Medicare Part B Drug Pricing
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What is Medicare Part B?

- Medicare entitlement is based on age, disability, or ESRD (distinguish from Medicaid)
- Medicare Part B beneficiaries: 33,366,109 M (2018) (https://www.cms.gov/files/document/2018-mdcr-enroll-ab-9.pdf)
- Medicare has 4 parts:
  - Part A (Hospital Insurance) (bundled payment includes some drugs)
  - Part B (Medical Insurance) – many items or services besides drugs
    - Physician's Services (including "incident to" drugs)
    - Outpatient Care (including some hospital outpatient drugs)
    - Other Medical Services (including some drugs)
  - Part C (Medicare Advantage) (payment includes some drugs including those covered under Part B)
  - Part D (Prescription Drug coverage)

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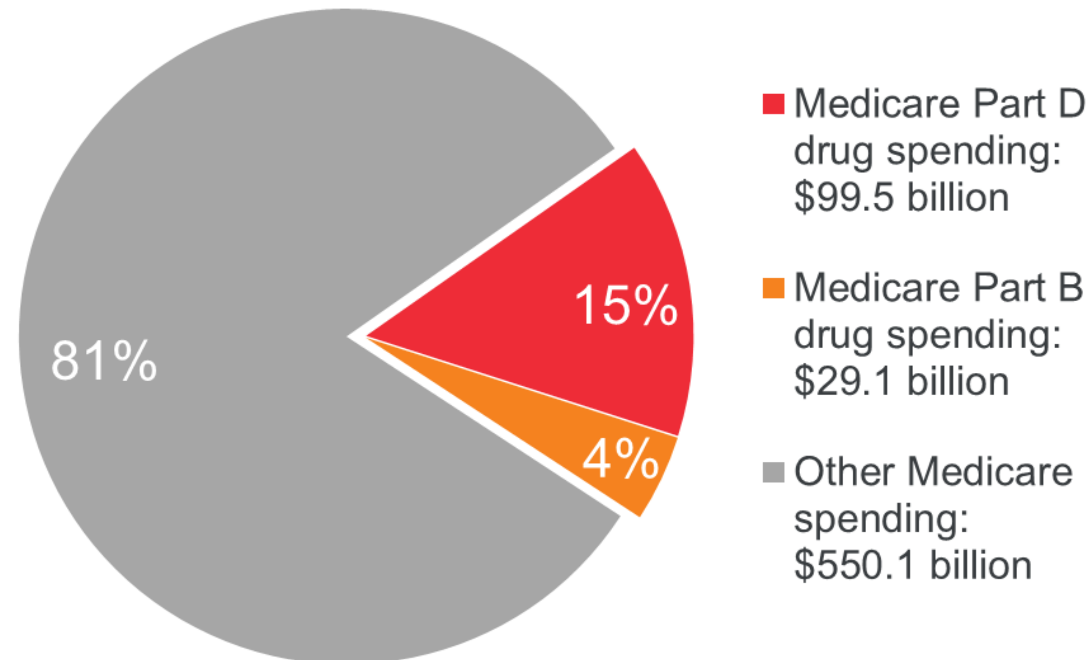
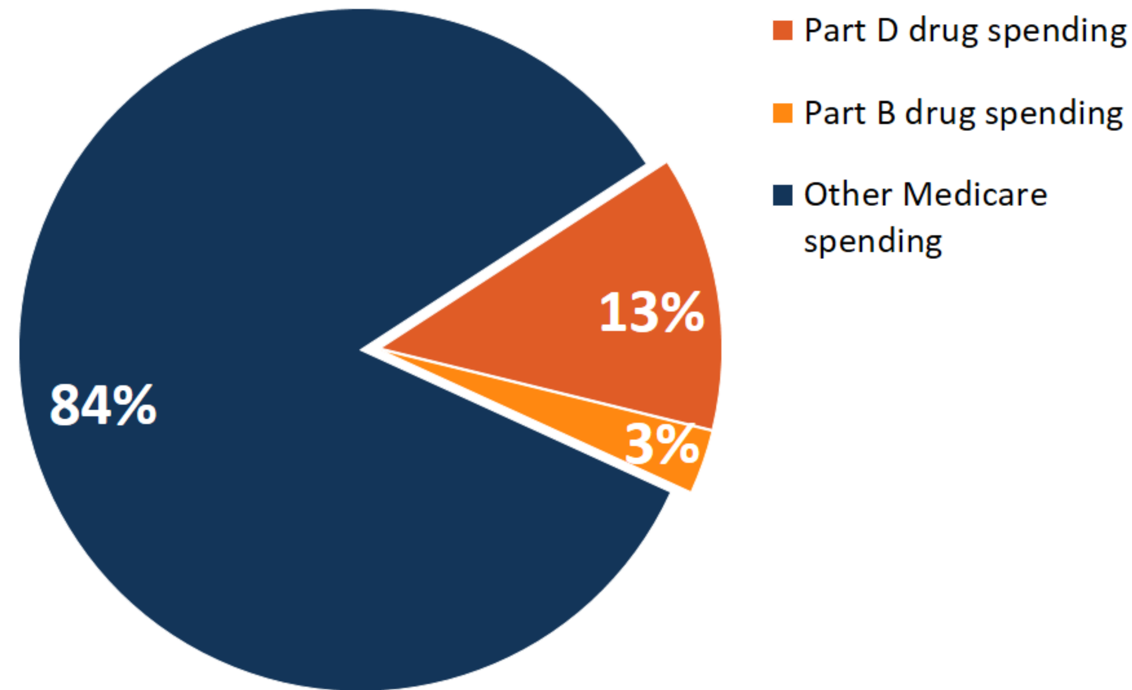
Medicare Spending on Drugs (2016)



