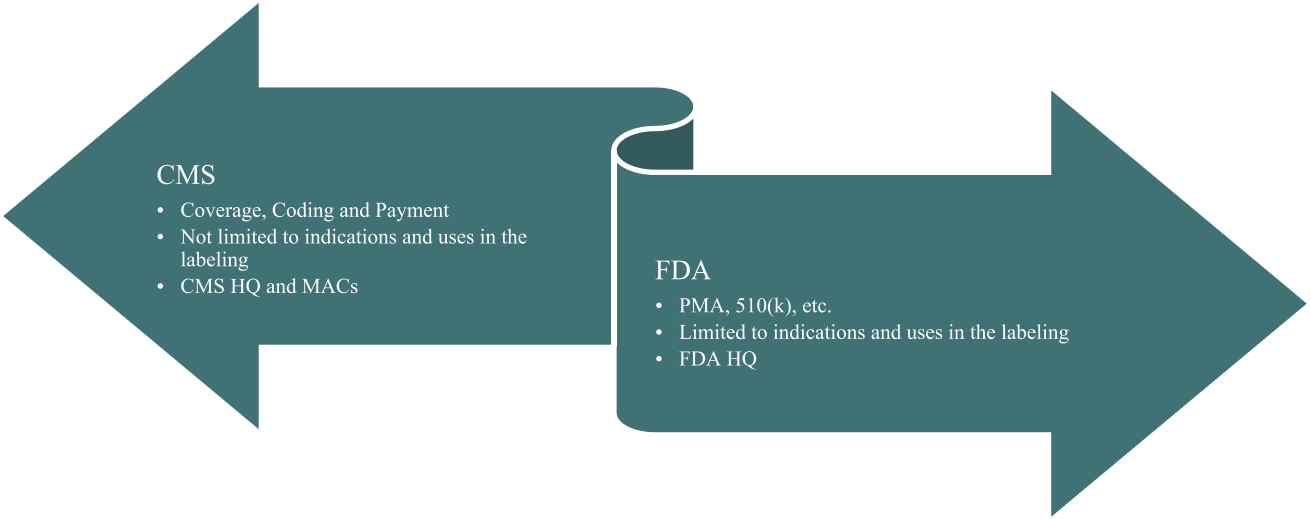
"Actual list charge" is the publicly available rate on the first day the new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date

After the initial period, payment is based on the weighted median private payer rate paid to the single laboratory and reported to CMS annually

CMS vs. FDA: Regulatory Expectations



CMS vs. FDA: Decisions



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

CMS vs. FDA

CMS	FDA
"reasonable and necessary"	"reasonable assurance of safety and effectiveness"
CMS coverage determination (formal or informal)	FDA-approved labeling
Focus on health benefits	Focus on device function and clinical risk vs. benefits
Economic data is important	Economic data is irrelevant
Superiority endpoint required	Non-inferiority endpoint acceptable
Focus on Medicare beneficiaries	Focus on intended population
Public processes	Generally not public processes
Publishes proposed decisions	Does not publish proposed decisions

FDA-CMS Parallel Review Program

Voluntary pilot program launched in November 2011 (now permanent)

Goals:

- Decrease time between FDA approval and NCD issuance
- Quicker patient access to innovative devices
- Provide efficiencies in creation and submission of clinical studies

Program only applicable to devices that meet the following criteria:

