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scan Medicare Part B Step Therapy

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Objectives



Provide the Rationale and Strategic intent behind the Part B Step Therapy



Review Program Components



Present the Part B Drug List



Discuss Stakeholder Roles and Impacts

Part B vs. Part D Medication Coverage

Part B

- **Administered by healthcare provider at doctor's office, hospital outpatient setting, infusion centers, or home health care**
 - Injected, infused, surgically implanted
 - Examples: IV chemotherapy (Keytruda), intravitreal injection for macular edema (Eylea)
- **Additional Coverage:**
 - Medications requiring administration via DME (e.g., Budesonide administered via nebulizer)
 - Certain oral anti-cancer medications (e.g. Capecitabine)
 - Certain vaccines (e.g., Flu vaccine)

Part D

- **Self-administered at home**
 - Oral, topical, subcutaneous injection
 - Examples: cholesterol medication (lovastatin), cream for psoriasis (Elidel), long-acting insulin (Lantus), other injectable diabetic medications (Ozempic)
- **Exclusions:**
 - Medications for weight loss (e.g., Wegovy, Zepbound)
 - May be covered for Part D indications; e.g., sleep apnea and adverse cardiovascular event risk prevention (e.g., heart attacks and strokes).
 - Prior authorization may apply.



Medicare Part B Spending Growth



GROWTH

Part B is one of the fastest growing Medicare cost areas, outpacing other drug spending such as Part D.

- Average 9.2% annually per enrollee (2008-2021) vs 2.6% for Part D.
- Growth driven by specialty biologics (89% of spending growth).
- Rising drug costs continue to place a significant financial strain on patients, providers, and payers.



PART B SPEND

Highest concentration in oncology, rheumatology, and ophthalmology.



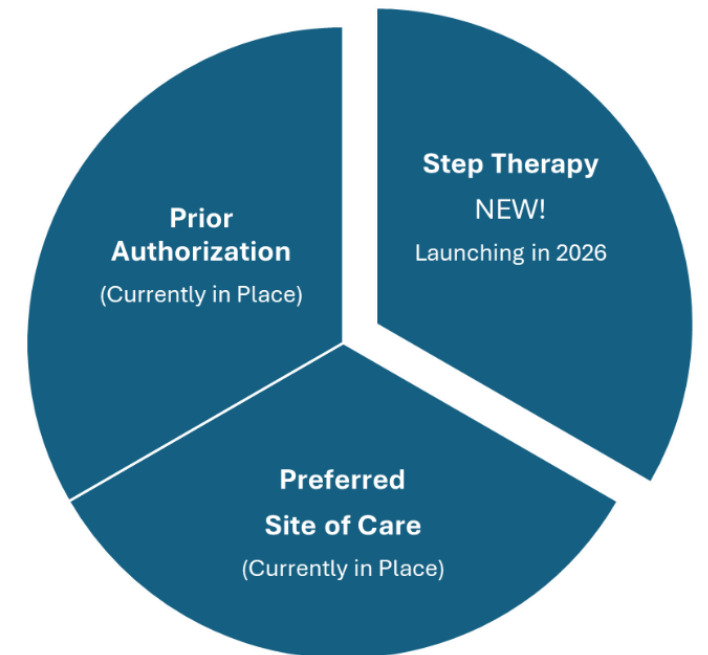
PART B STEP THERAPY ADOPTION

- In 2018, CMS issued new guidance allowing Medicare Advantage (MA) plans to implement step therapy for Part B drugs.
- Step therapy protocols increasingly used by commercial and public payers.



SCAN'S VISION

- Adopt a holistic approach that integrates pharmacy and medical benefits for injectable and infused therapies.
- Improve member experience by fostering collaboration among healthcare stakeholders.



