Medicare Part D: Coverage of Drugs under Part B versus Part D

The Part D outpatient drug benefit enacted as part of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (P.L. 108-73) is providing necessary medications to millions of Americans. However, with respect to questions as to whether a particular drug will be covered under the Part D benefit or under Medicare’s Part B program, provisions in MMA have created confusion and uncertainty that has confounded beneficiaries, plan sponsors and providers, and placed some of these entities in legal peril. Because of this uncertainty, delays in coverage adjudication may place beneficiary health in jeopardy. The Academy of Managed Care Pharmacy (AMCP) recommends specific legislative action to reduce this confusion and uncertainty.

Coverage under Part B

The traditional Medicare benefit, designed in the 1960s, did not provide beneficiaries with coverage for prescription drugs, except within a narrowly defined framework under Medicare Part B. Under the Part B program, drug coverage is generally provided for medications administered by a health care professional in a physician’s office, as part of a sustained clinical treatment such as chemotherapy, or for other specified drugs that cannot be patient self-administered, such as vaccines. For the most part, payments for these drugs are made directly to the entity that has purchased and administered them, for example, doctors, hospitals, nursing homes or clinics. As a rule, the specific outpatient drugs and treatments that have always been covered under Part B continue to be covered under this benefit.1

Coverage under Part D

The Medicare Part D benefit was designed to provide coverage for outpatient prescription drugs. These drugs are ordinarily patient self-administered (e.g., tablets, capsules, creams and liquids), and are used for a broad array of common diseases and treatments. In the legislative language describing this new benefit, the drugs that had been included under Part B of the Medicare benefit were specifically excluded. Section 1860D-2(e)(2) of PL 108-173 states:

(B) MEDICARE COVERED DRUGS.—A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is
available (or would be available but for the application of a deductible) under part A or B for that individual.

**Overlapping Coverage Determinations**

Unfortunately, what may appear to be a clear distinction from the above descriptions of Part B and Part D coverage is not. Some categories of drugs covered under Part D continue, in some circumstances, to be covered under Part B in a variety of settings, under a variety of payment methodologies and in varying clinical situations. Many of these drugs may now be covered under either Part B or Part D. Drug classes where uncertainty as to which Medicare program provides coverage include, but are not limited to:

- Drugs requiring the use of durable medical equipment (DME)\(^1\)
- Drugs furnished “incident to” a physician service
- Immunosuppressant drugs\(^2\)
- Oral anti-cancer drugs
- Oral anti-emetic drugs\(^3\)
- Erythropoietin (EPO)\(^4\)
- Prophylactic vaccines
- Parenteral nutrition\(^5\)

**Resulting Administrative Confusion**

Drugs in the above categories can be covered under Part B or Part D depending on the beneficiary’s diagnosis, the site of service, and/or the medical use of the drugs. Frequently, it is not discernible at the point of sale in the pharmacy whether a drug will be covered under Part B or Part D, which creates significant challenges for Medicare Part D plans, pharmacies, prescribers and beneficiaries.

To ensure that Part D plans pay only for Part D covered drugs and not for drugs covered under Part B, additional information must be obtained. Part D plans that mistakenly submit cost data for Part B covered drugs as part of their Part D prescription drug event (PDE) data submission to the Centers for Medicare & Medicaid Services (CMS) can be charged with fraud and forced to pay significant penalties. More troubling, annoyed and confused (and presumably ill)

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\(^1\) Drugs that require administration via covered DME – for example, inhalation drugs, insulin via infusion pump, blood glucose testing strips and lancets.

\(^2\) A medication that suppresses normal immune response. These are used both to control autoimmune diseases (rheumatoid arthritis) and to decrease the chance of rejection of transplanted tissues and organs.

\(^3\) Medication that prevents or relieves nausea and vomiting.

\(^4\) A hormone that regulates red blood cell production. Erythropoietin is available as a therapeutic agent produced by recombinant DNA technology. It is used in treating anemia resulting from chronic kidney failure or from cancer chemotherapy.

