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Chapter 18

Medicare Reimbursement for Drugs and Devices

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MEDICARE REIMBURSEMENT FOR DRUGS AND DEVICES

Coverage

There is no reimbursement without coverage. Medicare coverage issues are addressed separately in this Deskbook.

Coding

Unless a drug or device has a separate code associated with it, there is no separate payment for the item under Medicare. The following are the major coding categories used by the Medicare program:

A. ICD-9-CM Codes

These codes are part of an international classification system. ICD-9 codes consist of codes describing diagnoses, as well as codes describing procedures. The Centers for Medicare and Medicaid Services (CMS), which is the agency that administers the Medicare program, is the U.S. governmental agency responsible for overseeing changes to these codes. These codes are rarely used to describe the use of an individual drug or device.

B. CPT Codes

CPT codes are codes used to identify medical services and procedures. These codes are developed by the American Medical Association (AMA). AMA accepts applications from interested parties seeking a new code or a change to an existing code. CPT codes sometimes describe a procedure involving the use of a particular device. They do not, however, describe the particular drug or device itself. For instance, placement of a coronary stent is identified with CPT code 92980, which has as its description: “Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel.” This code describes the procedure. There is no CPT code to describe the coronary stent itself.

C. HCPCS Codes

HCPCS codes are codes developed by CMS to supplement AMA’s CPT codes. These codes are used to describe products, supplies, and services that are not identified by a CPT code. CMS is responsible for assigning new codes or modifying existing codes. CMS accepts applications from interested parties seeking a new code or a change to an existing code. HCPCS codes are often used to identify individual drugs or devices.

For instance, HCPCS code C1874 identifies: “Stent, coated/covered, with delivery system.”

Inpatient Reimbursement

A. Overview

Hospitals are paid a predetermined, prospective amount per discharge for all hospital admissions. Discharges are classified by a patient’s diagnoses and procedures into different groups, referred to as diagnosis-related groups (DRGs). Each DRG is assigned a weighting that indicates its relative cost as compared with all other DRGs. This weighting is used to calculate the payment rate for that DRG. The payment rate is all-inclusive, with no separate payment for individual items and services. Therefore, the use of a particular drug or device does not generally change the inpatient payment rate for a given type of case. Over time, however, changes in the technology employed in furnishing care for a given type of case could affect its payment rate. On an annual basis, CMS reviews data it has collected regarding the costs of the procedures in each of its DRGs and recalibrates the relative payment rates for the DRGs accordingly. The data used to recalibrate the weightings of the payment rates, however, are sometimes several years old. Therefore, if a newly launched drug or device increases the costs of a given procedure, it may take several years before those increased costs result in additional Medicare reimbursement for that procedure.

B. Special Cases

1. Inpatient new technology add-on payments

- a. Reimbursement amounts do not reflect the use of new technologies that increase costs for a number of years because of the lag in the data used by CMS in recalibrating its payment rate. This creates a disincentive to the diffusion of new technologies for Medicare beneficiaries. To counterbalance this disincentive, Congress has enacted statutory provisions that allow for additional payments for certain new technologies.
- b. An additional payment is available for a drug or device that represents a new technology when it is used in treating an inpatient and it meets the following criteria: (a) the technology represents a substantial improvement over existing technologies, (b) the technology has been available on the market for no more than three years, and (c) the costs of the technology are high relative to the payment rate applicable to the DRG with which the use of the technology is associated.
- c. The amount of the supplemental payment is equal to the lower of 50% of the costs of the new technology or 50% of the difference between the costs of a particular case and the DRG payment.
- d. ICD-9 codes are key to new technology add-on payments. CMS uses the ICD-9 codes to determine whether the costs of the technology are high relative to the applicable DRG payment rate. Hospitals must also report the ICD-9 code on their claim forms in order to get the extra payment.

Therefore, it is critical for a manufacturer that believes that its drug or device may qualify for inpatient new technology status to apply early for an ICD-9 code.

