
Medication Rx Coverage: The A, B, C, and Ds

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The Medicare Part D program is not the first coverage of medications by Medicare. It simply extends the coverage that has been available in various settings to now include most outpatient medications. Since Medicare began in 1965, the program has provided medication coverage in acute settings under Medicare Part A and within physicians' offices under Medicare Part B. Now, with the implementation of Medicare Part D, coverage has been extended to cover prescription drugs in outpatient settings. Exactly what, if any, coverage is available is critical to knowing which treatment option has the best opportunity for being filled secondary to convenience and lowered out-of-pocket expenditures. Knowing the payor and coverage is essential to gaining access to medically necessary therapy. Without this understanding, physicians and patients will be subject to frustration, inappropriate treatment, or no treatment at all. Additionally, patients may be subject to unnecessarily high copayments.

Medicare Part A

Medicare Part A is commonly referred to as hospital insurance. Most beneficiaries receive Medicare Part A without paying any premium as a result of prepaying for this benefit through payroll taxes during their working years. Beneficiaries are automatically enrolled in Medicare Part A on their 65th birthday. This insurance helps pay for inpatient care in hospitals, including critical access hospitals and skilled nursing facilities, but not custodial or long-term care facilities. Medicare Part A also helps cover hospice care and some home health care services (Table 1).¹

Acute care hospitals, skilled nursing facilities, and hospice programs are responsible for the medications utilized during patients' stays within each setting. Each fa-

cility receives a capitated payment, which includes the cost of medications. As a result, each facility commonly has a formulary that controls the medications used. Hospice programs are responsible only for the medications that are required to manage the hospice diagnosis.

Because a patient moving from these facilities to a community or other setting is likely to encounter a different formulary, the possibility exists for a need to change med-

ications. To maintain continuity of medication access, the Centers for Medicare and Medicaid Services (CMS) has outlined a transition period as patients move from one level of care to another. This transition period allows for the continued use of the medication(s) started under Medicare Part A coverage, even though the particular medication(s) may not be on the formulary of the patient's Medicare Part D plan. It is important to note that the transition period is limited to a one-time refill for those transferring to a community setting and to a 90- to 180-day supply for those transitioning to a long-term care facility. Thus, the change to a formulary medication is ultimately required for those medications utilized during the transition period. Pharmacy and Therapeutic (P&T) Committees and those involved in caring for patients in these settings would benefit from an understanding of these regulations so that transitioning from levels of care can be accomplished with the least disruption to patients' care plans.

Table 1.
Facilities Providing Medicare Part A Drug Coverage¹

- Acute care facility;
- Nursing facility during the skilled nursing stay, which cannot exceed 100 days; and
- Hospice programs (only medications required to manage the hospice diagnosis).

Medicare Part B (medical insurance) helps cover doctors' services and outpatient care.

Medicare Part B

Known as medical insurance, Medicare Part B requires patients to opt out if they do not wish to be enrolled; however, 92% choose to maintain coverage. Currently, Medicare Part B carries a monthly premium of \$88.50 per month, which is an increase from \$78.20 per month in 2005. Medicare Part B helps cover doctors' services and outpatient care. It also covers other medical services that Part A doesn't cover, such as some of the services of physical and occupational therapists and certain home health care services and supplies when they are medically necessary. In addition, Medicare Part B provides coverage for injectable medications available in physicians' offices.

With regard to medication coverage under Medicare Part B, with the introduction of Medicare Part D coverage through prescription drug plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) plans, there are incentives to shift medication coverage to other plans. For example, PDPs are at risk only for medications; thus, their incentive is to shift medications from Part D to Part B coverage, where coverage is provided by Medicare rather than the plan. Similarly, because MA-PD plans are at risk for Medicare Part A, B, and D expenditures, they have an incentive to move medications from Part B to Part D coverage. This is the result of CMS providing reinsurance to plans' high expenditures on the Part D side, as opposed to plans being responsible for all expenses on the Part B side.