\(^5\) Providing caloric needs intravenously (IV) for a patient who is unable to take nutrition orally.
beneficiaries can be kept waiting for necessary medications while wrangling over Part B/Part D determination takes place.

CMS instructs Part D plans to rely on prescriber information included with a prescription, such as a diagnosis. According to CMS, Part D plans may consider information written on a prescription and relayed by the dispensing pharmacist to the same extent as they rely on similar information acquired from prescribers on a prior authorization form.\(^6\) However, as more fully described under *Diagnosis as a Part B/Part D Determinant* below, diagnoses are not typically included on a prescription; therefore the required information is not generally available.

Yet Part D plans have been instructed to rely on pharmacists’ reporting of appropriate information to make coverage decisions under Part D. This guidance from CMS could potentially provide Part D plans with a reasonable process to demonstrate due diligence. However, it is unclear as to whether this guidance provides protection from the risk of fraud allegations, and it does not solve the underlying confusion. In many instances, the Part D plan must contact the prescriber or dispensing pharmacist to obtain defining information. This step creates not only an administrative burden; it also adds frustration, cost and bureaucracy to the process, and the potential for delay in the delivery of care to the beneficiary.

In limited instances, this information can be communicated electronically at the point of sale by the pharmacist during the claims adjudication process, if the appropriate information is included by the prescriber on the prescription. But even with automated processing of some Part B versus Part D drug claims, it is difficult for beneficiaries to understand why some drugs are covered (or not covered) under their Part D benefit in different circumstances. These delays in decisions cause beneficiary disruption, consternation and dissatisfaction.

During the Medicare Part D implementation process, CMS published a reference table for the most frequent Part B/Part D coverage determination scenarios facing Part D plans and pharmacies *(Appendix A)*. However, administration of the benefit requires very specific details, such as indication (condition for which the drug is being prescribed) or location of administration. There are coverage rules for most situations that require case-by-case patient-specific definitive information in order to be applied. As described elsewhere in this paper, attempting to obtain such precise, verifiable information in order to adjudicate the coverage decision not only makes this process administratively burdensome, it drives up cost, and can seriously delay treatment.

The following are just a few of the many examples of a benefit that is extremely difficult to administer for certain medications:

• Immunosuppressant medications are covered under Part B for a beneficiary who receives a transplant from a Medicare-approved facility, and who is entitled to Medicare Part A benefits at the time of transplant. If these conditions are not met, or if a drug is used for purposes other than immunosuppression, the drug must be covered under Part D.

• There are different rules for different vaccines: Influenza and pneumococcal vaccines are always covered under Part B. Vaccines administered directly related to the treatment of an injury or direct exposure to a disease are also always covered under Part B. Hepatitis B vaccines are covered under Part B for intermediate to high-risk patients and under Part D for low-risk patients. All other vaccines are covered under Part D.7

• Oral anti-emetic medications are covered under Part B when given within 48 hours of chemotherapy and as a full replacement for IV anti-emetic therapy, and under Part D in all other situations. This requires the Part D plan to determine precisely at what time chemotherapy took place and if the oral anti-emetic prescription is limited to 48 hours post-chemotherapy.

• Oral anti-cancer drugs in which there is an infusible form of the drug are covered by Part B for the treatment of cancer. However, one of these drugs, methotrexate, is also used for the treatment of rheumatoid arthritis. If a patient has received a prescription for methotrexate, a Part D plan must determine if the patient is being treated for rheumatoid arthritis before it can be reimbursed under the Part D benefit.

The Academy’s primary concerns are as follows:

Risks for Beneficiaries

The difficulties imposed and the delays occasioned by the confusion over Part B versus Part D determinations can create situations where beneficiaries cannot obtain needed medications in a timely or safe fashion. If a patient is instructed to obtain medication at a pharmacy using their Part D benefit and transport it to the physician’s office for administration, the physician is forced to make judgments regarding the length of time the medication has been in transit; whether it has been kept away from heat, cold or humidity as required; or if the medication has been tampered with in any way. Delays or confusion in obtaining critically needed medications in scenarios such as this can result in further complications to a beneficiary’s medical condition.