Total Medicare Drug Spending in 2016 = $128.6 billion
Total Medicare Spending in 2016 = $678.7 billion

SOURCE: MedPAC, June 2018 Data Book (Part B drug spending) and 2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, Tables III.D1 and V.B1.

Part B vs. Part D Spending (2014)

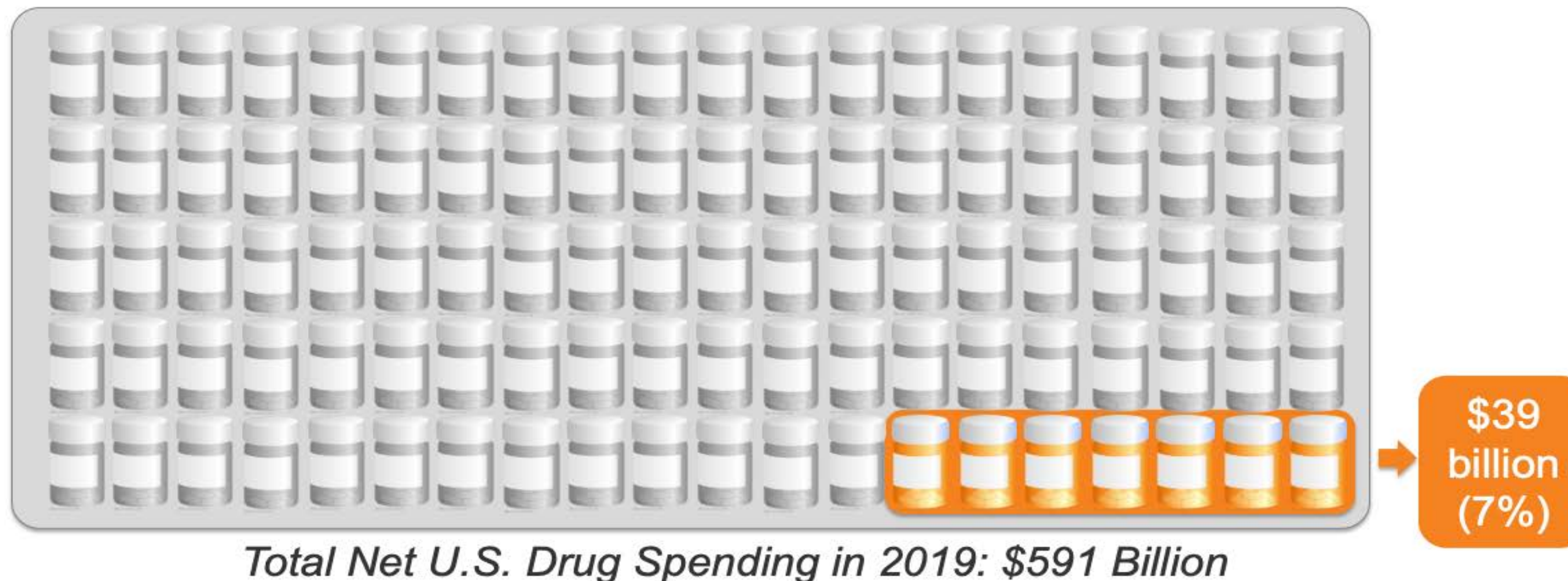


Total Medicare Spending in 2014 = $613.3 billion

SOURCE: DHHS ASPE Issue Brief, "Medicare Part B Drugs: Pricing and Incentives," Table 1, March 2016, and 2016 Medicare Trustees Report (Tables III.D3 and V.B1).

Most Favored Nation Approach

https://www.kff.org/wp-content/uploads/2020/08/Figure-1-Most-People-Are-Unlikely-to-See-Drug-Cost-Savings-From-President-Trumps-Most-Favored-Nation-Proposal.png