Given that CMS is able to capitate the payment to plans for Medicare Part D, providers should

expect a movement of more medications from Medicare Part B to Medicare Part D coverage. A step in that direction is to continue to remove incentives from physicians for dispensing Part B medications. This initially occurred with a movement from reimbursement determined using the average wholesale price (AWP) to that utilizing the average sales price (ASP) and to yet another new system called CAP, or Competitive Acquisition Program.

In most cases, CAP should be less burdensome than the current system. The new program allows physicians to obtain many cancer drugs and other office-administered medications from one of several vendors selected by the government. It is a voluntary program, which was set to begin January 1, 2006 under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (commonly referred to as the Medicare Modernization Act, or the MMA), but has been put on hold for at least 6 months. Participating practices no longer will be required to pay for these drugs upfront and seek subsequent reimbursement from Medicare and patients. Practices will order all of their needed drugs within the eligible categories from 1 of the 5 lowest bidders competing for Medicare's business

in their region of the country. Drug vendors will be responsible for billing Medicare for the costs of the medications and the patients for any coinsurance or deductibles that apply.

Oncologists will be particularly affected by the new CAP system. CMS anticipates that the competitive bidding process will save money for both the federal government and Medicare beneficiaries. The success of CAP hinges on attracting enough doctors to the program with the promise of reducing current reimbursement and administrative hassles. Some doctors have complained that the need to find lower prices on the open market and seek a portion of the reimbursements from their patients drains substantial time and resources from their practices. However, physicians will continue to bill Medicare directly for the costs of actually administering the medications. Under the proposed rule, vendors will not be able to receive full payment for the prescribed drugs until the physician submits his or her drug administration claims. The receiving physician must record and subsequently report these numbers to Medicare when filing for reimbursement for administering a medication.

Doctors who participate in CAP also give up the opportunity to capture any federal payments for Medicare Part B drugs that exceed the actual purchase costs of the medications. Medicare traditionally has reimbursed oncologists and other doctors more for the drugs than the physicians pay for them, though this coverage has been scaled down significantly. Any added money on the drug

cost side is used to offset underpayments on the drug administration side. Practices will need to determine if the added benefit of offloading the work required to navigate the current reimbursement system is enough to forgo the added federal funds that they might receive after paying for the drugs on the open market. Medicare currently reimburses for drug purchases at 106% of the ASP offered by manufacturers. Participating in the new program will not affect the amount of the drug administration reimbursements that physicians receive.

The recent changes to the drug payment formula reduce the chances that physicians remaining in the current system can expect significant positive margins on the drug purchase side of the equation. Larger practices that administer a significant volume of drugs, however, could face a more complicated financial decision when they decide to sign up for CAP during the fall enrollment period. If a physician practice chooses to participate, it will not be able to leave the program or use another vendor until the next year. In addition, physicians can be barred from the program if they fail to submit necessary drug administration claims on a timely basis.

CMS is seeking public comments on the proposed rule until April 26, 2006. The agency is asking for physician input on such questions as whether to phase in the program for certain specialties or drugs, and how many competitive regions to establish.

Based upon the definition of the term “Part D drug” and the general categories of coverage under

Medicare currently reimburses for drug purchases at 106% of the ASP offered by manufacturers.

Part B (Table 2), CMS believes that Part D plans could implement utilization management strategies to identify potential Part B drug coverage overlap for individual beneficiaries and verify appropriate coverage accordingly. For example, if a Part D beneficiary is filling a retail prescription for an antiemetic, prior authorization could be used to ensure that the drug is not covered by Part B. Similarly, prior authorization could be

used to flag drugs dispensed via home infusion that are covered under the Part B durable medical equipment (DME) policy. Plans will need to ensure that they do not cover any drugs that as prescribed, dispensed, or administered are covered under Medicare Part B in a specific region under its local medical review policy (LMRP).

Unfortunately, Medicare Part B coverage is available for medications administered only in a physician’s office and billed incident to the physician visit. Since these same medications administered in a nursing facility cannot be billed incident to a physician office visit, they are instead covered by Medicare Part D.