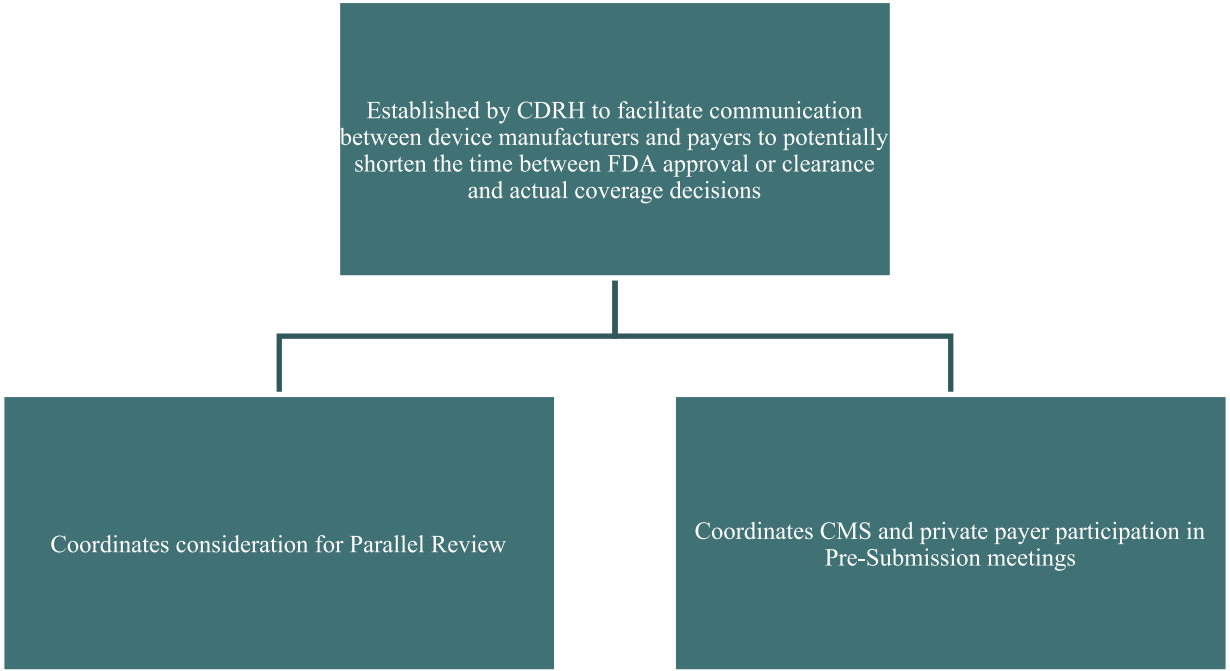
- New device that would require an original or supplemental application for PMA or petition for de novo review
- New device that would fall within the scope of a Part A or Part B Medicare benefit category and is not subject to an NCD

FDA-CMS Parallel Review Program

Review Process Is Still a Serial Review

- FDA/CMS consideration – meet within 30 days of receiving a nomination
- Sponsor/Requester notification
- Acceptance meeting
- FDA review
- CMS review – CMS will begin informal NCD review process sometime after submission of the PMA or de novo petition
  - Sponsor/requester should file formal request for NCD

