Medicare Part B Drug Pricing
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Medicare – the basics

Medicare: entitlement is based on age, disability or ESRD (end stage renal disease). It is distinct from Medicaid.
There are four parts (generalized):

Part A	Part B	Part C	Part D
Covers drugs under a Medicare covered stay in a hospital or skilled nursing facility (SNF).	Covers drugs that are typically not self-administered. For example, they are drugs administered by a provider or at a dialysis center.	Medicare Advantage plans (an alternative to traditional Part A & B coverage) - includes prescription drug coverage (variation will exist among plans).	Prescription drug coverage

Drugs – the definition

- The detailed definition for **drugs or biologics** is from the Soc. Sec. Act 1861(t)(1).
- Direct link: **https://www.ssa.gov/OP_Home/ssact/title18/1861.htm.**
- Key points within the definition (see full definition):
  - The drug or biologic has to be part of an approved Compendia.
  - Includes any drug or biologic used in an anticancer chemotherapeutic regimen for a "medically accepted indication."
    - "Medically accepted indication" means an indication approved by the FDA and includes another use of the drug if it is:
      - Approved by the FDA
      - Supported by one or more citations in certain compendia
      - The carrier determines based on guidance provided by the Secretary whether such use of the drug is medically accepted based on clinical evidence.

Medicare Coverage for Part B Drugs:

- Covers drugs that are furnished “incident to” a physician’s services provided that the drugs are not usually self-administered by patients who take them, and hospital outpatient departments (HOPD), and it also covers certain drugs provided by pharmacies and suppliers.
- In general, drugs & biologics are covered only if all of the following requirements are met:
  - They meet the definition of drugs or biologics.
  - There are of the type that are not usually self-administered.
  - They meet all of the general requirements for coverage of items as incident to a physician’s services.
  - They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice.
  - They are not excluded as noncovered immunizations; and
  - They have not been determined by the FDA to be less than effective.
- Additional information (detail) may be found in the Medicare Benefits Policy Manual.

Polling Question

Medicare Part B only pays for drugs that have approved indications (FDA approved labeling).

(a) True.

(b) False.

Medicare Coverage for Part B Drugs

- Must be reasonable and necessary for diagnosis or treatment of illness or injury, or approved preventive (vaccines) covered by statute, limited to influenza, pneumococcal, hep B. *(Covid)*
- Covered for labeled uses, and in some situations for off-label use, e.g. for some cancer drugs when off-label use is supported by recognized drug compendia; non-cancer drugs if reasonable and necessary. Both situations are limited to physician offices and hospital outpatient departments (HOPDs).

See Medicare Benefit Policy Manual, Ch. 15, Section 50.

Polling Question # 2

Medicare Part B may cover and reimburse:

(a) Drugs which are incident to a physician's service and not self-administered.

(b) Any drug furnished by a pharmacy so long as prescribed by a physician.

(c) Injectable drugs furnished directly by the prescriber.

(d) All of the above.

(e) None of the above.

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 and not usually self-administered
- Hospital Outpatient – Pass-Through transitional payments 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), (Covid)
- Parenteral Nutrition – Part B if permanent dysfunction of digestive tract
- Clotting Factors
- Biosimilars

Price has been the largest driver of Part B drug spending growth (per MedPAC publication)

https://www.medpac.gov/wp-content/uploads/2021/10/Part-B-drugs-MedPAC-01-Sept-2022.pdf

	Part B
Spending in 2020:	• $40.7 billion*
Spending growth from 2009-2020:	• Over 9 percent per year on average
Largest driver of the spending growth from 2009-2020:	• Growth in average price per Part B drug, which reflects post-launch price growth; launch of new, higher-priced products; and shifts in mix of drugs
Spending is highly concentrated:	• 20 products account for 52% of spending • Examples of indications of top products: cancer, macular degeneration, inflammatory conditions

Costs to Beneficiaries for Part B Drugs

(based on 2019 data)

- Note limitations in data – these numbers do not reflect *actual* payments.
- Beneficiaries in traditional Medicare are charged 20% of the cost of Part B drugs, with no annual limit on their out-of-pocket costs.
- (Updated: 2023 implementation of capped insulin costs)
- One-fourth of the 4.1 million traditional Medicare beneficiaries who used one or more Part B drugs in 2019 had average annual cost-sharing liability of at least $1,000.
- Like beneficiaries in traditional Medicare, Medicare Advantage enrollees typically face 20% coinsurance for Part B drugs, but can be exposed to higher cost-sharing requirements for these drugs when administered by an out-of-network provider.
- Some drugs have very high cost-sharing, e.g. Opdivo (cancer) used by more than 30,000 beneficiaries, with an annual cost-sharing liability of $10,200; Dazalex (multiple myeloma) used by nearly 12,000 beneficiaries, with average cost-sharing liability of $12,900.

https://www.kff.org/medicare/issue-brief/medicare-part-b-drugs-cost-implications-for-beneficiaries-in-traditional-medicare-and-medicare-advantage/ (March 2022)

CMS Guide to Drug Payment Methodology (please refer to link on previous slide for reference. Image used for summarized explanation).