Drugs furnished “incident to” a physician’s service are injectable or intravenous (IV) drugs that are
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Table 2.
Medicare Part B Coverage¹

- Drugs that require administration via DME (eg, inhalation drugs, IV drugs “requiring” a pump for infusion, and insulin via infusion pump).
- Blood glucose testing strips and lancets.
- Oral drugs used for cancer treatment that contain the same active ingredient as injectable dosage forms that would be covered as:
 - Not usually self-administered, and
 - Provided incident to a physician’s service.
- Oral antiemetic drugs used as full therapeutic replacements for IV antiemetic drugs within 48 hours of chemotherapy.
- Erythropoietin (EPO) treatment for anemia in patients with chronic renal failure who are undergoing dialysis.
- Influenza, pneumococcal, and hepatitis B prophylactic vaccines (for intermediate- to high-risk beneficiaries).
- Parenteral nutrition for individuals with “permanent” dysfunction of the digestive tract. The physician must determine that the impairment will be of indefinite duration.
- Medicare-covered transplant drugs used as immunosuppressive therapy for beneficiaries who underwent organ transplantation at a Medicare-approved facility and who were entitled to Medicare Part A at the time of the transplant.

¹DME=durable medical equipment; IV=intravenous.

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administered predominantly by a physician or under a physician's direct supervision as "incident to" a physician's professional service. The statute limits coverage to drugs that usually are not self-administered. If a drug is not self-administered by more than 50% of Medicare beneficiaries, it is considered "not usually self-administered." Sumatriptan succinate injection (Imitrex[®]) and insulin are considered to be self-administered.

Medicare Part C

Medicare Part C received an overhaul as the result of the MMA, including increased reimbursement, a mandate to include pharmacy benefits, and capitated payments based on the Hierarchical Conditions Categories (HCC) Reimbursement System. These changes, plus a renaming of Medicare + Choice to Medicare Advantage, are an attempt to increase enrollment in these plans. At a minimum, coverage by Medicare Advantage (MA) plans must include all coverage available through Medicare Parts A, B, and D (Table 3).

Medicare Part D

Medicare Part D is the outpatient prescription drug coverage benefit that started on January 1, 2006. Most people will pay an average monthly premium of \$32.20 per month for this coverage. Basically, this program is open to all Medicare beneficiaries, providing them with lower prescription drug costs and helping to protect against higher drug costs in the future. Medicare prescription drug cover-

Table 3.

Medicare Part C Coverage²

- Renamed from Medicare Managed Care plans to Medicare Advantage (MA) plans.
- MA plans are responsible for all benefits available under Medicare Parts A and B.
- MA plans provide coverage under a capitated funding system.

Table 4.

Medicare Part D Coverage¹

- Drugs that require administration via DME (eg, inhalation drugs, IV drugs requiring a pump for infusion, and insulin via infusion pump when administered outside the physician's office, such as a nursing facility).
- Self-administered injectables.
- Insulin and medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze. Note that blood sugar test strips are covered under Medicare Part B.
- Oral drugs used for cancer treatment that do not contain the same active ingredient as injectable dosage forms.

age needs to be thought of as "insurance" rather than a "benefit" provided by private companies. Beneficiaries choose the drug plan and pay a monthly premium. Like other insurance, if a beneficiary decides not to enroll in a drug plan when they are first eligible, they may pay a penalty if they choose to join after the open enrollment deadline of May 15, 2006, as well as being locked out of Medicare Part D coverage until the next open enrollment period. This late enrollment penalty and lock out are the principle drawbacks of not participating in Medicare Part D.

