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*Important Information about Medicare Coverage of Drugs under Part B and the New Medicare Prescription Drug Coverage (Part D), and Vaccines Administered in a Physician's Office – The Ninth in the MLN Matters Series on the New Prescription Drug Plans*

**Note:** While this article correctly described Medicare policy when it was initially issued in 2005, some of the policy has been revised since 2005. Most recently, this article was updated on November 25, 2014, to include links to the most current publications and articles that reflect the changes in Medicare policy that have occurred since SE0570 was published in 2005. CMS encourages providers to review the more current publications referenced in this article.

## Provider Types Affected

This article is intended for physicians, healthcare professionals, providers, suppliers, and their staff

## Key Points to Remember

- Drugs covered under Fee-For-Service (FFS) Medicare Parts A/B that are paid to institutional providers (hospitals, SNFs, etc.) as part of a bundled payment are paid by A/B Medicare Administrative Contractors (MACs).
- Drugs covered under FFS Medicare Part B that are billed by physicians are paid by A/B MACs.
- Drugs covered under FFS Medicare Part B that are billed by Durable Medical Equipment, Prosthetics, Orthotics, and Supply (DMEPOS) suppliers are paid by DME MACs.
- A/B MACs and DME MACs do not, and will not, pay claims for Part D drugs. Providers should not submit claims for Part D covered drugs to A/B MACs and DME MACs.

### Disclaimer

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- Drugs covered under Part D are paid by Medicare Part D Drug Plans, such as Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDs), for enrolled beneficiaries.
- Providers must have a contractual relationship with a Medicare Part D Drug Plan to bill these plans for drugs provided to enrolled beneficiaries.
- Providers may not bill a Medicare Part D Drug Plan for drugs and biologicals that are part of a bundled payment under Medicare Part A or Part B.

This article highlights the differences in how drugs are covered and which drugs are covered by Medicare Part B and the new Medicare prescription drug coverage (Part D). It also offers additional guidance on the effect of Part D on vaccines given to Medicare patients in a physician's office. Those currently billing Medicare Part B for drugs or for vaccines may wish to pay particular attention to this article.

## Drugs Covered Under Part B and Part D

### *Part A/B Covered Drugs Set by Statute*

Traditional Part A/B Medicare does not cover most outpatient prescription drugs. Under Part A, Medicare bundled payments made to hospitals and skilled nursing facilities (SNFs) generally cover all drugs provided during a covered Part A stay. (An exception is clotting factor supplied during a stay, which is paid separately from the bundled payment.)

Medicare also makes payments under Part B to physicians for drugs or biologicals that are **not** usually self-administered. Coverage is usually limited to drugs or biologicals **administered by infusion or injection**. If the injection is self-administered (e.g., Imitrex), it is not covered.

Physicians, healthcare professionals, providers, and suppliers may also bill Medicare Part B for other limited types of drugs as follows:

### **Durable Medical Equipment (DME) Supply Drugs**

These are drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, or external or implantable pump). The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function.

The largest Medicare expenditures for drugs furnished as a DME supply are for inhalation drugs, (e.g., albuterol sulfate, ipratropium bromide) which are administered in the home through the use of a nebulizer. The other category of drugs Medicare covers as a DME supply are drugs for which administration with an infusion pump in the home is medically necessary (e.g., some chemotherapeutic agents).

### **Immunosuppressive Drugs**

These include drugs used in immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a Medicare covered organ transplant.

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**Hemophilia Clotting Factors**

These include hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors.

**Oral Anti-Cancer Drugs**

These are drugs taken orally during cancer chemotherapy, provided they have the same active ingredients and are used for the same indications as are chemotherapy drugs that would be covered if they were not self-administered but were administered instead as incident to a physician's professional service.

**Oral Anti-emetic Drugs**

These are 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 24 or 48 hours of chemotherapy administration depending on the drug.

**Pneumococcal Vaccine**

This refers to the vaccine and its administration to a beneficiary if ordered by a physician.