Cost Comparison: Evenity vs. Preferred Agents for the treatment of osteoporosis

Zoledronic Acid/Prolia/Jubbonti Annual Cost Savings of \$26-\$30k per patient

Drug Name	# Doses per year	Total Annual Drug Cost (ASP)	Patient Annual Cost Share	Annual Cost savings per patient: Evenity to Preferred
Zoledronic Acid	1	\$25	\$5	\$30,386
Prolia®/Jubbonti®	2	\$3,526	\$705	\$26,185
Evenity®	12	\$30,416	\$6,083	\$0.00

ASP reference: Optum 360. (n.d.). *EncoderPro.com* [Online medical coding software]. Retrieved from [Optum EncoderPro.com for Payers - Average Sales Price \(ASP\) Pricing](https://www.encoderpro.com) on October 22, 2025.

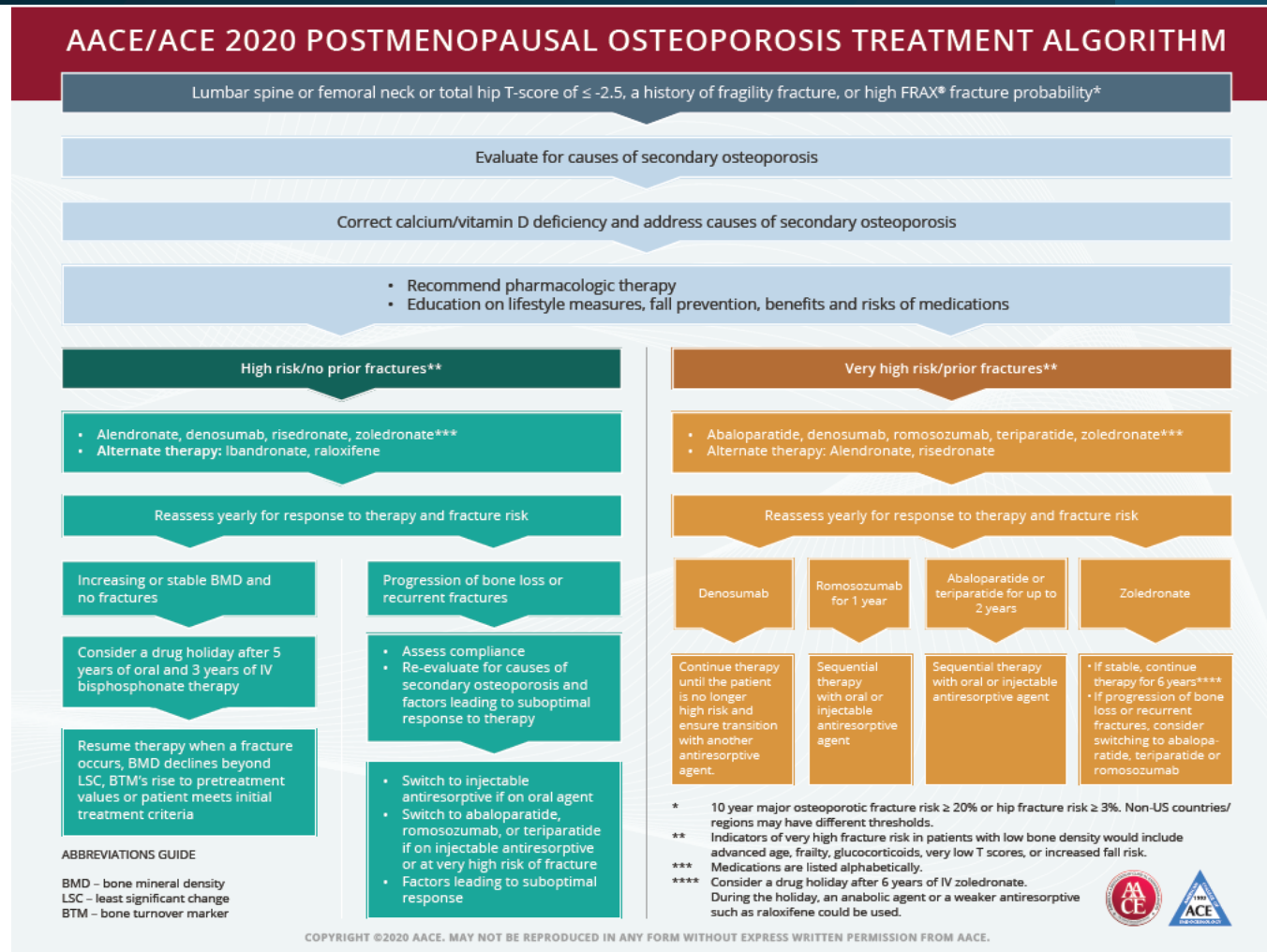
ALERT: US Boxed Warning

Potential risk of myocardial infarction, stroke and cardiovascular death

Evenity

Romosozumab may increase the risk of myocardial infarction, stroke, and cardiovascular death. Romosozumab should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. If a patient experiences a myocardial infarction or stroke during therapy, romosozumab should be discontinued.

AACE/ACE 2020 Postmenopausal Osteoporosis Clinical Practice Guideline



2026 Part B Step Therapy Program

Step therapy is a utilization management (UM) tool that requires initiation of treatment with a preferred clinically effective medication before progressing to non-preferred alternatives.

It supplements Medicare National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) in establishing coverage under Part B benefits.

Step Therapy will apply under the following conditions

- ❖ Proposed preferred drugs must have a medically accepted indication for the member's condition.
- ❖ **NEW STARTS ONLY:** Existing therapies within the past 365 days are exempt.
- ❖ Preferred status does not exempt a drug from prior authorization.
- ❖ Exceptions and appeals are permitted for access to non-preferred drugs.
- ❖ Will apply to all of CA and select plans in AZ, beginning **01/01/2026.**

Step Therapy Target Categories 2026

Drug Category		Preferred	Non-preferred
Oncology	Bevacizumab	Alymsys®, Mvasi®, Zirabev®	Avastin®, Vegzelma®