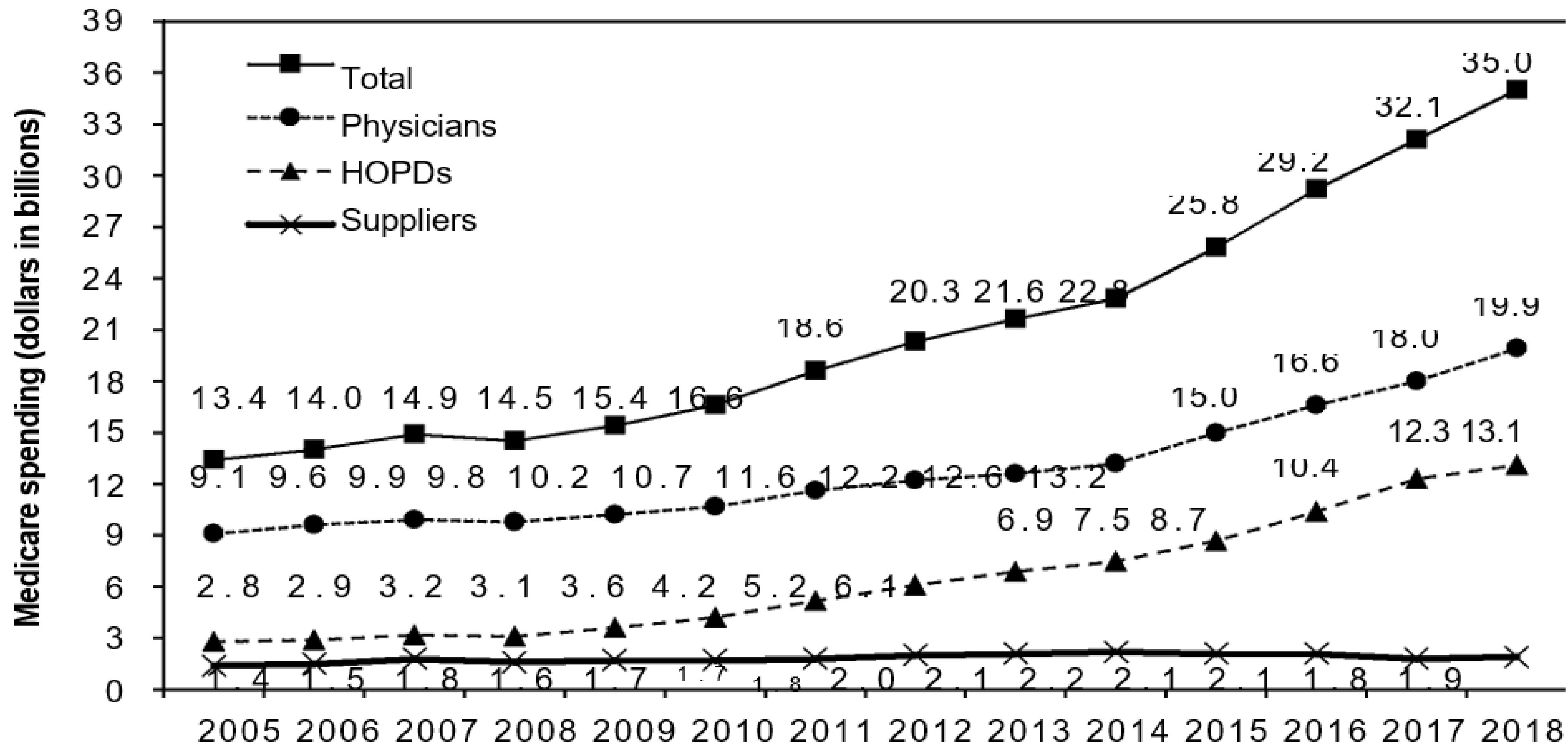


Medicare Part B Drug Spending (2018 data)

- $35 billion (includes physicians, suppliers, hospital outpatient departments (HOPDs)), up 9% from 2017
- Physicians accounted for about 57% of drugs billed; suppliers about 5%, HOPDs about 38% ($13.1B – thought to be reduced from estimated $15B if the 340B payment reduction had not occurred, which reduced the payment rate for certain drugs to ASP – 22.5%)
- Vaccines: influenza ($706M), pneumococcal ($627M), hepatitis B ($38M)
- Top 10 drugs accounted for 42% of Part B drug spending (all 10 are biologics)
  - #1 = Eylea - $2,577 M

MedPac*, A Data Book: Healthcare Spending and the Medicare Program,"* (July 2020), www.medpac.gov

Medicare spending for Part B drugs furnished by physicians, hospital outpatient departments, and suppliers, 2005–2018



http://medpac.gov/docs/default-source/data-book/july2020_databook_entirereport_sec.pdf?sfvrsn=0

Change in Medicare payments and utilization for separately payable Part B drugs, 2009–2018

	2009	2018	Average annual growth 2009–2018
Total payments: Separately payable Part B drugs (in billions)	$11.9*	$33.1*	12.0%
Total payments: All Part B drugs excluding vaccines (in billions)	$11.7	$31.8	11.7
Number of beneficiaries using a Part B drug (in millions)	2.7	3.9	4.3
Average total payments per beneficiary who used a Part B drug	$4,402	$8,165	7.1
Average number of Part B drugs per beneficiary	1.39	1.35	–0.4
Average annual payment per Part B drug per beneficiary	$3,158	$6,047	7.5