Imposing Artificial Requirements for Prior Authorization

Determining whether a medication is covered under Part B or Part D consumes resources without adding value. The complexities of Part B/Part D coverage determinations demand that

cumbersome, expensive prior authorization processes be implemented. [Prior authorization is the process by which plans would obtain the necessary type of information needed to make coverage determinations.] Each time the prescription processing activity is stopped because additional information is needed, dispensing is delayed, care is disrupted and plan and pharmacy costs increase. As costs to Part D plans and pharmacies increase, those costs will eventually translate into higher Part D premiums to be paid by both the beneficiary and the federal government.

**Drug-Specific Definition versus Method of Delivery Determination**

Part B/Part D coverage determination problems would be greatly mitigated by defining the Part B or Part D status at a drug-specific level rather than introducing the circumstances of delivery (e.g., oral versus injectable). To best serve beneficiaries, these prescriptions must be adjudicated at the pharmacy in a matter of seconds, in line with current prescription claims processing industry standards. A clear definition of these categories, with each drug being covered by only one method, would significantly improve operational efficiencies.

**Site Determination**

A Part B/Part D coverage determination based upon the specific site of the delivery of the drug (e.g., physician’s office), the patient’s diagnosis or the route (oral versus infusion) or timing of administration is inherently confusing. Such determinations by Part D plans can be very challenging to operationalize. This becomes even more complex when considering the special coverage rules for drugs administered in long term care facilities. Several of the medications caught in the Part B/Part D overlap are medications for which the overhead cost associated with processing a prior authorization greatly exceeds the cost of the drug itself. For example, a one-month supply of the widely used medication prednisone costs less than a dollar. For the vast majority of prescriptions it is covered under Part D, but when used as an immunosuppressant, it is covered under Part B. However, hours may be spent by Part D plans, pharmacies, prescribers and beneficiaries trying to establish appropriate coverage for an individual patient.

**Diagnosis as a Part B/Part D Determinant**

With respect to patient diagnosis being a determining factor in Part B/Part D coverage, it should be noted that most state laws do not require prescribers to include a diagnosis or medical indication on a prescription not billed to Part B. Therefore, pharmacists typically do not have access to this information. For example, if a pharmacist receives a prescription for methotrexate and no diagnosis is provided, the pharmacist cannot determine whether the medication is being prescribed for the treatment of cancer or rheumatoid arthritis. The process necessary to obtain this required information adds time, expense and delay. It is unworkable to have the same medications covered under different parts of Medicare if the provider (in this case, the

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pharmacy) does not have the information necessary to facilitate determination of coverage by the payer. During normal office hours, while inconvenient, this situation can be remedied by making a series of phone calls. More problematic, however, when prescriptions are presented after hours, on weekends or in an emergency situation, a rapid resolution becomes impossible.

**Unintended Consequences: Changes in Behavior Based on Part B/Part D Complexity**

If a pharmacy and/or a Part D plan must explore all options before being able to expediently resolve authorization issues for a medication, beneficiaries will eventually learn to obtain medication in a dosage form or from a location that does not require authorization. This may include receiving medications in a physician’s office, receiving an infused rather than a safer, less costly oral version of a medication, or transporting medications from site to site for administration as previously described. Besides raising potential patient safety concerns and creating hassles for beneficiaries, this leads to more expensive claims under Medicare Part B. Even more troubling, some beneficiaries may forego medications altogether to avoid these administrative barriers, putting their health in jeopardy.