2. Outlier payments

- a. Outlier payments are additional payments made to hospitals when the costs of treating a particular patient are extraordinarily high, as compared with the costs of care for other cases assigned to the same DRG. Outlier payments are calculated by taking 80% of the difference between the costs of a case and the outlier threshold. The outlier threshold is composed of the DRG payment plus a fixed amount. The fixed amount in 2008 is \$22,185. In other words, if the costs of care exceed the payment rate by \$22,185, then an additional outlier payment is payable.
- b. If the costs of using a drug or device are significant when compared to the payment rate for a given DRG, the use of the drug or device may also result in an outlier payment.

3. Payment implications for noncovered uses of drugs and devices

- a. A drug or device may be experimental in nature, or it may be used for an off-label indication. In each case, coverage is limited (though not categorically excluded).
- b. Generally, there is a presumption that inpatient DRG payments are made only for covered care. The fact that noncovered services are also rendered does not ordinarily affect payment.
- c. However, if the receipt of noncovered services is the primary reason for the admission, or if the use of the noncovered drug or device changes the applicable DRG, payment may be denied in whole or in part.
- d. Outlier payments are also based on the costs of covered items and services. If a noncovered drug or device is particularly costly, and those costs are not even partially reimbursable through an outlier payment, there is a strong economic disincentive against use of that particular drug or device.

4. Defective devices

Reimbursement is reduced for certain procedures involving the implantation of a device when the implantation affects the DRG assignment. This reduction occurs if the hospital obtains the device at no charge, as would be the case if the defective device is under warranty, or if the hospital receives a partial credit on the device that exceeds 50% of the device's costs. Under such circumstances, an amount is subtracted from the DRG payment equal to the amount of the price reduction received by the hospital on the device, up to the full cost of the device.

Hospital Outpatient Reimbursement

A. Overview

Outpatient payment is paid on the basis of the ambulatory payment classification (APC) coding system. Each APC is composed of many component procedures that are identified with either a CPT code or a HCPCS code. Procedures generally are grouped into APCs such that they resemble each other clinically and in terms of resource use. The APC payment rate is intended to reflect the costs of all resources used in the delivery of the component procedures, including overhead, supplies, and equipment. Therefore, frequently, the use of a particular drug or device does not change the payment rate for a given procedure. Over time, however, changes in the technology employed in furnishing care for a given type of case could affect the payment rate applicable to that type of case. On an annual basis, CMS reviews data it has collected regarding the costs of the procedures in each of its APCs and recalibrates the relative payment rates for the APCs accordingly. The data used to recalibrate the weightings of the payment rates, however, are sometimes several years old. Therefore, if a newly launched drug or device increases the costs of a given procedure, it may take several years before those increased costs result in additional Medicare reimbursement for that procedure.

B. Outpatient Transitional Pass-Through Payments for New Technologies

1. To avoid the disincentives created by the delay in recognition of additional costs of a procedure due to new drugs or devices, special, supplemental pass-through payments are available for new drugs and devices.
2. For a new device to qualify for pass-through payment, it must meet the following criteria:
 - a. If applicable to the medical device at issue, FDA approval must be obtained.
 - b. The device must be found to be reasonable and necessary for the diagnosis or treatment of disease or injury or the improvement of functioning of a part of the body.
 - c. The device must (a) be integral to, and a subordinate part of, the service furnished; (b) be used with one patient only; (c) come into contact with human tissue; and (d) be surgically implanted or inserted, even if removed prior to the patient's release from the hospital.
 - d. The device cannot fall into certain exclusions, including an exclusion covering all capital equipment.
 - e. The device must be described by a CMS new-technology device category for which pass-through treatment has not yet expired, or the device must qualify for the creation of a new category because it represents a substantial improvement over existing technologies.
 - f. The costs of the device must not be insignificant in comparison to the applicable payment rate.

