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Summary of CMS Innovators' Guide

Payment for many technological advances can be made under one of Medicare's payment methodologies without being preceded by an explicit coverage determination, coding change, and/or payment decision by CMS.

There are three areas that impact new technology: Coverage, Coding and Payment. CMS states that "Coverage, coding, and payment decisions are not necessarily made in any particular order."

COVERAGE CONSIDERATIONS

Medicare's authority to cover or exclude certain items or services is governed by the Social Security Act (the Act) and implementing regulations.

When looking at a new technology, the following questions should be asked:

- *Benefit Category* – Does the new technology fall into at least one defined benefit category?
- *Statutory Exclusion* – Does the new technology involve an item or service that is specifically excluded?
- *Reasonable and Necessary* – Is the new technology "reasonable and necessary" for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member?

Oversight of Coverage Determinations

CMS and its administrative contractors the Medicare Administrative Contractors (MACs), have the authority to develop coverage determinations for particular items or services or to decide claims on a case-by-case basis. CMS may choose to develop a national coverage policy to ensure that similar claims will be adjudicated under uniform criteria. Coverage policies are more likely to be developed when the item or service produces significant clinical consequences for beneficiaries, when the medical community is

divided about the merits of an item or service for a particular population, or when the item or service has a significant impact on the Medicare program.

The MAC develops Local Coverage Determinations (LCDs) that apply only within the jurisdiction served by the individual MAC. Administrative Law Judges (ALJs) must give substantial deference to LCDs but are not bound to follow the policies. Medicare Advantage (Part C) health plans are required to cover all items and services that are offered under Part A and Part B. Thus, plans must cover items and services that are covered under an NCD. NCDs do not apply to Part D plans.

National Coverage Determination (NCD) Development

The NCD process consists of three major steps: 1) initiation, 2) review, and 3) completion. NCDs also can be modified upon request to expand coverage, for example, related to a new diagnosis or modality.

Time frames required for the NCD process are mandated but do not begin until CMS formally accepts an NCD request. Once a completed request is accepted, CMS notifies the requester and posts a tracking sheet announcing the NCD review on the CMS coverage website.

For NCD requests not requiring an external technology assessment (TA) or Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) review, CMS must post a proposed decision within six months. For NCDs that require either a TA or MEDCAC review, or both, the proposed decision must be posted within nine months.

CMS then issues a notice to the MACs regarding how to process claims (e.g., when to pay, when not to pay, pay only when certain clinical conditions are met). CMS will provide detailed coding and billing instructions with the NCD instructions.

Sometimes CMS will impose or alternatively it can be requested to have temporary coverage under a Coverage with Evidence Development (CED). These

NCDs require additional data collection, such as data collected in a clinical trial, as a condition of coverage. The purpose of CED is to provide Medicare coverage for a particular item or service and to develop evidence of its impact on the health of Medicare beneficiaries.

Local Coverage Determination (LCD) Development

The time clock for an LCD begins with the initiation of a minimum 45-day comment period following publication of a draft LCD. During this time, comments on the draft LCD must be solicited from outside parties. In addition to the draft LCD comment period, contractors provide open meetings for the purpose of discussing draft LCDs prior to presenting the policy to the Contractor Advisory Committee (CAC). Once the contractor has considered all the comments and developed the final LCD, it must be published on Medicare's coverage website. A minimum notice period of 45 days is required prior to the effective date of implementation

CODING CONSIDERATIONS

CMS states: "In most cases, new items and services are adequately described in existing codes. However, some new technologies may warrant differentiation through the creation of new codes."

A coding review should be undertaken for a new technology to determine how it might be billed. The type of code needed will depend on whether the service is going to be provided on an inpatient

or outpatient basis or both. Coding is distinct from coverage; assignment of a new code does not automatically imply coverage by any payer. However, for items and services newly covered by Medicare, CMS may assign either an existing code that describes a similar item or service, a miscellaneous code (e.g., a not elsewhere classified code or a not otherwise specified code), or a new code for payment purposes.