	Trastuzumab	Kanjinti®, Ogivri®, Ontruzant®, Trazimera®	Herceptin®, Herceptin Hylecta®, Hercessi®, Herzuma®
Rheumatology	Infliximab	Avsola®, Inflectra®	Remicade®, Renflexis®
	Rituximab	Riabni™, Ruxience®, Truxima®	Rituxan®, Rituxan Hycela®
Immune Globulin	Subcutaneous	Cutaquig®, Hizentra®, Xembify®	Cuvitru®, HyQvia®
	Intravenous	Gammagard®, GamunexC®	Alygot™, Asceniv™, Bivigam®, Gammaked®, Gammaplex®, Octagam®, Panzyga®, Privigen®
Endocrinology	Bone density agents for osteoporosis	Zoledronic acid, Denosumab (Jubbonti®/Prolia®)	Evenity®
Ophthalmology	VEGFi Inhibitors	Bevacizumab, Beovu, Byooviz™, Eylea®/Eylea® HD	Cimerli®, Lucentis®, Pavblu™, Susvimo™, Vabysmo®
Granulocyte-Colony Stimulating Factors	Short-Acting G-CSF	Nivestym®, Releuko®	Granix®, Neupogen®, Nypozi®, Zarxio®
	Long-Acting G-CSF	Fulphila®, Nyvepria™, Udenyca®	Fylnetra®, Neulasta®/Neulasta Onpro®, Rolvedon™, Stimufend®, Ziextenzo®



BCG0317- PART B STEP THERAPY CRITERIA FOR INTRAVENOUS IMMUNOGLOBULIN (IVIG)

Benefit Type: Medicare
Category: Utilization Management
Effective Date: 01/01/2026
Last Updated: 09/18/2025
Plan Info: SCAN Plan Documents
Network Coverage: In Network; Out of Network

This step therapy protocol applies to intravenous immunoglobulins (IVIGs). It is intended to supplement Medicare National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and relevant Medicare manuals when determining coverage under Part B benefits. In instances where coverage criteria are not fully established, SCAN Part B Drug Criteria documents will be utilized, in accordance with the [Prior authorization and Step Therapy for Part B Drugs Medicare Advantage Memo, in August 2018.](#)

Indications subject to step therapy (applicable to new starts only):

- All FDA-approved indications, or when use is supported by at least one of the CMS-approved authoritative compendia

Table 1. Intravenous Immunoglobulin (IVIG)

Preferred*	Non-Preferred
Gammagard® liquid (J1569) or GamunexC® (J1561)	Alyglo™ (J1552) Asceniv™ (J1554) Bivigam® (J1556) Gammaked™ (J1561) or Gammaplex® (J1557) Octagam® (J1568) Panzyga® (J1576) Privigen® (J1459)

*Preferred products may require a prior authorization review for medical necessity.