DRUG TABLE

Provider/Drug	Hepatitis B Vaccine	Pneumococcal & Influenza Vaccines	Hemophilia Clotting Factors	Immuno Suppressive	Erythropoiesis Stimulating Agents ESA's)	Self Admin Anti-Cancer Anti-Emetic for cancer treatment	Other Drugs
Hospital Inpatient (IP) A -Prospective Payment System (IPPS)	3	3	2	1	1	1	1
Hospital IP A - not IPPS	3	3	3	3	3	3	3
Hospital Outpatient Prospective Payment System (OPPS)	3	3	3	5 (30 day supply)	5	5	5
Skilled Nursing Facility (SNF) IP	3	3	1	1	1	1	1
SNF OP or IP B	3	3	3	3	6	6	6
End Stage Renal Disease (ESRD) Facility	2	2	6	6++	1 or 2†	6	1 or 2†
Comprehensive Outpatient Rehabilitation Facility (CORF)/ Outpatient Rehabilitation Facility (ORF)	2	2	6	6	6	6	6
Community Mental Health Center (CMHC)	6	6	6	6	6	6	6
Rural Health Clinical (RHC)/Federally Qualified Health Clinic (FQHC) -hospital based	1	8	5	5	5	5	5
RHC/FQHC-independent	1	8	6	6	6	6	6
Home Health Agencies (HHA)	3	3	6	6	6	6	6 (except for osteoporosis)

Provider/Drug	Hepatitis B Vaccine	Pneumococcal & Influenza Vaccines	Hemophilia Clotting Factors	Immuno Suppressive	Erythropoiesis Stimulating Agents ESA's)	Self Admin Anti-Cancer Anti-Emetic for cancer treatment	Other Drugs
Hospice	6	6	6	6	1	1	1
Physicians	2	2	2	2	2	2	2
Pharmacy	2	2	2,7	2, A	2	2, A	2,7
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier	2	2	2	2	2	2	2
Critical Access Hospital (CAH) IP or OP Method I or II	3	3	3	3	3	3	3

CMS Guide to Drug Payment Methodology

- Medicare Claims Processing Manual, Ch. 17 – Drugs and Biologicals, Sec. 10, Table 1
- Refer to the following link for additional information: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.

Key **to the following Table:**

NOTES:

DME MACs do not process claims for blood clotting factors.

Unless noted otherwise, claims for these drugs are submitted to the A/B MAC (B)

† - Drugs & biologicals outside the composite rate and/or ESRD PPS are paid as described in 2 below. Those inside the composite rate and/or ESRD PPS are paid as described in 1. (ESRD PPS effective January 1, 2011)

1 - Included in PPS rate, or other provider-type all inclusive encounter rate

2- Price taken from CMS drug/biological pricing file effective on the specific date of service

3 - Based on reasonable cost (101% reasonable cost in CAH)

4 - Lower of cost or 95% AWP paid for drug in addition to PPS rate, or in addition to reasonable cost if excluded from PPS

5 - OPPS-APC, whether pass-thru drug or not

6 - Cannot furnish as that "provider" type

7 - May not bill DME-MAC or MAC for drugs furnished incident-to a physicians' service

8 - Payment made at the time of cost settlement

- **A - Bills are submitted to the DME MAC**

Physician Office Setting

"Incident to" Items and Services

“Incident to” a 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
  - May be rendered without separate charge to the patient
  - An expense to the physician

“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%
- ASP calculation explained in 42 C.F.R. § 414.904

Hospital Outpatient Department Setting

APCs and Transitional Payments

Hospital Outpatient Drugs and Transitional Pass-Throughs

- Most services are paid on a bundled payment basis (the Hospital Outpatient Prospective Payment System), including some drugs.
- Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biological agents.
- Current orphan drugs, current drugs and biological agents and brachytherapy used for the treatment of cancer, current radiopharmaceutical drugs and biological products 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.
- Some “drugs” go through device pass-through process, e.g., skin products.