Inpatient Services and ICD-9

If just an inpatient service, then an existing ICD-9 procedure code may apply. ICD-9 procedure codes describe the procedure performed and also may indicate insertion of a device. New ICD-9 codes requests are submitted to a Coordination and Maintenance (C&M) Committee, co-chaired by representatives from the National Center for Health Statistics and CMS. The C&M holds public meetings twice a year to discuss proposed revisions. A background paper, including a CMS recommendation, is created and shared with the requestor prior to the meeting. Throughout the process there is amply opportunity for the requestor and public to comment at the meetings and in writing. Finalized ICD-9 codes are published in April of each year. The ICD-9 will be updated to the ICD-10 in 2013 to allow for more detail and flexibility in codes.

Outpatient Services and HCPCS

Payers including CMS use the Healthcare Common Procedure Coding System (HCPCS) for items and services furnished in outpatient settings such as hospital outpatient departments, physicians' offices, and patients' homes. In contrast to coverage decisions, changes to coding systems are made at the national level. The HCPCS code sets are updated at least annually.

The HCPCS code set is divided into Level I and Level II codes. Level I consists of the Current Procedural Terminology (CPT), a coding system maintained by the American Medical Association to identify medical services and procedures furnished by physicians and other health care professionals. Level II is used primarily to identify products, supplies, and services not included in the CPT codes.

Level I HCPCS

There are three categories of CPT codes:

- Category I codes consist of five numeric digits and represent procedures and services performed by physicians, other health care professionals, and facilities. Category I codes are divided into six sections: Evaluation and Management; Anesthesiology; Surgery; Radiology; Pathology and Laboratory; and Medicine.
- Category II codes are performance measurement codes that support data collection for services that are generally agreed to contribute to positive health outcomes.
- Category III codes are emerging technology codes that support data collection for services that do not yet have FDA approval or are not widely used.

Proposals to add, modify, or delete CPT codes are considered by the CPT Editorial Panel, a 17-member group comprised of representatives from the AMA, private health insurers, the American Hospital Association, the Health Care Professionals Advisory Committee, and CMS. The CPT Editorial Panel is supported in its efforts by the CPT Advisory Committee, which is made up of representatives of more than 90 medical specialty societies and other health care professional organizations.

The AMA recommends that parties interested in requesting a CPT code answer several questions before submitting a request:

- Is the suggestion a fragmentation of an existing procedure/service?
- Can the suggested procedure / service be reported by using two or more existing codes?
- Does the suggested procedure /service represent a distinct service?
- Why aren't the existing codes adequate?

The CPT Editorial Panel meets regularly, at least three times a year. Applications for new codes

are accepted on a rolling basis but proposed CPT changes must be received at least four months in advance for consideration at the next meeting.

Category I CPT codes are updated annually to reflect changes in medical technology and practice. Coding changes are effective for use on January 1 of each year.

Category I vaccine product codes, Category II, and Category III codes are typically released either CPT cycle and become effective six months subsequent to the date of release, e.g., codes released on January 1 are effective July 1, allowing 6 months for implementation, and codes released on July 1 are effective January 1.

Level II HCPCS

Level II HCPCS codes represent approximately 4,000 separate categories of like items or services that encompass millions of products from different manufacturers. To avoid any appearance of endorsement, brands or trade names generally are not used in HCPCS to describe the products represented by a code unless brand distinction is deemed necessary in order to facilitate compliance with laws regarding single source drugs.

HCPCS codes are distributed and maintained by CMS. The CMS HCPCS Workgroup considers coding requests and recommends whether a change to is warranted. Recommendations for a revision to the HCPCS are reviewed at regularly scheduled meetings of the CMS HCPCS Workgroup. CMS makes final HCPCS coding decisions.