**AMCP Recommendations**

While the Academy believes that there are legitimate policy arguments favoring billing of all Medicare-covered medications under Part D regardless of type or site of administration, it recognizes that pursuing such a fundamental structural change in Medicare at this point in time may not be feasible. However, for the reasons described in this paper that relate to patient safety and the need to eliminate confusion, delay and unnecessary expenses, it is imperative that Congress proceed immediately to enact legislation that clarifies Part B versus Part D coverage policies. Accordingly, the Academy urges consideration of the following:

**Part B/Part D coverage determination problems would be greatly mitigated by defining Part B/Part D status at a drug-specific level, rather than introducing the circumstances of delivery.** Many drugs currently covered under Part B can be more efficiently and appropriately accessed by the beneficiary as a part of a definitive Part D pharmacy benefit. Therefore, the most clinically appropriate setting in which drugs should be provided, including any skilled support associated with the administration of therapy, has been considered in the development of the recommendations below.

1. **The Academy recommends that the following drugs, which can be self-administered, be moved from Part B, where they are covered in certain situations, to Part D coverage in all situations:**
   - Oral chemotherapeutics
   - Oral anti-emetics
   - Inhalation and blood glucose monitoring DME supply drugs
   - Immunosuppressants
Current Part B covered drugs that typically can be self-administered are ideal candidates to be moved to coverage under Part D, which would result in a reduced administrative burden to Part D plans and prescribers, and prevent unnecessary confusion and delay in the delivery of care to beneficiaries. AMCP recognizes that those beneficiaries who do not have Part D coverage would require coverage under Part B.

2. **To decrease confusion, all vaccines should be covered under the same part of the Medicare benefit—in this case Part B.** The Academy recommends that Part B is the appropriate section for two reasons. While pharmacies can put systems in place to bill for vaccines provided under Part B or Part D, physicians do not have the appropriate systems that would permit them to bill under Part D. Additionally, by moving all vaccine coverage under Part B, barriers to beneficiary access to vaccines will be minimized, particularly for beneficiaries who do not have Part D coverage.

3. **The Academy recommends that Medicare Part D plans that have made a coverage determination that can be demonstrated to have been in good faith, and after exercising due diligence, be exempt from legal jeopardy.** Under the current system, plans must be concerned about fraud implications and consequent penalties if a medication that should be billed under Part B is paid under Part D. Such a statutory change would ensure that penalties are only imposed for intent to defraud the program.

**Potential Consequences of the Above Recommendations**

In the standard Medicare Part B benefit, beneficiaries are responsible for 20% coinsurance for drugs. The movement of the drugs from Part B to Part D, while simplifying beneficiary access and plan sponsor administration, would increase beneficiary cost share to 25% (100% in the deductible and coverage gap phases, less any applicable manufacturer coverage gap rebates) for beneficiaries in a standard Part D benefit plan. However, such a move could significantly decrease cost share for beneficiaries in enhanced or alternative Part D benefit plans with no deductible, low co-payments, and/or coverage during the gap.

On the other hand, the movement of selected drugs from Part B to Part D coverage may ultimately reduce costs for the Medicare program. Accessing these drugs through Part D plans’ pharmacy networks with manufacturer negotiated rebates could potentially reduce costs within the Medicare program and promote beneficiary access to these drugs in a less costly setting. The extent to which a Part D plan will be able to negotiate additional rebate revenue on this increased utilization, the net impact on cost, and the extent to which net change in beneficiary cost share will be affected will require further study.

Of course, adding or removing drugs to or from coverage under Part D would also affect overall plan costs and ultimately, plan bids. A study conducted in 2010 by CMS examined the impact of consolidating four drug categories with overlapping coverage: oral anticancer and antiemetic drugs, vaccinations, insulin and inhalants. The study predicted a small impact on overall plan costs, however, either because the population of Medicare beneficiaries that would be affected
by the change is relatively small, or the reduction in costs to the plan would be relatively small. Therefore, it would not be expected that consolidation, at least for those four drug classes, would negatively affect overall plan costs.⁹

**Conclusion**

The administrative burdens resulting from certain medications being eligible for coverage either under Part B or Part D has created confusion, delay and expense for all involved: beneficiaries, Part D plans, providers and the Medicare program itself. The Academy of Managed Care Pharmacy suggests that remedial legislative action on this issue is one of the most important corrective actions that Congress can take as it addresses modifications to the current Medicare Part D program. It is also an issue that can have a dramatic, valuable impact on beneficiary health and well-being, as well as taxpayer savings.

