AAVBC

American Academy
of Value Based Care

AAVBC Medicare Part B IV/IM (Physician administered) to Part D SubQ (Patient self-administered) Utilization

Quick Reference Guide

2026

AAVBV Medicare Part B IV/IM (Physician administered) to Part D SubQ (Patient self-administered) Guide

1. INTRODUCTION: IV/IM and SubQ ADMINISTRATION PRIMER

Value-Based Care (VBC) models encourage shifts in drug delivery that improve patient outcomes and reduce costs. One emerging strategy is transitioning eligible injectable medications from **Medicare Part B** (typically IV/IM infusions in clinics) to **Part D** (self-administered subcutaneous injections at home). This initiative hinges on recent advances that make self-injection feasible without sacrificing efficacy, while navigating Medicare's coverage rules. By empowering patients to self-administer when appropriate, providers can enhance convenience and potentially lower total medical spending. Below, we outline the clinical rationale, regulatory landscape, and operational tactics for a successful Part B-to-D drug transition program in a VBC framework.

Formulations and Bioequivalence:[1-3]

High-concentration biologics face formulation challenges (viscosity, aggregation) that historically required IV administration, but new solutions are enabling subcutaneous (SubQ) versions. Manufacturers are using **viscosity-lowering excipients** and advanced device designs (autoinjectors, wearable pumps) to allow large doses in small volumes.

- **Overcoming Dose Volume Limits:** Historically, SubQ delivery was limited to small volumes (typically 1–2 mL), posing a challenge for high-dose biologic drugs. Newer technologies now enable the delivery of larger fluid volumes (often >3 mL).[1]
- **Managing Viscosity and Concentration:** High drug concentration, often required for high doses, can increase **viscosity** and lead to formulation instability (e.g., aggregation). Manufacturers utilize excipients (like salts and amino acids) and specialized formulation technologies to reduce viscosity.[1]
- **Role of Hyaluronidase:** Many SubQ formulations are **co-formulated with recombinant human hyaluronidase (rHuPH20)**. Temporarily breaks down the hyaluronic acid barrier in subcutaneous tissue, allowing for the rapid dispersion and absorption of large-volume injections.[1]

Equivalence and Dosing:

- **Pharmacokinetic (PK) bridging studies** are the standard regulatory approach to confirm that the SubQ dose achieves drug exposure comparable to the approved IV form (non-inferiority)[1-4]
- Goal is for fixed-dose SubQ regimens to match the efficacy of weight-based IV dosing[1, 5]
- **Clinical Vigilance is Required:** Clinicians must be mindful that **flat SubQ dosing** (not based on weight) may risk under-dosing in patients at the extremes of body weight, necessitating monitoring and potential dose adjustment[5]

Immunogenicity and Long-Term Safety:

The **route of administration** can affect how the immune system recognizes a drug, influencing long-term efficacy. However, in clinical practice, the **incidence of anti-drug antibodies (ADAs)** is generally **similar between subcutaneous (SubQ) and intravenous (IV) routes** for most biologics, and the theoretical increased immunogenicity with SubQ delivery **rarely leads to clinically significant differences** in safety or effectiveness.

- **Risk of Anti-Drug Antibodies (ADAs):** The subcutaneous space contains specialized antigen-presenting cells (APCs)
  - Since SubQ administration brings the drug directly into contact with these cells, there is a theoretical potential for an **enhanced immune response**, leading to the development of **Anti-Drug Antibodies (ADAs)**.[1, 6]
  - **Impact on Efficacy:** An ADA response can potentially **impact the drug's pharmacokinetics and efficacy**, which is a significant clinical risk for long-term chronic therapy.[1,6]
- **Current Evidence:** While some individual therapeutic proteins have shown a higher incidence of ADAs with SubQ administration, a recent meta-analysis comparing 17 therapeutic proteins found **no statistically significant difference in ADA incidence between the IV and SubQ routes overall.** The specific therapeutic protein itself, rather than the route, appears to be the most significant factor.[1]

Quality of Life (QoL) and Patient Preference[7]

- A 2024 meta-analysis of 30 studies found that **83% of adults with immune-mediated disorders** preferred **subcutaneous (SubQ)** administration over **intravenous (IV)** therapy, citing greater **convenience, flexibility, and autonomy.**
- Patients reported **lower emotional distress** and **higher treatment satisfaction** with self-administered SubQ formulations, primarily due to reduced clinic time and greater control over scheduling.
- Transitioning to home-based SubQ delivery has been associated with **improved adherence** and **reduced treatment fatigue** compared with traditional infusion-center models.