PDPs are at risk only for prescription drugs (Table 4), whereas MA-PDs are at risk for all Medicare-covered services. Incentives result in issues similar to those related to excluded medications, namely, restricting access to medications. For instance, because PDPs are not at financial risk for hospitalizations

and related services, they have a disincentive to provide coverage for expensive medications, even when they effectively reduce even more costly hospitalizations. An example is the coverage of low-molecular-weight heparins (LMWHs). A PDP has no incentive to provide coverage for this relatively expensive medication, despite its value in often eliminating the need for other costly treatments and extended hospitalizations. Even if PDPs weighed the broad cost benefits of specific medications, they still have no incentives to provide coverage for Part D-excluded medications because such products won't be covered by Medicare Part D.

Protected Classes

To ensure access to a broader list of medications than would be provided under a strict interruption of MMA's formulary requirement of at least 2 medications from each

Table 5.

Protected Drug Classes Under Medicare Part D¹

CMS expects that best-practice formularies will contain all or substantially all drugs within the following therapeutic classes:

- Antidepressants,
- Antipsychotics,
- Anticonvulsants,
- Antiretrovirals,
- Immunosuppressants, and
- Antineoplastics.

Table 6.

Excluded Medications Under Medicare Part D¹

With the exception of smoking cessation agents, medications restricted from Medicare Part D coverage based on their class and use include:

- Agents used for anorexia, weight loss, or weight gain;
- Agents used to promote fertility;
- Agents used for cosmetic purposes or hair growth;
- Agents used for the symptomatic relief of cough and colds;
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations;
- Nonprescription drugs;
- Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale;
- Barbiturates; and
- Benzodiazepines.

approved category and class (unless only 1 drug was available) and at least 1 drug in each of the *Formulary Key Drug Types* identified by the US Pharmacopeia (USP), CMS added several principles that plans had to meet. One of those principles was based on the fact that in certain classes, CMS considers there to be less of a class effect, meaning that the medications within that class are less interchangeable because of certain unique characteristics. As a result, if a patient was controlled on a medication in 1 of these classes, he or she could continue on that medication because changing could result in an adverse event.

Therefore, substantially all medications available prior to December 31, 2005 listed in the therapeutic classes above should be available for prescribing (Table 5).

Excluded Medications

Not all prescription drugs are covered under Medicare Part D. Specific medications that the Medicare Part D legislation excludes from coverage are listed in Table 6.

So who will pay for these excluded drugs in the case of the dually eligible beneficiary? Although these medications are excluded from basic Part D coverage, PDPs can choose to provide them as part of

supplemental benefits to the extent that they otherwise meet the definition of a Part D drug. Because nonprescription drugs are not considered Part D drugs, they cannot be included as a supplemental benefit. However, under certain conditions (eg, as part of plan utilization management [step-therapy] programs), nonprescription drugs can be provided at no cost to enrollees. The costs of these drugs would be treated as administrative costs under such programs. Some PDPs have chosen to cover these medications using non-Medicare Part D funds. While all states will cover some or all benzodiazepines and barbiturates for dual eligibles, Texas and Tennessee are the exceptions.³

However, PDPs are highly unlikely to offer medications for which there is no coverage available, such as the excluded medications. On the other hand, MA-PDs may cover excluded medications from a source of funds other than Medicare Part D. MA-PDs may choose to cover excluded medications because they find this approach less costly overall. This strategy currently is used by several State Medicaid programs that cover nonprescription proton pump inhibitors at a significant savings over their prescription counterparts.

If the states do not add coverage for excluded medications, those products will be unavailable to dually eligible seniors unless they are willing to pay privately. To illustrate this problem, consider a dually eligible skilled nursing facility resident who has been receiving a benzodiazepine to control anxiety for many years. He or she will be forced to pay out-of-pocket or have their physician substitute a covered

medication for their current treatment. Sometimes, these substitutions can be made successfully without incident. In many cases, however, they may result in complications associated with the sudden discontinuation of a medication or an inappropriate substitution. The costs associated with the exclusion of these medications could be significant in human, as well as financial terms, since low-cost generics are available for most of the excluded medications, whereas their covered counterparts tend to be high-cost brand name medications.