OPPS – Pass-Throughs

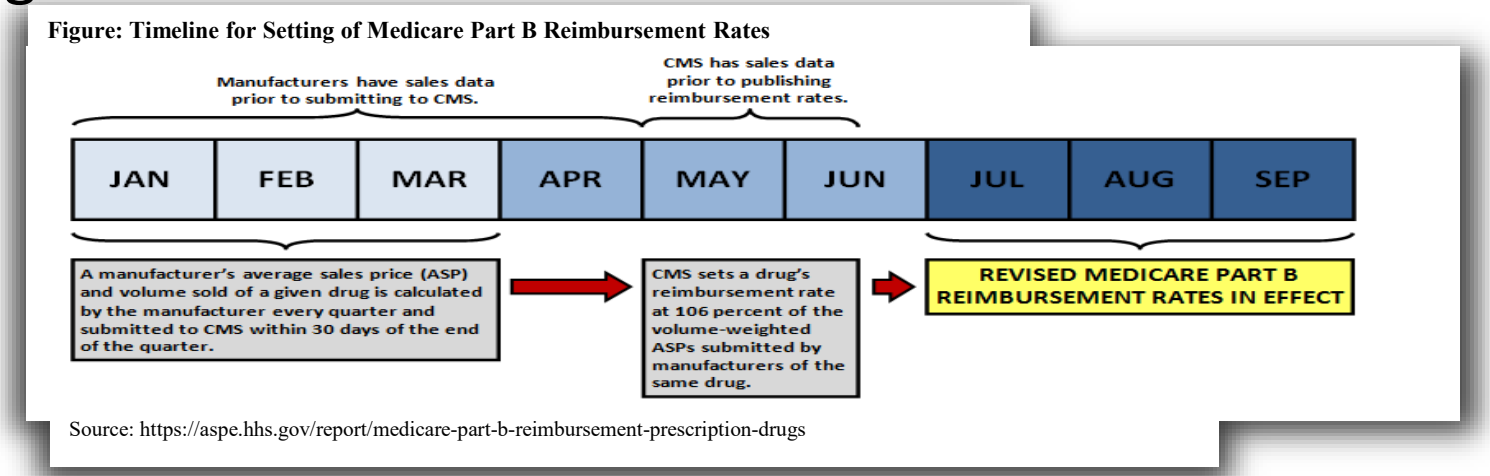
- Drugs that have pass-through status may have coinsurance amounts that are less than 20 percent of the OPPS payment amount. This is because pass-through payment amounts, by law, are not subject to coinsurance. CMS considers the amount of the pass-through drug payment rate that exceeds the otherwise 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

Average Sales Price (ASP)

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 to eligible purchasers
  - "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.)*

- 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
    - " 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 (cont.)*

- By statute, the 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
- Prices exempt from Best Price are excluded from ASP

ASP Calculation: *Generally (cont.)*

Key Best Price Exclusions (42 C.F.R. § 447.505(c))

- Prices to VA, DoD, PHS, IHS
- FSS purchases
- "Any price" to 340B covered entities
- Manufacturer-sponsored drug discount cards, coupons, co-pay assistance programs, patient refund or rebate programs (as long as patient gets full value of program, no benefit goes to pharmacy or other entity)
- Free goods (e.g., vouchers), but must not be contingent on any purchase requirement and full value of free good must go to patient (no benefit to pharmacy or other entity)
- "Bona fide service fees"
- PBM price concessions, with exceptions
- Prices to Medicare Part D plans, or "qualified retiree prescription drug plans," for Part D drugs
- Reimbursement by manufacturer for recalled, damaged, expired, otherwise unsalable returned goods (including reimbursement for cost of the good and for costs of returning it)

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 associated with sales subject to the ASP reporting requirement
- The term “lagged” is not defined in available CMS ASP guidance
- CMS AMP regulations define “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” (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
- Manufacturers permitted, but not required, to smooth indirect ineligible sales

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 in ASP
- MDRP bundling approach is one potential option, but not a requirement
- Consider 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

ASP Calculation:
Bona Fide Service Fees (cont.)