Total payments: All Part B vaccines (in billions)	$0.2	$1.3	21.9
Number of beneficiaries using a Part B vaccine (in millions)	13.4	16.8	2.5
Average total payments per beneficiary who used a Part B vaccine	$16	$77	18.9
Average number of Part B vaccines per beneficiary	1.08	1.20	1.2
Average annual payment per Part B vaccine per beneficiary	$15	$64	17.5

http://medpac.gov/docs/default-source/data-book/july2020_databook_entirereport_sec.pdf?sfvrsn=0

Top 10 Part B drugs paid based on ASP, by type of provider, 2017 and 2018

	Dollars (in millions)					
	Total Part B drug spending		Physician and supplier Part B drug spending		HOPD Part B drug spending	
	2017	2018	2017	2018	2017	2018
Eylea	$2,469	$2,577	$2,312	$2,435	$158	$142
Keytruda	1,037	1,813	394	764	643	1,049
Opdivo	1,474	1,718	695	827	778	891
Rituxan	1,758	1,703	857	867	900	836
Prolia/Xgeva	1,243	1,420	763	909	481	511
Neulasta	1,405	1,373	653	640	751	733
Lucentis	1,039	1,217	1,006	1,186	32	30
Remicade	1,347	1,154	821	745	526	408
Avastin	1,071	1,014	524	503	547	511
Herceptin	786	823	354	386	432	438
Total spending, top 10 drugs	**$13,627**	**$14,812**	**$8,379**	**$9,263**	**$5,249**	**$5,549**
Total spending, all Part B drugs	**$32,083**	**$34,955**	**$19,801**	**$21,832**	**$12,282**	**$13,123**

http://medpac.gov/docs/default-source/data-book/july2020_databook_entirereport_sec.pdf?sfvrsn=0

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Why is it Important to Understand the Payment Methodology?