Permanent national codes are updated once a year on January 1. Codes categories are:

A codes — Ambulance, medical and surgical supplies, respiratory DME, miscellaneous investigational
B codes — Enteral and Parenteral Therapy
D codes — Current Dental Terminology (CDT) codes
E codes — Durable Medical Equipment(DME)
J codes — Drugs that are not self-administered
L codes — Orthotics and prosthetics and Other Medical Services
M codes — Other Medical Services
P codes — Pathology and laboratory services, and blood products
R codes — Diagnostic radiology services
V codes — Vision Services(e.g., lenses),audiology, and speech-language pathology

Temporary codes allow CMS the flexibility to establish codes that are needed to meet the national program operating needs of a particular insurer (i.e., Medicare, Medicaid, private insurance sector), before the next January 1 annual update or until consensus can be achieved on a permanent national code. They are developed based on programmatic needs and cannot be requested by other parties. The CMS HCPCS Workgroup has set aside the following sections of the HCPCS code set for temporary codes: Code categories are:

C codes — Items and services for hospital outpatient use, including pass-through devices, pass-through drugs and biologicals, brachytherapy sources, and new technology and certain other services.

G codes — Professional health care procedures and services that would otherwise be coded in CPT but for which there are no CPT codes.
H codes — Mental health services for which State Medicaid agencies are mandated by State law to establish separate codes.
K codes — Drugs, biologicals and other medical equipment or services not identified by national Level II codes, but for which codes are needed for Medicare claims processing.
Q codes — Temporary codes assigned by CMS
S codes — Temporary national codes assigned by private payers
T codes — Miscellaneous Codes

Temporary codes do not have established expiration dates and can be added, changed, or deleted on a quarterly basis. Once established, temporary codes for Medicare are usually implemented within 90 days, the time needed to prepare and issue policy and implementation instructions, enter the new code into the claims processing computer systems, and initiate user education.

Miscellaneous Codes

CMS states that "The absence of a specific code for a distinct category of products does not preclude a provider's or supplier's ability to submit claims to private or public insurers and does not affect patient access to products." Miscellaneous codes are available when there is no existing national code that adequately describes the item or service for billing and there is FDA marketing approval.

A miscellaneous code may be assigned by an insurer for use while a request for a new code is being considered under the HCPCS review process, permitting establishment of a claims history to support the need for a national permanent code.
Except for hospital outpatient claims, Medicare claims with miscellaneous codes are generally manually reviewed by the claims contractors. The provider must provide a clear description of the billed item or service, pricing information, and documentation to explain why the item or service is needed by the beneficiary.

In most cases, under the hospital outpatient prospective payment system (OPPS), unlisted procedure codes are assigned to the lowest level APC within the clinical category that includes the unlisted code. The assignment of an unlisted code to the lowest level APC in the clinical category in which the code falls provides a reasonable means for interim payment until such time as there is a code that specifically describes the services being performed and paid.

Requesting a Modification to the Level II HCPCS Code Set

The HCPCS coding review process is an ongoing, continuous process. Requests may be submitted at any time throughout the year. Requests that are received and complete by January 3 of the current year are considered for inclusion in the next annual update. Requests received or completed after January 3, and requests received earlier that require additional evaluation, are included in a later HCPCS review cycle.

PAYMENT CONSIDERATIONS

A payment analysis for the new technology should answer the questions:

- Which fee-for-service payment system(s) does the new technology fit into (e.g., hospital inpatient prospective payment system, physician fee schedule)?
- If the new technology warrants a new code, how will the payment amount be determined?
- Does Medicare's inpatient and outpatient prospective payment systems include provisions designed to provide an extra payment amount for certain new technologies?

Hospital Inpatient Prospective Payment System

As an incentive for hospitals to adopt new technologies during the period before their costs

are recognized in the DRG payments which are historically based, certain new medical services or technologies may be eligible for new technology add-on payments.

