Medicare Part B: Drug Pricing

Rx Drug Pricing: Master Course

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Topics Covered

- Coverage, Coding, and Payment
- ASP Calculation
- Demonstration Programs
- “Hot Topics”

COVERAGE, CODING AND PAYMENT

Definition of a Part B Drug

- Must be "included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary . . . or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital."
- Cannot be usually self-administered.

Definition of a Part B Drug *(cont.)*

- Special rules apply to anti-cancer agents
- Coverage applies to “medically accepted indications”, which include those that are supported by citation in compendia approved by CMS.
- Current list of approved compendia are:
  - American Hospital Formulary Service Drug Information
  - Gold Standard Inc. Clinical Pharmacology Compendium
  - NCCN Drugs and Biologics Compendium
  - Thomson Micromedex DrugDex ® Compendium
  - Thomson Healthcare DrugPoints® Compendium)
  - Wolters Kluwer Clinical Drug Information Lexi-Drugs

Definition of a Part B Drug *(cont.)*

- Other covered drugs include
  - Blood clotting factors
  - Immunosuppressants
  - EPO for dialysis patients
  - Certain oral anti-cancer agents
  - Anti-emetics used in chemotherapy regimens
  - IVIG
  - Certain radiopharmaceuticals
  - Infusion drugs incident to DME
  - Certain vaccines

Coding

- Identification on a claim form helps, but is neither necessary nor sufficient, to ensure payment at the proper rate
- J Codes (for drugs) and Q codes (for drug-like products) are assigned by either CMS or the HCPCS Committee
- Applications are due in early January and decisions take effect the following year
  - Process of getting a code has become increasingly uncertain

Coding *(cont.)*

- Receipt of a code does not guarantee placement on the national drug pricing file
- Can be placed on the national file with a “NOC” code

Reimbursement

- In large part, separate reimbursement for Part B drugs is only available to physicians and hospitals in their hospital outpatient departments
- For drugs qualifying as “incident to” a physician’s service, payment is at the rate of ASP + 6% (adjusted for sequestration)

Reimbursement *(cont.)*

- The hospital outpatient department reimbursement system includes the following categories of drugs
  - New drugs subject to pass-through payments
  - Packaged drugs, including diagnostic drugs and drugs used like a supply in surgery, and drugs that (in 2016) cost less than $100 per administration – proposed to be increased to $110 for 2017
  - “SCODs”
  - Therapeutic radiopharmaceuticals

Reimbursement *(cont.)*

- For separately payable drugs, in 2016, payment is at ASP + 6% (adjusted for sequestration)
- Subject to change year to year
- Therapeutic radiopharmaceuticals are paid at their mean unit costs

Reimbursement *(cont.)*

- Other drugs (paid at 95% of AWP)
  - Vaccines
  - Clotting factor
  - Immunosupressants received from a pharmacy
  - Infusion drugs administered through DME

Reimbursement *(cont.)*

- Volume Weighting
  - In applying an ASP-based reimbursement rate to a HCPCS code with multiple NDCs, CMS volume weights the ASPs…
    - CMS sums the product of the manufacturer's ASP and the number of units of the 11-digit NDC sold for each NDC assigned to the HCPCS code, and then divides this total by the sum of the product of the number of units of the 11-digit NDC sold and the number of billing units in that NDC for each NDC assigned to the HCPCS code

ASP CALCULATION

ASP Process

- Collect data in one quarter
- Submit data within 30 days of end of quarter
  - Includes an assumptions letter
  - Must be certified by CEO, CFO, or designee
- CMS uses data to calculate an ASP value for the following quarter, resulting in a two quarter lag between accrual of pricing data and its use
  - ASP value used in real time, and thus it is very difficult to recalculate if later recognized to be in error

Included and Excluded Customers

- All sales in the "United States," excluding those excluded under the Best Price calculation
  - VA, DOD, FSS
  - All sales to 340B covered entities
  - PBM sales, except for mail order or where used to reduce prices at retail or provider level
  - Qualified SPAPs

Included and Excluded Transactions

- Expressly inclusive of:
  - Prompt pay discounts
  - Cash discounts
  - Volume discounts
  - Chargebacks
  - Rebates (other than Medicaid rebates)
  - Free goods contingent on a purchase requirement

Included and Excluded Transactions *(cont.)*

- Excludes:
  - Copay or PAP assistance (but July 2016 GAO report calls into question whether this is a good thing)
  - Free goods not contingent on a sale
  - Qualifying nominal sales
  - Bona fide service fees that meet the four-part test

Related Calculations

- Smoothing
  - Manufacturers must use 12-month rolling average methodology to estimate value of lagged price concessions
  - Many manufacturers also smooth ineligible sales lagged price concessions
- Unbundling
  - Questions as to how to handle intertemporal bundles

Substituting AMP for ASP

- Payment is AMP+3% for a billing code when all of the following criteria are met:
  - ASP for code ≥ 105% of AMP for code in 2 consecutive Qs, or 3 of the previous 4 Qs immediately preceding the Q to which the price substitution would be applied; and
  - AMP and ASP for the code are calculated using the same set of NDCs
  - AMP+3% is < ASP+6% for the quarter in which the substitution would be applied
  - The drug and dosage form described by the HCPCS code is not identified by the FDA to be in short supply at the time that ASP calculations are finalized

DEMONSTRATION PROGRAMS

Oncology Care Model

- From 7/1/16 through 6/30/21
- Multi-payer
- 195 practices nationwide
- Compare actual Medicare expenditures to expected Medicare expenditures using a risk-adjusted baseline data set
- Share excess expenses or savings
- Adjustment for novel therapies in their first two years on the market and when being used for their labeled indication

Part B Demonstration Program

- Phase I
  - Different geographic locales will be subject to different payment systems
  - Some will be remain in an ASP+6% environment, while others will receive ASP + 2.5% and a flat fee of $16.80
- Phase II
  - Benchmark pricing
  - Indication-based pricing
  - Voluntary agreement for outcomes-based pricing
  - Episode-based pricing
- CBO estimates savings of $395 million
- Unclear if will be promulgated in final under Obama

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Other Models

- ACOs
- MACRA
  - "MIPS" program incentivizes cost efficiency
  - Advanced APM model encourages participation in ACOs

“HOT” TOPICS

Biosimilars

- Statute states that reimbursement methodology is to use 6% of the *reference product* and add that to the ASP for the biosimilar's sales data
- CMS has (mis)interpreted the statute to suggest that the sales data for all biosimilars to the same reference product are to be combined together for one price applicable to all products
- Expected to lead to a "race to the bottom", but ignores that these drugs are not interchangeable

MDRP Requirements for ASP Drugs

- Statute requires that manufacturers of “covered outpatient drugs” reimbursed under Medicare Part B must enter into MDRP agreements for Part B coverage
- Question of what is a “covered outpatient drug”
- 2013 OIG report acknowledges that further legislation would be necessary