- Enforcement examples
  - 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; **Lilly - $61 million (2022)**)
    - 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-based payment rate is calculated at the smallest unit using weighting by package size, for all NDCs assigned to the HCPCS code
  - Combines data across multiple products where the products are therapeutically, pharmaceutically, and bioequivalent.
- Volume Weighting
  - 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-Based Reimbursement *(cont.)*

- Previously, 340B drugs were reimbursed at ASP – 22.5%
- As of the 2023 Final Rule, that has been restored to ASP + 6%
- Going forward, all separately payable drugs will be paid at ASP + 6%

Polling question #3

True or False: Entities that receive ASP reimbursement must participate in 340B

Inflation Reduction Act

- Signed into law on August 16, 2022
- Drugs are not the entirety of the legislation, but are a significant part
- Finally overrides the MMA non-negotiation provision (20 years later)

Inflation Reduction Act *(cont.)*

- Certain Part B drugs become eligible for a negotiated price in 2028
  - A maximum of 15 drugs, combination of Part B and Part D drugs, can be subject to negotiation in that year
  - Negotiations begin approximately 2 years before price goes into effect
- Applies to single source drugs with a high spend that for NDA-type drugs have been on the market for at least 7 years, and for BLA-type products have been on the market at least 11 years
  - Exception applies for certain biologics if the launch of a biosimilar is imminent
  - Orphan drugs also excepted

Inflation Reduction Act *(cont.)*

- CMS negotiates a “maximum fair price,” which is capped at a percentage of non-FAMP that becomes increasingly smaller the longer the product is on the market
  - 75% for small molecule drugs that are between 9 and 12 years past approval
  - 65% for drugs between 12 and 16 years
  - 40% for drugs beyond 16 years

Inflation Reduction Act *(cont.)*

- CMS uses various factors to start the negotiations
  - R&D costs
  - Costs of alternatives
  - Comparative effectiveness

Inflation Reduction Act *(cont.)*

- Part B drugs subject to an MFP will need to be available to customers at that price
  - Hospitals can choose the MFP or 340B, but not both
- Hospitals and physicians will get paid MFP plus 6%
- Pricing also figures into BP

Inflation Reduction Act *(cont.)*

- A new inflation penalty applies to virtually all Part B drugs
- That penalty is calculated by comparing a drug's ASP in a quarter beginning in 2023 to its ASP in Q3, 2021, and determining if it exceeded the CPI-U during the period from Jan., 2021 to the current period
- The excess is multiplied by Medicare units purchased
- For new drugs, the 3rd full quarter after launch is the benchmark, and penalties begin from 6th calendar quarter after the drug is marketed

Infrastructure Investment and Jobs Act

- Passed on Nov. 15, 2021
- Requires that manufacturers of single-dose containers or single-use package drugs refund the Medicare program for wastage of their drug, if more than 10% of the total
- CMS has implemented in its Physician Final Rule
- Will require that physicians (and hospitals) use either a JW modifier with an amount, or a JZ modifier, indicating no waste
- CMS will send invoices to manufacturers at a date that is TBD

ASP Calculation: *Generally (cont.)*

- As of 2022, manufacturers of any product that is reimbursed under Medicare Part B as a drug or biologic are required to submit ASP or face CMPs
- This applies, for instance to hyaluronic acid products and HCT/Ps
- Submission of data is not a guarantee of ASP reimbursement

ASP Calculation: *Generally (cont.)*

- 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 FSS contracting

Biosimilars

- Biosimilar is defined as a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA). S/S/A 1847A(c)(6)(h).
- Per ACA, after 7/1/2010, payment amount would be the sum of (1) ASP as determined using the methodology described under 1847A(b)(6) applied to a biosimilar biological product for all NDCs assigned to such product in the same manner as is applied to drugs described in such paragraph; and (2) 6% of the payment amount using the methodology of section 1847A(b)(4) for the corresponding reference biological. Final Rule notes the first FDA approval of the biosimilar product under ACA pathway did not happen until March 6, 2015.
- Per PFS Final Rule for CY 2016, above methodology revised to single ASP payment limit for biosimilars that are assigned to a specific HCPCS code, i.e., products that rely on a common reference biologic's license application will be grouped into the same payment calculation for determining the single ASP payment. Eff. Date Jan. 1, 2016.

Biosimilars, cont.

- In PFS Proposed Rule for 2018, CMS solicited comments and data on the 2016 approach, and received more than 200 comments, most opposed on grounds of access, limit introduction of products to the U.S. market, fail to maximize competition and savings. CMS changed the payment policy to provide for the separate coding and payment for products approved under each abbreviated application, rather than grouping all biosimilars with a common reference product into "group" codes. Effective date likely mid-2018 (per CMS).
- Per Inflation Reduction Act, Medicare payment for qualifying biosimilars is required to be ASP + 8% (not 6%) of the reference biological for a 5 year period as defined in the statute. "Qualifying biosimilar" defined as a biosimilar with an ASP that is not more than the ASP of the reference biological. ASP drug pricing file reflects this approach beginning 10/22.

HAVE A QUESTION?

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