EXCEPTION CRITERIA

Coverage for non-preferred agent is provided when the member meets one or more of the following criteria:

1. Member has received the requested product in the past 365 days;
2. Use of at least one preferred alternative for the current condition;
3. Intolerable adverse event, inadequate response or contraindication to a preferred alternative

Step Therapy Criteria

UM Workflow Enhancements

- Update citation table to include SCAN medical policy references related to Step Therapy
- Document medical necessity criteria in alignment with CMS hierarchy, along with SCAN-specific Step Therapy requirements when the requested medication is subject to Step Therapy.

CMS Level of Hierarchy

Federal and State Law Mandates:

US Preventative Services Task Force (USPSTF)

CMS National Coverage Determination (NCD)

CMS Local Coverage Determination (LCD)

CMS Local Coverage Article (LCA)

CMS Medicare Managed Care Manual

CMS Medicare Benefit Policy Manual (MBPM)

- Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual Chapter 15

42 CFR 422.136 Medicare Advantage (MA) step therapy for Part B drugs

SCAN Medical Policy

- SCAN Part B Step Therapy Criteria

Nationally recognized evidence-based guidelines/criteria, in conjunction with the clinical judgement of a qualified health professional.

Areas for Collaboration

Challenge	Approach
Access, delays, and clinical concerns	<ul style="list-style-type: none">• Increase treatment flexibility by offering multiple preferred options per category.• Provide targeted provider education and regular collaboration meetings.• Strengthen referral-stage collaboration through peer discussions.• Restrict oncology step therapy to same-class medications, offering biosimilars to maintain clinical choice and cost efficiency.
Patient concerns about biosimilars	<ul style="list-style-type: none">• Promote shared decision-making and provider endorsement to build confidence in biosimilars.• Offer patient education and support tools (materials, websites, email, hotlines).
Operational complexity	<ul style="list-style-type: none">• Deliver comprehensive staff training on standardized workflows, documentation, tracking, and audit readiness to ensure consistent execution and compliance.• Integrate the program with existing claims systems and prior authorization tools and automation.• Ensure adequate staffing to support effective implementation and long-term operational success.

Program Support and Resources

EDUCATION MATERIALS

Access a comprehensive library of educational materials, including policies and step therapy criteria by visiting <https://medicalpolicy.scanhealthplan.com>.

TRAINING OPPORTUNITIES

Stay informed about upcoming training sessions, including schedules and registration instructions, to ensure your team is fully prepared.



CONTACT INFORMATION

For questions or additional support, please reach out to Member Services and Network Management via the following channels:

Phone: 1-800-559-3500

Email: PartBmeds@scanhealthplan.com

Provider Portal: [Availity](#) or [SCAN Portal](#)

ANNOUNCEMENTS

Check your emails for the **Provider Today Newsletter** for any Step Therapy changes or updates.

Q&A

Thank you!

Pharmacologic Treatment of Primary Osteoporosis or Low Bone Mass to Prevent Fractures in Adults: A Living Clinical Guideline From the American College of Physicians

Publication: Annals of Internal Medicine Volume 176, Number 2
<https://doi.org/10.7326/M22-1034>

• Recommendation 3:

- *ACP suggests that clinicians use the sclerostin inhibitor (romosozumab, moderate-certainty evidence) or recombinant PTH (teriparatide, low-certainty evidence), followed by a bisphosphonate, to reduce the risk of fractures only in females with primary osteoporosis with very high risk of fracture (conditional recommendation).*

Part B vs. Part D Medication Coverage



Treatments to Reduce Fractures in Postmenopausal Females With Primary Osteoporosis

Recommendations

RECOMMENDATION: ACP recommends that clinicians use bisphosphonates for initial pharmacologic treatment to reduce the risk of fractures in postmenopausal females diagnosed with primary osteoporosis (strong recommendation; high-certainty evidence).