- Determine Business Plan
  - Who will be the customers?
    - Physicians
    - Hospitals
    - Suppliers
  - What is the most financially attractive payment venue?
    - Part B or part D?
    - HOPD vs physician office
  - Develop clinical trial evidence to support the delivery avenue

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Coverage Comes Before Payment!

- "Innovator's Guide to Navigating Medicare", Version 3.0, available at http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf
- Product must (1) fit a Benefit Category; (2) not be statutorily excluded; (3) reasonable and necessary for diagnosis and treatment.
    - National Coverage Determinations (NCDs), Local Coverage Determinations (issued by a Medicare Administrative Contractor) - May limit coverage to certain diagnoses, other conditions for payment (e.g., evidence supporting use of product); use only when other product fails, etc.)
- Three general Part B categories: (1) drugs furnished "incident to" the service of a physician; (2) drugs administered through a covered item of durable medical equipment (DME); or (3) drugs specified by statute.
- Coding (HCPCS) – not necessarily indicative of coverage

Part B Drugs

- DME Mail Order or pharmacy (e.g., insulin provided for use with a pump); hemophilia clotting factors; antigens intravenous immune globulin provided in the home
- Physician Office – drugs “incident to” a physician service
- Hospital Outpatient – Pass-Through for some drugs
- Immunosuppressive drugs – Part B coverage for Medicare Covered Transplant
- Oral Anti-Cancer Drugs – Part B coverage for cancer treatment
- Oral Anti-emetic Drugs – Part B coverage within 48 hours of chemotherapy
- EPO – mostly billed by dialysis facility as part of bundled rate
- Vaccines – Influenza, pneumococcal and hepatitis B (in certain circumstances)
- Parenteral Nutrition – Part B if permanent dysfunction of digestive tract
- Clotting Factors

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Infusions and Injections

- Medicare Part B covers drugs that are administered by infusion or injection in physicians' offices and HOPDs if they (1) meet the statutory definition of a drug or a biological; (2) are usually not self-administered, (3) are incident to a clinician's service, (4) are reasonable and necessary for the diagnosis or treatment of an illness or injury, and (5) have not been determined by the Food and Drug Administration (FDA) to be less than effective.

Part B vs. Part D

- Part B covers drugs that are not usually self-administered (subject to some exceptions).
- Part D-covered drugs are drugs available only by prescription, and used for a medically-accepted indication, which are not covered under Part B (or Part A). Some drugs are excluded from Part D coverage (e.g., barbituates).
- CMS recommends (but does not require) that a physician note on the prescription that it should be "Part D" status if there is likely to be confusion.

CMS, "*Medicare Part B versus Part D Drug Coverage Determinations,*" www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0652.pdf (updated Oct. 2012).

Medicare Parts B/D Coverage Issues

- DME Supply Drugs: Part B for home; Part D for LTC Facility
- "Incident to" Physician Service – No Part D Coverage
- Immunosuppressant Drugs – Part B for Medicare Covered Transplant; Part D for other situations
- Oral Anti-Cancer Drugs – Part B for cancer; Part D for other indications
- Oral Anti-Emetic Drugs – Part B within 48 hours of chemo; Part D for other situations
- EPO – ESRD benefit; Part D otherwise
- Vaccines: Part B for influenza, pneumococcal and hepatitis B (intermediate to high risk); Part D for other hepatitis B vaccinations, other vaccinations (unless direct exposure in which case covered under Part B when provided incident to a physician service)
- Parenteral nutrition – Part B if "permanent dysfunction of digestive tract," Part D for other situations

www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/BvsDCoverageIssues.pdf

Physician Office Setting

“Incident to” Physician Service

- Drugs are billed in addition to the physician service
- Billed by the physician or certain non-physician practitioners – treatment generally in the office
- Must be part of the normal course of treatment, during which a physician personally performed an initial service and remains actively involved in the course of treatment.
  - An integral part of the patient’s treatment course
  - Commonly rendered without separate charge to the patient
  - An expense to the physician