*February 2013*

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*The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's more than 6,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.*

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Coverage under Medicare Part B is usually limited drugs or biologicals administered by infusion or injection. However, if the injection is generally self-administered, e.g., Imitrex, it is not covered. Despite the general limitation on coverage for outpatient drugs under Part B, the law specifically authorizes coverage for the following:

- **Durable medical equipment (DME) supply drugs** – drugs that require administration by the use of a piece of covered DME;
- **Immunosuppressive drugs** – drugs used in immunosuppressive therapy for a beneficiary who has received a Medicare covered transplant;
- **Hemophilia clotting factors** – hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision;
- **Oral anti-cancer drugs** – drugs taken orally during cancer chemotherapy provided that they have the same active ingredients and are used for the same indications as chemotherapy drugs that would be covered if they were not self-administered.
- **Oral anti-emetic drugs** – oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen as a full therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration.
- **Pneumococcal vaccine**
- **Hepatitis B vaccine**
- **Influenza vaccine**
- **Antigens** – prepared by a physician (usually an allergist) for a specific patient. The physician or physician’s nurse generally administers them in the physician’s office. In some cases the physician prepares antigens and furnishes them to a patient who has been taught to self-administer them at home.
- **Erythropoietin (EPO)** – EPO for the treatment of anemia for persons with chronic renal failure who are on dialysis.
- **Parenteral nutrition** – Parenteral nutrients are covered under the prosthetic benefit. They are available to beneficiaries who cannot absorb nutrition through their intestinal tract.
- **Intravenous immune globulin (IVIG) provided in the home** – coverage is provided if a physician determines that the administration of IVIG in the patient’s home is medically appropriate.
- **Part B covered drugs in the context of a professional service** – drugs furnished “Incident To” a Physician’s Service. These are injectable or intravenous drugs that are 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 are not usually self-administered.
- **Drugs furnished by a Medicare Advantage organization “incident to” a physician’s service** – if a drug could be covered under Part B when furnished by a physician who incurred an expense in procuring the drug, it could also be covered under Part B in the case of a Medicare Advantage (MA) plan physician when the MA organization has incurred the expense of procuring the drug, and the drug is administered to an enrollee in the MA plan.
- **Separately billable end stage renal disease (ESRD) drugs** – Most drugs furnished by dialysis facilities are separately billable. The largest Medicare expenditures for such drugs are for erythropoietin (EPO) which is covered for dialysis beneficiaries when it is furnished by independent and hospital-based ESRD facilities, as well as when it is furnished by physicians.”
- **Separately billable drugs provided in hospital outpatient department** – Medicare continues to pay separately for drugs, biologicals, and radiopharmaceuticals who median cost per administration exceeds an amount (or threshold amount) determined by CMS, while packaging the cost of drugs, biological and radiopharmaceuticals whose median cost per administration is less than an amount(or threshold amount) determined by CMS into the procedures with which they are billed.
• **Drugs covered as supplies or “integral to a procedure”** – some drugs are covered as supplies that are an integral part of a procedure which is a diagnostic or therapeutic service, including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media.

• **Blood** – Medicare does not make separate payment for blood and blood products and these products are regulated as biological agents by the FDA.

• **Drugs furnished as part of a service in these provider settings:** 1) drugs packaged under the hospital Outpatient Prospective Payment System (OPPS); 2) drugs furnished by ESRD facilities and included in Medicare’s ESRD composite rate; 3) osteoporosis drugs provided by home health agencies under certain conditions; 4) drugs furnished by critical access hospitals (CAH) outpatient departments; 5) drugs furnished by a rural health clinic (RHC); 6) drugs furnished by federal qualified health centers (FQHC); 7) drugs furnished by community mental health centers (CMHC); 8) drugs furnished by ambulances; 9) separately billable drugs provided in comprehensive outpatient rehabilitation facilities (CORF).