Medicare Part B Drug Pricing
ACI Rx Pricing Master Course

November 5, 2015
New York, New York

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Topics Covered

- Coverage, Coding, and Payment
- ASP Calculation
- “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
  - "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 Calculation: *Generally*

- ASP defined as manufacturer's sales to all purchasers (excluding sales exempt from Medicaid Drug Rebate Program's Best Price calculations and sales at a "nominal price") divided by the total number of units sold
  - "Unit" defined as product represented by 11-digit NDC
  - "Nominal price" defined via regulation by reference to Medicaid Drug Rebate Program's definition
- Report and certify ASP on a quarterly basis for each 11-digit NDC
- 2-Quarter lag for ASP to be used in reimbursement formula

ASP Calculation: *Generally (cont'd)*

- By statute, following price concessions must be included in ASP (in other words – ASP is reduced by):
  - Prompt pay discounts
  - Cash discounts
  - Volume discounts
  - Chargebacks
  - Rebates (other than Medicaid rebates)
  - Free goods contingent on a purchase requirement
- CMS may identify other price concessions to be included in ASP, based on OIG recommendations

ASP Calculation: *Generally (cont'd)*

- In the absence of specific guidance, manufacturers may make reasonable assumptions that are consistent with intent of statute and regulations
  - Unlike Medicaid, assumptions documentation submitted to CMS

ASP Calculation: *Smoothing*

- Manufacturers must use 12-month rolling average methodology to estimate value of lagged price concessions
- The term "lagged" is not defined in available CMS ASP guidance
- In the July 17, 2007 final rule (withdrawn) on *AMP*, CMS defined "lagged price concession" as:
  - "Any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts" (former 42 C.F.R. § 447.502)
  - The AMP guidance is not directly controlling of ASP, but may be one consideration in determining the reasonableness of ASP assumptions
- Lack of clarity on smoothing of *exempt* price concessions

ASP Calculation: *"Bundled" Price Concessions*

- CMS affirmatively declined to establish a specific methodology for manufacturers to use to apportion price concessions resulting from bundled sales
  - CMS stated in 2007 that it is paying close attention to this issue and may provide specific guidance in the future
- AMP/BP guidance relevant?

ASP Calculation: *Bona Fide Service Fees*

- "Bona fide service fees" = "fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client of an entity, whether or not the entity takes title to the drug"
  - Mfrs should use "the most appropriate, industry-accepted method for determining fair market value of drug distribution services for which they contract"
  - "If a manufacturer has determined that a fee paid meets the other elements of the definition . . . then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of an entity"
- Other fees = price concessions

ASP Calculation:
Bona Fide Service Fees (cont'd)

- It is not "safer" to call something a discount or a service fee: what is it really?
  - Amgen: settled December 2012 ($762M)
    - Allegations included reporting inaccurate ASP for various products by, among other things "failing to account properly for price concessions, including group purchasing organization volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, and price concessions disguised as bona fide service fees, in the calculation of ASP"
  - U.S. ex rel. Ronald Streck v. AstraZeneca, LP, et al.: settled July 2015 (AZ: $46.5M; Cephalon: $7.5M; and Biogen: $1.5M)
    - Case related to calculation of "average manufacturer price" (AMP)
    - Involved distributor service fee payments that were allegedly mischaracterized as "discounts" for AMP

HOT TOPICS

Overfill

- ASP payment limit calculated based on the amount of product included in a vial or other container as reflected on the FDA-approved label
  - Additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit

AMP Substitution

- 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
- (CMS also has authority to substitute payment based on a 5% differential between ASP+5 and "widely available market price" or "WAMP" but has not exercised this for various reasons to date)

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

Sales to 340B Covered Entities

- General rule is that sales excluded from best price are excludible from ASP
- This includes 340B program sales
- Statute excludes “any prices charged . . . a covered entity . . . (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act)”
- CMS takes the position that sales must be through the 340B program
- Apexus takes the view that sales for use with “non-patients” also covered
- Question of how “plain” is the plain meaning of the statute

Operational Challenges

- Crosswalking policies/procedures/Systems to BP policies for consistent treatment of exclusions
  - Because the ASP calculation directly references the Best Price determination with respect to exclusions, there should not be a situation where a transaction is "included" in ASP but excluded for purposes of Best Price (42 C.F.R. 414.804(a)(4)(i))
- Compare ASP to Quarterly AMP
  - Under the current regulations, CMS may disregard the ASP and reimburse providers based on a percentage of AMP, if there is greater than a 5% differential between the numbers
  - Note that changes in AMP rules could impact this differential
- Identification/treatment of chargebacks as "lagged" for smoothing purposes

Operational Challenges

- Process for meaningful certification of ASP
  - Each ASP report must be signed by one of the following:
    - (i) The manufacturer's CEO
    - (ii) The manufacturer's CFO, or
    - (iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO (42 C.F.R. § 414.804(a)(6))
  - " I certify that the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes."
- Assumptions documentation/submission

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