FDA Payer Communication Task Force



Medicare Coverage of IDE Devices

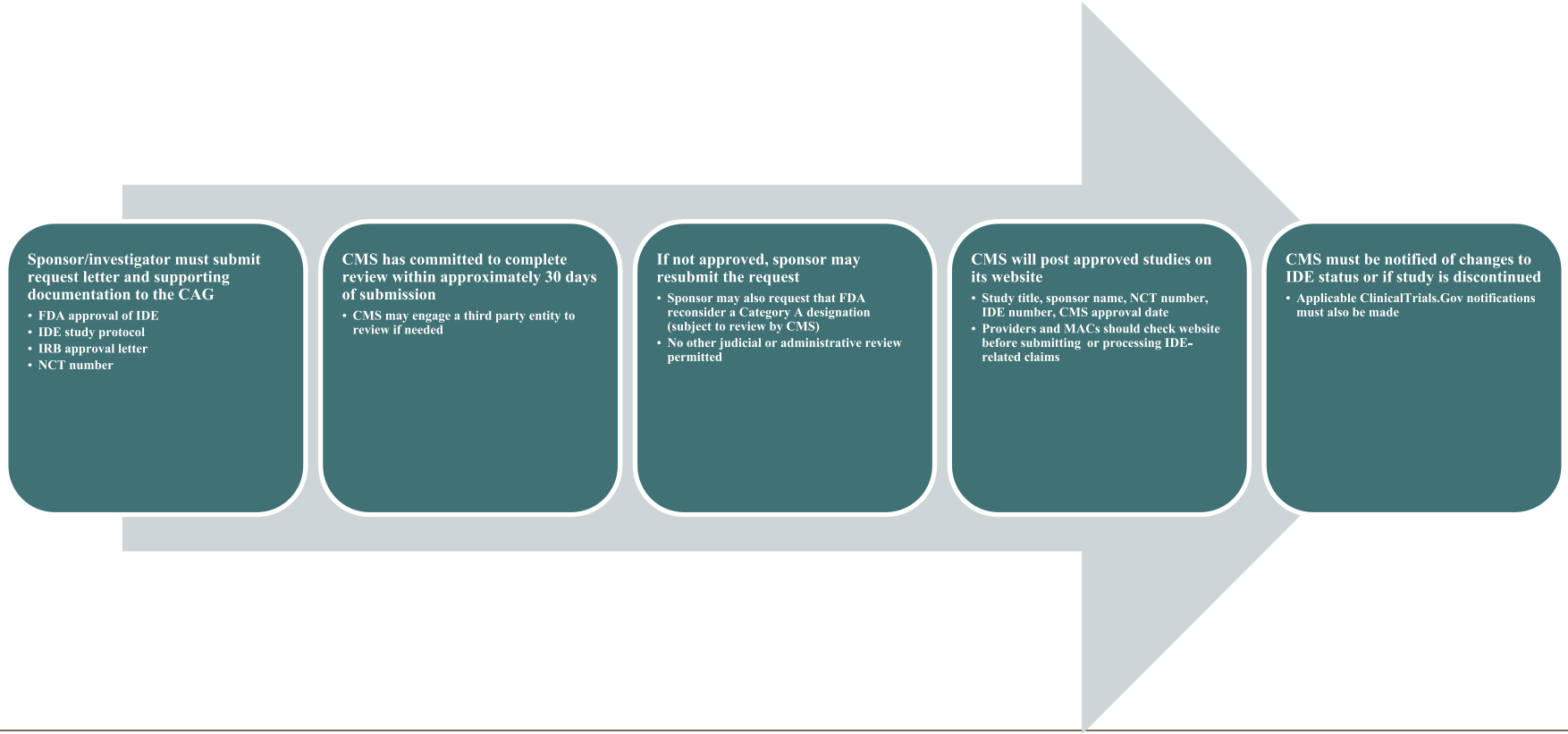
FDA Categorization of Approved IDEs

New FDA-CMS Memorandum of Understanding effective June 2016 allows for change from Category A to Category B

2015 Changes to IDE Coverage Rules

- 42 C.F.R. § 405.201 *et seq.*
- Two Major Changes:
  - **Process** for making coverage decisions centralized at CMS (Coverage & Analysis Group)
  - **Standards** used in making coverage decisions are 10 criteria applied to coverage decisions for (1) Category B devices, and (2) routine care items and services for both Category A and B devices
- Changes were effective January 1, 2015
  - IDE studies approved by MACs prior to January 1, 2015 will continue to be administered by MACs
  - MACs will continue to determine coverage of clinical trials for non-significant risk devices

Process for IDE Coverage



Criteria for IDE Coverage

1. Principal purpose is to test whether the device improves health outcomes of appropriately selected patients
2. Rationale is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use
3. Results are not anticipated to unjustifiably duplicate existing knowledge
4. Study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate
5. Study is sponsored by an organization or individual capable of successfully completing the study
6. Study is in compliance with all applicable Federal regulations concerning the protection of human subjects
7. Study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals (studies may be exempt only if the disease/condition being studied is life threatening and the patient has no other viable treatment options)
8. Study is registered with ClinicalTrials.gov
9. Protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early
10. Protocol must describe how Medicare beneficiaries may be affected by the device, and how the study results are/are not expected to be generalizable to the Medicare beneficiary population

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 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

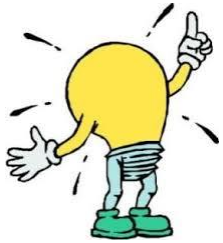
- Comparative effectiveness studies important to demonstrate value proposition
- Medicare requires its beneficiaries to be part of study population
- Must demonstrate an improvement in overall outcomes (safe and effective is not enough)
  - Quality of life, reduced medications, return to activities of 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!