RECOMMENDATION: ACP suggests that clinicians use the RANK ligand inhibitor (denosumab) as a second-line pharmacologic treatment to reduce the risk of fractures in postmenopausal females diagnosed with primary osteoporosis who have contraindications to or experience adverse effects of bisphosphonates (conditional recommendation; moderate-certainty evidence).

RECOMMENDATION: ACP suggests that clinicians use the sclerostin inhibitor (romosozumab, moderate-certainty evidence) or recombinant PTH (teriparatide; low-certainty evidence), followed by a bisphosphonate, to reduce the risk of fractures only in females with primary osteoporosis with very high risk of fracture (conditional recommendation).

RATIONALE: Bisphosphonates had the most favorable balance among benefits, harms, patient values and preferences, and cost among the examined drugs in postmenopausal females with primary osteoporosis and should be used as first-line treatment. Denosumab also had a favorable long-term net benefit, but bisphosphonates are much cheaper than other pharmacologic treatments and available in generic formulations. Evidence showed that the benefits of recombinant PTH (teriparatide) or the sclerostin inhibitor (romosozumab) may have outweighed harms compared with placebo in a select population of postmenopausal females (mean age >74 years) with osteoporosis and very high risk for fracture. Bisphosphonates were associated with higher risk for osteonecrosis of the jaw and atypical femoral fractures. Teriparatide may have resulted in no difference in risk of serious adverse events but probably increased the risk of withdrawal due to adverse events in RCTs after 36 months.

Pharmacologic Treatment of Primary Osteoporosis or Low Bone Mass to Prevent Fractures in Adults: A Living Clinical Guideline From the American College of Physicians