At the same time, the impact of the excluded medications on long-term care facilities and the pharmacists who serve them will be significant. By law, long-term care facilities must ensure that residents receive all necessary medications in a timely manner and that they must not receive unnecessary drugs or be subject to medication errors. Because a resident is unable to pay for a medication is not an acceptable excuse for the physician not to order it or the facility not to administer it.

In addition, these expenses do not count toward a beneficiary's true out-of-pocket (TrOOP) expenditures. Each beneficiary must spend \$3600 out of pocket to qualify for the catastrophic benefit, where the beneficiary is limited to out-of-pocket expenditures of 5%.⁴ Payment for any excluded Medicare Part D medications, such as non-prescription drugs or vitamins, is exclusive of TrOOP expenditures.

Benzodiazepines and Barbiturates

The exclusion of benzodiazepines and barbiturates is of particular

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concern because these medications are frequently used in elderly populations. In 2000 alone, approximately 10% of nursing home residents received anxiolytics, most commonly benzodiazepines.⁵ Since then, studies have found that this use has increased. Overall, benzodiazepines are the 13th leading class of medications in the United States, with 71 million prescriptions dispensed in 2002 alone.⁵

It is worth noting here that barbiturates and long-acting benzodiazepines are among the medications listed as potentially inappropriate for use in those aged 65 and older by the Beers' Criteria,⁶ which were adopted into the CMS Guidelines for Potentially Inappropriate Medications in the Elderly. With regards to benzodiazepines, this warning is based in part on data suggesting an association between benzodiazepine use and hip fractures in the elderly. Most recently, a study published in the *Archives of Internal Medicine* showed that contrary to the findings of several previous studies, short half-life benzodiazepines were not safer than those with a longer half-life.⁵

Medications Used for Weight-related Disorders

Unintended weight loss is a life-

threatening condition, particularly in the frail elderly. Residents suffering from involuntary weight loss may suffer a significant decline in health and function, resulting in a higher risk for infection, depression, and death.⁷ Approximately 13% of ambulatory older residents and 50% to 60% of nursing home residents suffer from involuntary weight loss. Lack of coverage for medications used for weight-related disorders has the potential to adversely impact nursing home residents and facilities. Given that weight loss is a quality measure, nursing homes are under pressure to treat this condition with whatever means possible.

If left untreated, unintended weight loss can result in serious side effects for the patient. Some of the consequences of unintended weight loss include infections, falls, hip fractures, immune dysfunction, anemia, decreased cognition, muscle loss, osteoporosis, and pressure sores. This is a major concern for nursing home administrators and medical directors since unintended weight loss is both a CMS skilled nursing facility quality indicator and quality measure, and these excluded medications have been associated with some levels of success in improving weight gain in seniors.

Other Medication Access Issues

Another problem that will affect access to medications is that plans are not obligated to provide coverage for off-label use of a drug. For example, many of the medications used to promote weight gain are utilized off label. As a result, plans could require prior authorization, making it nearly impossible to

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Part D funds cannot be used to cover nonprescription drugs and vitamins.

gain access to these medications for seniors who would benefit from their use.

Another difficulty associated with the use of many weight-related medications is the fact that Medicare Part D drugs are limited to those drugs that are utilized for a medically accepted indication, as defined in the Medicaid statute. The definition includes uses supported by a citation in 1 of the 4 compendia:

- American Hospital Formulary Service Drug Information,
- United States Pharmacopeia Drug Information,
- DRUGDEX Information System, and
- American Medical Association Drug Evaluation.

Indications that are supported in peer-reviewed medical literature, but not yet reflected in any of the compendia, are not “medically accepted,” as considered by CMS. As a result, Part D drugs do not include medications utilized for off-label uses, with many weight-related medications being excluded from coverage by PDPs.