3. For a new drug, the only criterion that need be met is that the costs of the new drug are not insignificant in comparison to the applicable payment rate.
4. Pass-through payments are intended to approximate the incremental costs of a new technology. For devices, the cost of the device is determined, and from this amount is subtracted the amount of the applicable APC payment associated with devices. The cost of a device is hospital-specific. Therefore, the pass-through payment amount varies from hospital to hospital. For drugs, the payment amount in 2008 will be average sales price (ASP) plus 6% (the ASP methodology is described under “Physician Reimbursement” beginning on the bottom of this page). For both drugs and devices, the new technology pass-through payments are only available for two to three years.

C. Separately Payable Drugs

1. Besides new technology pass-through payments, there are also certain types of drugs for which separate payment is made, in addition to the payment for the related procedure. These categories include:
 - a. Drugs referred to as “specified covered outpatient drugs,” which include (i) drugs and biologicals that had pass-through status prior to December 31, 2002, but for which pass-through status has expired, and (ii) radiopharmaceuticals.
 - b. Drugs and biologicals for which the average cost per day exceeds \$60 (for 2008).
 - c. Drugs, biologicals, and radiopharmaceuticals with HCPCS codes, but without any historical claims data.
2. The payment rate for 2008 for these drugs is ASP plus 5%. The expected payment rate for 2009 will be ASP plus 3%. If, however, the drug is covered under one or more competitive acquisition contracts, then the payment rate is the average price for that drug under such contracts.
3. Other drugs are packaged into the cost of the applicable procedure, and are not separately payable.

D. Defective Devices

1. If a device is replaced at no cost or a full or partial credit of greater than 50% of the device cost is issued with respect to a replaced device, CMS reduces the amount of the APC payment. This reduction only applies when:
 - a. The pertinent APC always involves the implantation of a device.
 - b. The cost of the device is at least 40% of the payment rate of the APC.
 - c. The device is costly.

Physician Reimbursement

A. Overview

Physicians are paid on a per-procedure basis, as indicated using CPT codes. Each CPT code has a relative weighting from which the reimbursement amount can be derived. Each weighting on the physician fee schedule has three components:

1. A physician work component, reflecting the time and intensity of the physician services;
2. A practice expense component, reflecting the costs to the physician's practice of performing a procedure, such as office rent, equipment, and supplies; and
3. A malpractice expense component that represents the costs of the related malpractice insurance.

CMS periodically reevaluates the weightings associated with various codes to determine whether they continue to accurately reflect resource utilization. CMS consults with the AMA and other groups when undertaking a weighting reevaluation. Since a physician's costs of performing a service decrease when the service is performed in an institutional setting, such as a hospital, there are usually two weightings associated with each CPT code—one reflecting the costs of performing the procedure in the physician's office and one reflecting the costs of performing the procedure in an institution. Generally, when a physician performs a procedure in an institutional setting, only the institution is paid for any drugs or devices used in the procedure.

B. Payments for Drugs Furnished by Physicians

Drugs furnished by physicians in noninstitutional settings are reimbursable under one of two payment methodologies.

1. ASP methodology

- a. Payment under this methodology is based on the manufacturer's ASP. The manufacturer's ASP is calculated by totaling all of a manufacturer's sales to all purchasers in the United States. From this amount, price concessions are subtracted. Price concessions offered on a lagged basis must be calculated on a rolling average basis and subtracted from total sales. Once the total sales amount for a quarter is calculated, that amount must be divided by the number of units sold in that quarter to arrive at the manufacturer's ASP. This amount must be calculated for each national drug code (NDC) number.
 - (i) Certain sales, such as sales to specified branches of the federal government, state pharmaceutical assistance plans, and other entities, are excluded from the manufacturer's ASP calculation.
 - (ii) Sales at nominal prices, which are defined as less than 10% of average manufacturer price, are also excluded.
- b. Manufacturer's ASP is used to calculate the payment rate for both single

source drugs and multiple source drugs. Multiple source drugs are drugs that are therapeutically equivalent, pharmaceutically equivalent, and bioequivalent. Multiple-source drugs are also drugs that shared the same code on October 1, 2003. Single source drugs are drugs that are not multiple source drugs, and are sold pursuant to a new drug application approved by FDA. All biologicals are single source drugs.

