



The Changing Reimbursement System: Interaction Between Medicare Part B and Medicare Part D



The intersection of business
strategy and public policy

“Part B” and “Part D” Drugs Defined

Part B drug*: Medical Benefit Incident to a physician service or explicit statutory coverage

- Prescription drug or biological that is:
 - » “Reasonable and necessary”
 - » FDA approved and commercially marketed
 - » Furnished incident to a physician service (product is usually not self-administered, includes IV, IM, and some SC)
 - » Furnished incident to DME
 - » Covered by statute: oral chemotherapy drugs, oral antiemetics, oral immunosuppressants, vaccines
- ESRD drugs used in dialysis also covered in Parts A, B***

Part D drug**: Pharmacy Benefit Outpatient prescription drug

- A prescription drug or biological that is:
 - » FDA approved
 - » Used and sold in the U.S
 - » Used for a medically accepted indication as defined in Medicaid laws
- Over-the-counter (OTC) medications are specifically excluded from Part D coverage
- CMS has no authority to exclude coverage to certain classes of drugs (i.e., “lifestyle” drugs) if products meet the statutory definition
- Vaccines that are “reasonable and necessary for the prevention of illness” if not covered under Part B, will be covered under Part D
- “Medical supplies associated with the injection of insulin” as mandated in the statute

* § 1861(s) of the Social Security Act (SSA)

** § 1860D-2(e) of the Medicare Modernization Act (MMA)

*** ESRD drugs are covered under separate statutory provision and are not part of the “incident to” physician services provision

There Is Specific CMS* Guidance Regarding Obtaining Medicare Part B Coverage for Injectable Drugs and Biologics

✓ 50 PERCENT RULE

- A drug is considered self-administered if more than 50 percent of Medicare beneficiaries self-administer the drug

✓ ROUTE OF ADMINISTRATION

- Absent evidence to the contrary, drugs delivered intravenously and by IM injection should be presumed to be not usually self-administered, while drugs delivered by SC injection should be presumed to be usually self-administered

✓ ACUTE versus CHRONIC CONDITIONS

- For the purposes of self-administration, Medicare defines acute as a “condition that begins over a short period, is likely to be of short duration and/or the expected course of treatment is for a short, finite interval”

✓ RELATIVE CONTRIBUTION OF EACH INDICATION

- Carriers should use a weighted average by indication to determine whether the product is self-administered

* CMS = Centers for Medicare & Medicaid Services

Part B Evolutionary History

Medicare Part B Drug Coverage

“Incident to” - Drugs billed and administered by a physician

Drugs billed to pharmacy suppliers and administered through DME

Drugs billed by pharmacy suppliers and self-administered by patient (immunosuppressive, oral anti-cancer, oral anti-emetic, hemophilia, EPO))

Separately billable ESRD drugs (EPO, Vitamin D)

Separately billable drugs in the Hospital Outpatient Department

**Unique
statutory
provisions,
and
coverage
criteria**

Some “B” Drugs Can Be Paid in “D” While Others Cannot

| Type of Medicare Product | Part B Coverage | Potential for Part D Coverage |
|--|--|---|
| IV, SC, IM | Drugs administered incident to a physician visit including drugs not usually self-administered | If drug is dispensed at a retail pharmacy it should be paid under Part D, even if it is not usually self-administered |
| Immunosuppressive | Covered if incident to a Medicare covered transplant | Covered for non-Medicare covered transplants |
| Oral anti-emetics, oral cancer pro-drugs | Statutorily covered | Cannot be covered under Part D |
| Vaccines | Pneumococcal, influenza, and hepatitis B vaccines are statutorily covered | Additional vaccines that are “reasonable and necessary for the prevention of illness” are covered |
| DME | Statutorily covered | Cannot be covered under Part D |

Medicare Part B and Part D Differ Dramatically

| | Part B | Part D |
|---------------------------------------|---|--|
| Coinsurance Responsibility | Consistent: 20% Coinsurance | Variable: 5% - 100% |
| Supplemental Insurance Options | ~90% Beneficiaries Have Supplemental (Medi-gap) Coverage | No Supplemental (wrap-around) Coverage Allowed |
| Coverage Guidelines | Cannot be Usually Self-Administered | Must be FDA-Approved; Covers What Part B Does Not |
| Length of Time to Coverage | Immediate Coverage Possible; Local Policy Development Takes Greater Than Three Months | 90 Day Formulary Review; 60 Days for Protected Drugs |
| Formulary | No Formularies | All Plans Have Formularies |
| Utilization Controls | No Utilization Controls Allowed (PA, Quantity Limits, etc); Coverage Restrictions Allowed | Utilization Controls Allowed; Certain Drugs Protected |
| Drug Reimbursement Rate | ASP + 6% (WAC + 6% at Launch) | Varies: Typically AWP/WAC- Based |
| Drug Codes Utilized | HCPCS Code: One Year Lag Time for Unique Code | NDC Codes; Available at Launch |
| National/Local Coverage | Coverage Likely at Local Carrier/FI Level | Coverage at Plan Level |
| Beneficiary Enrollment | About 95% of Beneficiaries Enrolled | ~88% of Beneficiaries will Enroll in 2006* |
| Manufacturer Discounts | No Discounts to Medicare Part B | Discounts to Part D Plans Encouraged |

*CMS Press Release Regarding Part D Enrollment Prior to May 15, 2006 Part D Enrollment Deadline



Why Are Part B Drugs Included on Part D Plan Formularies?

- Some drugs, “crossover drugs,” may be covered either under Part B or Part D based on:
 - » How the drug is prescribed and dispensed
 - » Indication of use
 - » How the drug is administered to a particular individual
 - » Site of service
- Part D plans and pharmacy providers need to make Medicare Part B vs. Part D coverage determinations for crossover drugs
 - » In some cases, it is hard to make a determination without documentation from physicians or additional information from beneficiaries
 - » Many plans currently face challenges when making Part B vs. Part D determinations

Medicare Part B vs. Part D Coverage Remains Confusing

- CMS continues to issue formal and informal guidance on these issues
 - » Open Door Forums
 - » Question and Answer Documents on CMS website
- Medicare carriers and Part D plans also have to make determinations
 - » Follow Local Coverage Determinations
 - » Monitor influence of Medicare Administrator Contractor (MAC) reform
 - » Watch evolution of Part D formularies and prior authorizations
- This is an issue that will continue to be “ironed out” over the next few years