To qualify for add-on payments, a service or technology must be new, represent a substantial clinical improvement over predecessor technology, and be high cost relative to the DRG payment that would normally be paid. Since it can take two to three years for reflection of cost data in the calculation of the DRG weights, technologies generally are considered new for two to three years after they become available.

Applicants must submit a formal request including a full description of the clinical applications of the technology, the results of any clinical evaluations demonstrating that the new technology represents a substantial clinical improvement, and data to demonstrate that the technology meets a high cost threshold. While CMS will not generally accept a coverage determination request for a device or pharmaceutical that is not approved or cleared for marketing by the Food and Drug Administration (FDA), applicants may apply for a add-on payment several months prior to the technology's receipt of FDA approval.

The actual add-on payments are based on the cost to hospitals for the new technology. If the costs of the discharge exceed the full DRG payment, the additional payment amount equals the lesser of the following:

- 50 percent of the costs of the new medical service or technology; or
- 50 percent of the amount by which the total covered costs of the case

Hospital Outpatient Prospective Payment System (OPPS)

All items and services paid separately under the OPPS are assigned to payment groups called Ambulatory Payment Classifications (APCs), which are intended to group together items and services that are similar in

clinical characteristics and cost. APC relative payment weights are based on estimated cost. Under OPPS new technology can qualify for a New Technology APC or a Transitional Pass Through Payment.

New Technology APC

Assignment to a New Technology APC for procedures and diagnostic tests allows CMS to gather actual cost data about the service before it is placed in an APC with other clinically similar services. The predetermined New Technology APC payment is based on CMS's best estimated cost of the new service.

New Technology APCs provide payment for complete services or procedures that cannot be appropriately reported under an existing HCPCS code or combination of codes. To qualify for assignment to a New Technology APC, among other criteria, the service must not be adequately represented in the claims data being used for the most current annual OPPS payment update, and does not qualify for transitional pass-through payment.

Applications for a New Technology APC assignment can be submitted at any point in the year and are considered for inclusion in a quarterly update that is at least four months away from the date of submission.

Transitional Pass-Through Payments

Subject to any budget neutrality reduction, the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment for the device. The cost of similar devices, if any, which are identified in the procedural APC with which the pass-through device is associated, is then subtracted from the device's cost to determine the pass-through payment amount for the device.

Transitional pass-through payments for devices are based on categories of devices. CMS can create a new category of pass-through devices to include an item only if that item cannot be described by any current or previous pass-through device category. Applications for pass-through status can be submitted at any point in the year and are considered for inclusion in a quarterly update that is at least four months away from the date of submission. To qualify, an item must have costs that are not insignificant compared with APC payments that would otherwise be made, including the costs of similar items. Applications for new devices must also demonstrate a substantial clinical improvement in the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

Physician Fee Schedule (PFS)

Medicare pays for services furnished by physicians and many other non-physician practitioners under a payment system known as the Medicare Physician Fee Schedule (PFS).

The PFS includes payments for the professional services as well as the direct expenses (i.e., staff, equipment, and supplies) and office overhead expenses needed to perform a specific service (e.g., supplies, equipment, clinical and administrative staff). With new technologies, there may be cases where the additional physician time, effort and technical skill warrants an higher physician work component. Unfortunately, review of the RVUs is done every five years but there is opportunity for all specialties to participate and make recommendations.

Clinical Laboratory Services

Medicare pays for clinical diagnostic laboratory tests at the lesser of three amounts: the actual charge for the test submitted by the laboratory; the local fee schedule amount; or the national limitation amount (NLA). CMS calculates rates for new tests through an annual public notice and comment process.

Depending on the nature of a new test, CMS uses one of two bases to determine payment. The first basis, called cross-walking is comparing the new test to related test(s). The new test code is assigned the existing local fee schedule amount and the existing NLA for the related test. The second method, called gap-filling, is used when no comparable, existing test is available and allows each local MAC to set the payment. The public may request CMS to reevaluate its decision of whether a code should be priced by cross-walking or gap-filling.

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