- c. For single source drugs, the payment rate is equal to the weighted average of the manufacturer's ASP for all NDCs assigned to the drug's HCPCS code, plus 6%. For multiple source drugs, the payment rate is the weighted average of the manufacturer's ASP for all the drugs assigned to the same HCPCS code, plus 6%.
- d. Payments are made to the physician administering the drug.

2. Competitive acquisition program methodology

- a. Prices under the competitive acquisition program (CAP) are determined based on a median of bids submitted by CAP vendors. The bids are submitted once every three years.
- b. CAP vendors bid on all drugs within a specified category of drugs. The contents of each such category are determined by CMS, which identifies each drug within the category by its HCPCS code. A CAP vendor must bid on each code, but it does not have to include each product within the code. Therefore, if two competing products share a single HCPCS code, it is possible that only one of those two products would be offered through a particular CAP vendor. The intent is to foster competition that reduces the cost to the CAP vendor of similar drugs, which then reduces the CAP vendor's bid amount, and the price paid by Medicare.
 - (i) CAP vendors can only furnish drugs that are identified in their bids, except under special circumstances, such as the launch of a new drug that was not on the market when the bid was submitted.
- c. Payments are made to the CAP vendor for drugs sold under CAP.
- d. Physicians choose annually whether to participate in CAP or be reimbursed under the ASP methodology.
- e. There are many requirements relating to a CAP vendor's operations and its contract with CMS.

- C. Physicians do not receive separate payments for devices, even those used in the physician's office. However, the costs of using a device may affect the weighting for a particular procedure.

Part D Drug Benefit

- A. The Part D drug benefit is a prescription drug benefit administered by private prescription drug plans that are subject to federal regulation.

- B. Only certain drugs qualify as “Covered Part D Drugs.” A drug must be available only by prescription, and it must be approved by FDA and sold in the United States. Off-label uses of a drug are covered, provided that such use constitutes a “medically accepted indication,” i.e., such use is supported by citation in one of the specified drug compendia. Drugs are excluded if they would be excluded under Medicaid. For instance, certain lifestyle drugs are not covered under Medicaid or Part D. Also excluded are drugs covered under Medicare Part A or Medicare Part B. There is some confusion, however, as to how to determine whether Medicare Part B or Medicare Part D covers a drug under a number of different circumstances.
- C. Not all drugs that qualify for coverage are covered by an individual drug plan. Part D prescription drug plans (Part D PDPs) have great flexibility as to which drugs they include in their formulary. Part D PDPs, however, cannot discriminate against certain groups of Medicare beneficiaries in their formulary design, which includes the drug classification structure within their formularies. Part D PDPs fall within a safe harbor for formulary classification structures when they use the same classification system as the Model Guidelines developed by the United States Pharmacopeia. Once the structure is established, a Part D PDP must offer at least two drugs within a particular therapeutic class or category.
- D. The price for which a drug is sold to Part D PDPs is determined by negotiations between the Part D PDPs and pharmaceutical manufacturers. Prices negotiated by the Part D PDPs are made available to each Part D PDP’s respective enrollees.

Durable Medical Equipment (DME)

A. Overview

Many items regulated by FDA as devices qualify as DME under Medicare. To qualify as DME that is payable when used in the home, an item must possess the following characteristics:

1. It must be able to withstand repeated use.
2. It must be primarily and customarily used to serve a medical purpose (as opposed to one aimed at providing comfort to a patient).
3. The item must not be generally useful to an individual in the absence of an illness or injury.
4. The item is appropriate for use in the home.