**Hepatitis B Vaccine**

This includes the vaccine and its administration to a beneficiary who is at high or intermediate risk of contracting Hepatitis B. High risk groups include the following:

- Individuals with End-Stage Renal Disease (ESRD);
- Individuals with hemophilia who received Factor VIII or IX concentrates;
- Clients of institutions for mentally handicapped individuals;
- Persons who live in the same household as a Hepatitis B Virus (HBV) carrier;
- Homosexual men; and
- Illicit injectable drug abusers.

Intermediate risk groups include staff in institutions for the mentally handicapped and workers in healthcare professions who have frequent contact with blood or blood-derived body fluids during routine work.

**Influenza Vaccine**

This refers to the vaccine and its administration when furnished in compliance with any applicable state law. The beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

**Antigens**

These are 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.

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**Erythropoiesis-stimulating agent (ESA)**

ESAs are used for treating anemia in persons with chronic renal failure who are on dialysis or persons with cancer. When furnished for the treatment of ESRD, ESAs are covered under the ESRD Prospective Payment System (PPS).

**Parenteral Nutrition**

Parenteral nutrients are covered under the prosthetic benefit. They are available to beneficiaries who cannot absorb nutrition through their intestinal tract. Parenteral nutrition is administered intravenously and is regulated as a drug by the FDA.

**Intravenous Immune Globulin Provided in the Home**

The MMA created a benefit for the provision of intravenous immune globulin (IVIG) for beneficiaries with a diagnosis of primary immune deficiency disease. Coverage is provided if a physician determines that the administration of IVIG in the patient's home is medically appropriate. Payment is limited to that for the IVIG itself and does not cover items and services related to administration of the product.

*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. (If a drug is not self-administered by more than 50 percent of Medicare beneficiaries, it is considered "not usually self-administered.")

**Separately Billable Drugs Provided in Hospital Outpatient Departments**

For Calendar Year 2005, Medicare continues to pay separately for drugs, biologicals, and radiopharmaceuticals whose median cost per administration exceeds \$50, while packaging the cost of drugs, biologicals, and radiopharmaceuticals whose median cost per administration is less than \$50 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 that is a diagnostic or therapeutic service, including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media. Other examples of drugs covered under the "integral to a procedure" provision include eye drops administered before cataract surgery.

**Blood**

Medicare does make separate payment for blood and blood products and these products are regulated as biological agents by the Food and Drug Administration (FDA).

**Drugs Furnished as a Part of a Service in Provider Settings**

Also covered are drugs furnished as a part of a service in the following provider settings:

- Drugs packaged under the Hospital Outpatient Prospective Payment System;

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- Drugs and biologicals used for the treatment of ESRD covered under Medicare's ESRD PPS;
- Osteoporosis drugs provided by home health agencies under certain conditions;
- Drugs furnished by critical access hospitals' (CAH) outpatient departments;
- Drugs furnished by a Rural Health Clinic (RHC);
- Drugs furnished by Federally Qualified Health Centers (FQHC);
- Drugs furnished by Community Mental Health Centers (CMHC);
- Drugs furnished by ambulances; and
- Separately billable drugs provided in Comprehensive Outpatient Rehabilitation Facilities (CORF).

### *Part D Covered Drugs*

#### **Definition of a Part D Covered Drug**

A Part D covered drug is a drug that is:

- Available only by prescription;
- Approved by the FDA (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Social Security Act);
- Used and sold in the United States; and
- Used for a medically accepted indication (as defined in section 1927(k)(6) of the Act).

A covered Part D drug includes prescription drugs, biological products, insulin as described in specified paragraphs of Section 1927(k) of the Act, and vaccines licensed under Section 351 of the Public Health Service Act. The definition also includes "medical supplies associated with the injection of insulin (as defined in regulations of the Secretary)." CMS defines those medical supplies to include syringes, needles, alcohol swabs, and gauze.

### *Part D Excluded Drugs*

The definition of a covered Part D drug excludes any drug for which, as prescribed and dispensed or administered to an individual, payments would be available under Parts A or B of Medicare for that individual, even though a deductible may apply.

In addition, the definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents.