Nonprescription Drugs and Vitamins

Also of concern is the fact that in some states, Medicaid covers all medications, including nonprescription drugs and vitamins. Under the MMA, however, Medicare Part D funds cannot be used to cover these medications. CMS hopes that states will continue to provide coverage to the dually eligible; however the non-dually eligible nursing home resident will be forced to pay out-of-pocket for these medications. States that do provide coverage for these exclud-

ed medications can still receive matching federal funds, but this coverage in no way reduces the states’ clawback amount or phased-down contribution. This is the amount that each state must pay the federal government for medication coverage for the dually eligibles. The amount is based on the number of dually eligible beneficiaries enrolled in Medicare Part D multiplied by what the state paid for coverage for these individuals in 2003 and then multiplied by 90%. This amount will be phased down to 75% by 2013.

Many nonprescription drugs are needed to work in synergy with prescription drugs and are essential for elderly residents. In many cases, nonprescription drugs are included in clinical practice guidelines. Some examples include iron supplements with erythropoietic agents, and calcium and vitamin D with osteoporosis therapies. Other nonprescription drugs, such as acetaminophen, are considered first-line therapy for the treatment of mild-to-moderate musculoskeletal pain in the elderly.⁸ Niacin extended-release tablets (Niaspan®) are an example of another product caught in this non-Medicare Part D definition. Despite its usefulness in the treatment of hyperlipidemia, it is not available for coverage under Medicare Part D because it is considered to be a vitamin.

In addition to their use as part of clinical practice guidelines, nonprescription drugs are used as cost-effective treatments. Such is the case with proton pump inhibitors currently covered by state Medicaid programs. The most recent trend in coverage for Medicaid residents is the transition to omeprazole (Prilosec-OTC™) from prescription proton pump inhibitors. Eight states (Florida, Illinois, Indiana, Kansas, Kentucky, Missouri, North Carolina, and Wisconsin) provide Medicaid coverage for this nonprescription drug because of its lower cost. The potential loss of this coverage with the implementation of Medicare Part D will lead to increased costs.

In the cases where the need for nonprescription drugs results in out-of-pocket costs, Medicare recipients are likely to request the physician to prescribe a more expensive covered medication at an additional cost to the program. One such example is the case where a physician recommends a nonprescription NSAID for a patient, but due to its Medicare Part D exclusion, he or she writes a prescription for a more costly COX-2 inhibitor so that the patient incurs no out-of-pocket expenses or a more limited copayment.

Help?

Given the level of complexity of Medicare Parts A, B, C, and D, how is a prescriber to know what and when certain medications are covered? Obviously, the first step is to understand the different parts of the Medicare program. Additional information on these

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Take-Away Message

- Medicare Part A provides coverage for medications through the provider, such as the hospital, hospice program, and nursing home for the subacute stay.
- Medicare Part B provides coverage for medications utilized “incident to” a physician visit, such as injectables provided in an office setting.
- Medicare Part C covers the services provided by Medicare managed care plans.
- Medicare Part D provides insurance for outpatient medications through private prescription plans.

ROI

- Knowledge about coverage is essential to ensure that patients are able to receive their medications, resulting in improved outcomes, which will affect pay-for-performance measures.
- The Competitive Acquisition Program (CAP) may present an opportunity for practices to administer medications in their office setting without the responsibility of purchasing those medications, thus opening an opportunity for additional services.
- By utilizing www.epocrates.com and developing “cheat sheets” of available medications, prescriptions can be written within the scope of the prescription plans, thus reducing phone calls for changes and authorization.

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programs is available by calling 1-800-MEDICARE and visiting the CMS Web site at www.Medicare.gov, which features the *Medicare & You* handbook. Besides knowing the basics, it is helpful for prescribers to write within the scope of coverage offered by having tools available at the bedside. These tools can include those offered free of charge at the Epocrates.com Web site, as well as one’s own developed “cheat sheets,” offering guidance on what the most common plans cover within high-use drug classes.

Through understanding the individual components of the Medicare program and having tools available to ensure that prescriptions are written within the scope of each part of the program and plan, patients can optimize their access to the medications that they need. This greater access can directly contribute to improved outcomes at reduced costs for patients and health care facilities. **MPM**

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