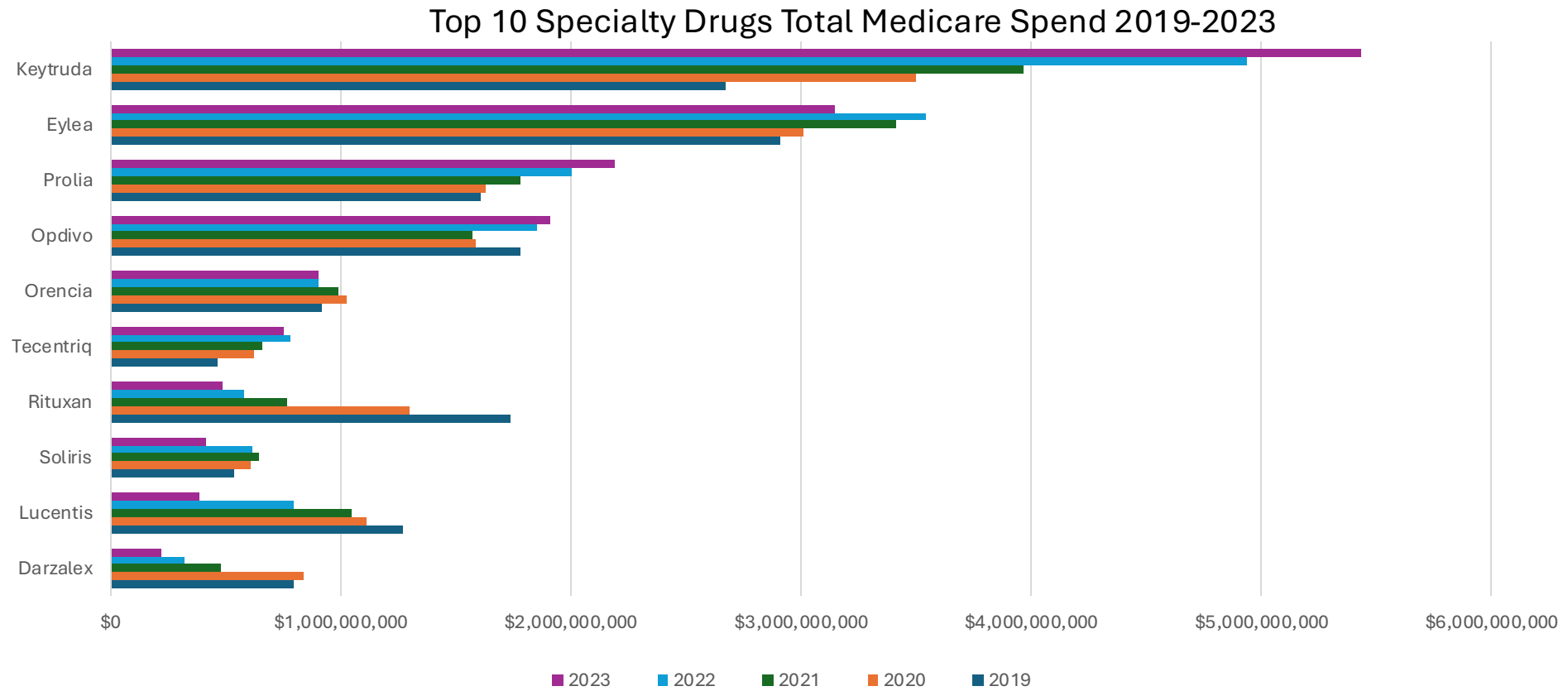
Considerations & caveats

- The recommendation for anabolic therapy in the “very high risk” group is *conditional*, reflecting lower certainty of evidence; shared decision-making is key.
- “Very high risk” is more of a clinical-judgement category than a rigid numeric cut-off in this guideline; documentation of risk factors and rationale should be clear.
- The choice of agent must consider patient comorbidities, contraindications (for example: recent MI/stroke may exclude romosozumab), renal function, ability to take oral medications, etc.

Part B vs. Part D Medication Coverage

- Part B
 - Not usually self-administered
 - Medications that are injected, infused, surgically implanted, etc. by healthcare provider
 - Additional coverage:
 - Medications requiring administration via DME, Immunosuppressive drugs for Medicare covered transplant, Hemophilia clotting factors, Antigens, IVIG provided at home for primary immunodeficiency, Certain oral anti-cancer/anti-emetic drugs, certain vaccines (flu, pneumococcal, Hep B for high-risk individuals), and parenteral nutrition
- Part D
 - Self-administered prescription drugs, **not covered under Part B (or Part A)**

Top 10 Specialty Drugs Total Medicare Spend 2019-2023



Source: CMS Website. [Medicare Part B Drug Spending Dashboard](#)

Medicare FFS Part B Spending Trends

Exhibit 2. Pharmaceutical Spending Trends: National Health Expenditures (NHE), Medicare Part D and Part B, 2014-2021*

Category	2014	2015	2016	2017	2018	2019	2020	2021	Percent Change 2008-2021
Medicare Part B Total Spending (\$B)	265.9	279	293.4	313.7	337.2	370.3	418.6	405.5	6.30%
Part B FFS Drug Allowed Charges (\$B)	21.8	24.1	27.5	30.6	33.5	37.3	38.8	40.5	8.70%
Part B FFS Drug Program Payment (\$B)	17.2	19	21.8	24.3	26.6	29.7	31.1	32.7	8.90%
Part B FFS Drug Program Payment per Enrollee (\$)	520	571	647	721	798	897	965	1,061	9.20%
Medicare Part D Spending per Enrollee (\$)	1,928	2,149	2,313	2,248	2,079	2,069	2,157	2,100	2.60%
NHE Retail Drug spending per capita (\$)	913	973	970	971	992	1,030	1,051	1,099	2.40%

Sources: (1) Analysis of physician office, durable medical equipment, and outpatient claims data 2006-2021 by Acumen for ASPE. Program payment amount does not include beneficiary cost-sharing; (2) Medicare Trustees Reports, 2022 and 2023