B. Classification

There are many classes of DME, each with special payment terms and limitations. These classes include

1. Inexpensive or routinely purchased items.
2. Items requiring frequent and substantial servicing.
3. Certain customized items.

4. Oxygen and oxygen equipment.
5. Prosthetic and orthotic devices.
6. Capped rental items.
7. Transcutaneous electrical nerve stimulators.

C. Payment

Payment is on the basis of a fee schedule. When new DME becomes available on the market, CMS uses a “gap-filling” procedure to evaluate the appropriate amount to pay for the DME, based on precursor technology.

D. DME Competitive Bidding

Pursuant to the MMA, payment for DME is to transition from fee schedule payment to payment through competitive bidding. Congress’s intent is to increase quality and lower costs by relying on market forces.

1. Competitive bidding areas

Competitive bidding occurred in 10 of the largest metropolitan statistical areas (MSAs) in 2007, and will occur in 80 of the largest MSAs in 2009. Winners of the 2007 competitive bidding program have not yet been announced. After 2009, a national or regional competitive bidding area will be established to allow beneficiaries to obtain certain items through a mail order outlet.

2. Competitive bid items

Included in DME are items used in infusion and drugs and supplies used with DME, enteral nutrition and supplies, and off-the-shelf orthotics. Initially 10 categories of items have been chosen because CMS believes that they are of high cost or high volume. Other categories may be added over time. Categories are defined as a grouping of related items used to treat similar medical conditions. A supplier need not bid on each category, but a supplier’s bid must include a bid for each code within each category for which it has submitted a bid.

3. Basis of payment

- a. For items sold to beneficiaries who permanently reside in a competitive bidding area, there would be a single payment amount derived through the competitive bidding process. The beneficiary must, as a general rule, obtain all items from suppliers that are contract suppliers for that beneficiary’s area.
- b. With certain exceptions, such as DME furnished by physicians, payment can only be made for items furnished under a competitive bidding program to successful bidders.
- c. Bidders are chosen based on the size of the market, the capacity of the bidder, and the proposed prices submitted as part of the bid. CMS is to create a “composite bid” which will be a weighted bid that takes into account

the supplier's bid for each item, as well as the expected utilization for such item. Bidders are to be accepted if their composite bid is less than the "pivotal bid," which would be the last bid that would need to be accepted to ensure sufficient capacity in the market.

- d. Award of contracts
 - (i) All bidders must meet certain accreditation standards before a contract will be awarded.
 - (ii) Certification regarding absence of any sanctions of key employees and officers is required.
 - (iii) Certain financial standards need to be met.
 - (iv) Wherever possible, CMS is to seek at least five bidders. At a minimum, CMS is to always accept at least two bidders, if there are two bidders.
- e. Determination of competitive bidding payment amounts
 - (i) All bids are to be used in setting the single payment amount.
 - (ii) The payment amount cannot exceed the amount that would have been paid under the DME fee schedule.
 - (iii) The amount per item would be the median bid of all successful bidders.

4. Physician authorization

Where medically necessary, physicians will be allowed to specify that a particular item of a stated brand is to be furnished to a beneficiary. Suppliers would be required to ensure that beneficiaries receive this particular item.

5. Changes in HCPCS in the middle of a bidding cycle

- a. If a single HCPCS code is broken down into two or more HCPCS codes, representing individual components of the original item, then in total the components must have a payment amount no more than the payment amount for the original HCPCS code.
- b. If items which previously grouped to one HCPCS code are separated into different HCPCS codes, then the payment rate for each such item shall be the same payment rate as the one applicable to the original HCPCS code.
- c. If multiple components of an item are merged into an item that is represented by a single HCPCS code, then the payment rate shall be the total of the payment rates previously applicable to the components.
- d. If multiple HCPCS codes for similar items are merged together into a single HCPCS code, then the payment rate will be governed by the Medicare fee schedule, and any supplier enrolled in Medicare can furnish the items represented by such an HCPCS code.