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“Incident to” Drugs - Payment

- Section 303 of the Medicare Modernization Act (2003 – same law that established Part D) established ASP as the reimbursement level, effective 1/1/2005.
- ASP is the manufacturer’s sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. Soc. Sec. Act. Section 1847A(c).
- ASP + 6%
- Medicare contractors get ASP pricing files – so payment amounts should be standard
- ASP calculation explained in 42 C.F.R. 414.904

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Hospital Outpatient Department Setting

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Hospital Outpatient Drugs – Pass Throughs

- Most services are paid on a bundled payment basis (the Hospital Outpatient Prospective Payment System), including some drugs.
- Current orphan drugs, current drugs and biological agents and brachytherapy used for the treatment of cancer, current radiopharmaceutical drugs and biological agents receive temporary additional payments.
- Certain new drugs and biological agents also receive pass-through payments if costs are "not insignificant." Payments are made for at least 2 years, but not more than 3 years.
- Special rules for nonimplantable biologics.

www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/drug-application-requirements.pdf

OPPS – Pass Throughs

- Drugs that are granted “pass through” payment status are required by law to be paid at either the amount paid under the physician fee schedule, or, if the drug is included in the Part B drug competitive acquisition program (CAP), at the Part B drug CAP rate [CAP is defunct].
- Drugs that have pass-through status may have coinsurance amounts that are less than 20 percent of the OPPS payment amount. This is because pass-through payment amounts, by law, are not subject to coinsurance. CMS considers the amount of the pass-through drug payment rate that exceeds the otherwise applicable OPPS payment rate to be the pass-through payment amount. Thus, in situations where the pass-through payment rate exceeds the otherwise applicable OPPS payment rate, the coinsurance is based on a portion of the total drug payment rate, not the full payment rate.

Medicare Claims Processing Manual (MCPM), Chap. 17, Sec. 10

ASP Reporting

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

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ASP Calculation: *Generally*

- 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."

ASP Calculation: *Generally*

- Failure to provide timely ASP data can result in fines of $10K per day
- Providing false information can result in fines of $100K for each false item
- Coverage under Part B also requires participation in Medicaid, 340B, and VA contracting

ASP Calculation: *Generally (cont.)*

- 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.)*

- 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: *Generally (cont.)*

- 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
- Companies differ in how to address intertemporal bundles

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"
  - "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

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ASP Calculation:
Bona Fide Service Fees (cont.)

- 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

ASP-Based Reimbursement

- ASP is calculated at the smallest unit using weighting by package size, and combines data across multiple products where the products are therapeutically, pharmaceutically, and bioequivalent.
- 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)

ASP-Based Reimbursement *(cont.)*

- 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)

ASP-Based 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 2019) cost less than $130 per administration – proposed to be increased to $110 for 2017
  - “SCODs”
  - Therapeutic radiopharmaceuticals
- 340B drugs are reimbursed at ASP – 22.5%

ASP-Based Reimbursement *(cont.)*

- Biosimilars are reimbursed at their own ASP plus the 6% of the *reference* drug

ASP-Based Reimbursement *(cont.)*

- In the proposed 2021 Physician Fee Schedule rule, CMS has proposed to purportedly "codify" its existing practice of considering *some* 505(b)(2) drugs as "multiple source drugs" that are reimbursed the same as the reference drug
- Will do its own review of the nature of the products, and will not necessarily use FDA's determination as the final word
- Does not necessarily line up with the statute

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Coding

- Hospitals and physicians indicate the Part B drugs they have used on their claim forms using “HCPCS” codes
- As of this year, new codes are now issued 4 times a year
- Requires filing an application with the HCPCS Committee

Future of Part B Drug Reimbursement

- All kinds of ideas have been generated previously, including:
  - Reduction in the 6% addition, and adding a fixed dispensing fee
  - Reinstating the competitive acquisition plan program
  - Using international pricing as a benchmark
  - Creating a value-add component that is based on negotiations

HAVE A QUESTION?

Please submit your questions on the Session Chat box on the right.

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