The drugs or classes of drugs that may currently be otherwise restricted under Medicaid include the following:

- Agents when used for anorexia, weight loss, or weight gain;

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- Agents when used to promote fertility;
- Agents when used for cosmetic purposes or hair growth;
- Agents when 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.

While these drugs or uses are excluded from basic Part D coverage, Medicare Part D drug plan sponsors can generally include them as part of supplemental benefits, provided they otherwise meet the definition of a Part D drug.

Because non-prescription drugs do not otherwise meet the definition of a Part D drug, the Part D drug plans may not include such drugs as part of supplemental benefits; however, under certain conditions as part of a plan utilization management program (including a step-therapy program), non-prescription drugs can be provided at no cost to enrollees. The cost of these drugs to the plan would be treated as administrative costs under such programs.

## Vaccines Administered in a Physician's Office

This section discusses the vaccines currently covered by Medicare Part B, and includes a few commonly asked questions regarding vaccine coverage under Medicare Part B and Part D. Basically, if a vaccine is currently covered under Part B, the vaccine will remain covered under Part B when the new Part D goes into effect on January 1, 2006.

### *Key Questions*

#### **Will All Vaccines be Covered under Part D, Effective January 1, 2006?**

No. As just mentioned, if a vaccine was previously covered under Part B, it will continue to be covered under Part B. If it was previously **not** covered, then it will need to be covered under Part D. Pneumococcal and influenza vaccines are not covered under Part D because of Part B coverage.

Hepatitis B vaccine is covered under Part B for individuals at high or intermediate risk; for all other individuals, it would be covered under a Part D benefit. All other currently available vaccines and all future vaccines would be covered under Part D, but could be subject to plan prior authorization requirements to determine medical necessity.

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**If a Company That Offers Medicare Part D Drug Plans Determines, Through a Prior Authorization Program, that a Hepatitis B Vaccine is Going to be Administered by a Physician, Can This Company Deny the Claim Based on Part B Coverage in the Setting?**

No. Since the Part B benefit for Hepatitis B vaccine is separate from the “incident to” benefit, the determination about whether it is a Part D drug depends solely on characteristics of the beneficiary. However, if the plan sponsor determines based on Medicare Part B guidelines that the individual is at high or medium risk for Hepatitis B, the company should deny the claim.

For all other individuals, the vaccine would be a “Part D drug,” and would be covered unless the plan had otherwise established medical necessity criteria for the vaccine as part of its approved prior authorization program. In this case, only low risk individuals who meet the plan’s criteria would be eligible to receive the vaccine.

**Additional Information**

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**Websites for Part B and Part D Coverage Information**

- The "Medicare Claims Processing Manual" is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html>;
- The "Medicare Benefit Policy Manual" is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html>;
- National/Local Coverage Determinations are available at <http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html>;
- The Medicare Drug Information Resource is available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html>; and
- Information on Prescription Drug Plans is available at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/index.html>.
- For more detailed information about Part B drugs and Part D coverage, please refer to the report at <http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11315-P.pdf> on the CMS website. This report provides excellent detail on the overall issue of Part B and Part D drugs.
- Vaccine Payments under Medicare Part D (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Vaccines-Part-D-Factsheet-ICN908764.pdf>) explains vaccine coverage under Medicare Part D, as well as how to submit claims for Medicare payment,
- Hospital Outpatient Prospective Payment System (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctsh.pdf>)

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- SE1431 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1431.pdf>) provides information for the 2014-2015 Influenza (Flu) season.
- MM8890 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8890.pdf>) provides and update for influenza vaccine payment allowance.
- MM8841 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8841.pdf>) adds a new Healthcare Common Procedure Coding System (HCPCS) code to drugs subject to the ESRD consolidated billing list.
- MM8675 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8675.pdf>) provides an update of the Ambulatory Surgical Center (ASC) payment system.
- MM8620 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8620.pdf>) provides an update for non-hospice providers furnishing vaccines to hospice beneficiaries and submitting claims to MACs.
- SE1336 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1336.pdf>) provides information for the 2013-2014 Influenza (Flu) season.
- SE1229 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1229.pdf>) provides information about Medication Therapy Management (MTM) programs.
- If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work.

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