Clinical efficacy and safety[7,8]

- SubQ administration achieves **comparable efficacy and pharmacokinetics** to IV formulations across multiple biologic and immunoglobulin therapies
- **SubQ immunoglobulin (SubQIG)** produces **more stable serum IgG levels**, fewer systemic adverse effects (e.g., headaches, chills, fatigue), and **lower incidence of infusion reactions** than IVIG
- SubQ therapy allows for **smaller, more frequent doses**, improving physiologic tolerance and patient independence without compromising clinical outcomes

Patient safety and administration barriers[7]

- Common issues include **incorrect storage**, **improper injection technique**, **site rotation errors**, and **sharps disposal** challenges
- Initial **self-injection anxiety** is frequent, especially among elderly or newly transitioned patients

Mitigation and support strategies:

- Offer **nurse-led injection training** sessions and **first-dose supervision** (in person or virtual)
- Provide **step-by-step visual guides** and leverage **autoinjector pens** with safety locks to standardize technique
- Offer **pharmacist or nurse follow-up** within 1–2 weeks, along with **24-hour support lines** and **digital adherence tools** to reinforce technique and confidence

Regulatory and Coverage Landscape

When a drug is available in both **intravenous (IV)** and **subcutaneous (SubQ)** forms, its Medicare coverage, whether under Part B or Part D, is determined by whether it is considered *"usually self-administered"* by the patient. This classification is primarily influenced by the **route of administration** and CMS contractor determinations. Always confirm with MAC LCD and **review Medicare Benefit Policy Manual section 50.2 Determining Self-Administration of Drug or Biological.**

Increasingly, high-cost **Part B biologics** with SubQ alternatives are being transitioned to **Part D** when evidence supports equivalent safety and efficacy. These transitions enable **self-administration at home**, reduce total medical spend, and enhance **patient convenience and satisfaction** without compromising therapeutic outcomes.

Within a **Value-Based Care (VBC)** framework, physicians can support this shift by identifying eligible therapies and prescribing **SubQ formulations** when clinically appropriate to advance personalized, cost-effective care.

CMS Coverage Rules – Part B vs. Part D Determination[9]

	Part B (Physician Administered)	Part D (Self-Administered)
Definition	Covers drugs administered **incident-to** a physician's service; not usually self-administered	Covers drugs **"usually self-administered"** by the patient at home
"Usually Self-Administered" 50% Rule	Covered if **<50%** of Medicare users self-administer	Excluded from Part B if **>50%** of users self-administer → billed under Part D)
Route of Administration Presumption	**IV** and **IM** drugs are **not** self-administered (default Part B)	MACs maintain **Self-Administered Drug (SAD) Exclusion Lists** (revised periodically)
Determining Authority	**Medicare Administrative Contractors (MACs)** decide SAD classification and update coverage lists	MACs maintain **Self-Administered Drug (SAD) Exclusion Lists** (revised periodically)
Clinical Implication	Encourages **home-based self-administration** when safe and effective	**Encourages home-based self-administration when safe and effective**

Self-Administered Drug (SAD) Exclusion List[9]

The SAD Exclusion List identifies medications that Medicare Part B will not cover because they are deemed "usually self-administered" by patients.
CMS Medicare SAD Exclusion List

- **Determining Authority:** Each Medicare Administrative Contractor (MAC) reviews drugs on a case-by-case basis as new utilization data and drug formulations become available. If >50% of Medicare users self-administer a drug, the MAC classifies it as a SAD and adds it to the exclusion list.
- **Coverage Impact:** Drugs on this list are excluded from Part B reimbursement and must be billed under Part D **with exceptions*(the outpatient prescription benefit)*
- **Typical Drugs Affected:** Subcutaneous (SubQ) biologics, autoinjectors, or home-injectable therapies (e.g., abatacept, tocilizumab, SubQ immunoglobulin)
- Providers **cannot "buy and bill"** these drugs under Part B. Instead, prescriptions must be coordinated through a **Part D specialty pharmacy** for patient self-administration.

Determining Coverage: Transitioning from Part B → Part D[9, 10]

Determining Factor	Coverage Implication	Explanation / Examples
Route of Administration	**IV/IM → Part B** **SubQ/SubQ → Part D**	IV or IM drugs generally require clinician supervision and are Part B-covered. Subcutaneous (SubQ) drugs are presumed "usually self-administered" and move to Part D when >50% of beneficiaries self-administer.
Condition and Duration	**Chronic → Part D Likely** **Acute → Part B Likely**	Drugs for chronic maintenance (> 2 weeks) are more likely to be self-administered. Example: long-term biologic therapy for autoimmune disease.
Frequency of Dosing	**Less Frequent → Part D** **Likely Frequent / Office-Based → Part B**	Monthly or bi-monthly injections favor home use; frequent dosing needing monitoring stays under Part B.
CMS > 50% Rule	If > 50% self-administer → Excluded from Part B	CMS and its MACs classify any drug self-administered by most beneficiaries as **SAD**, removing it from Part B and listing it on the CMS Medicare SAD Exclusion List
Clinical Principle		**If a medication has both an in-office (IV/IM) and a home (SubQ) form, and the SubQ form > 50% self-administered, the SubQ form shifts to Part D. Determinations are made by MACs as new utilization data emerge**

Examples of Drugs Commonly Transitioning from Part B to Part D[9]

Drug (Generic / Brand)	Part B Version (Physician-Administered)	Part D Version (Patient Self-Administered)	Indication / Notes
Prolia (Denosumab)	SubQ injection administered by clinicians	SubQ self-administered at home	Osteoporosis; coverage depends on indication and site of administration
Orencia (Abatacept)	IV infusion	SubQ prefilled syringe /autoinjector	Rheumatoid arthritis; on SAD list since 2013
Cimzia (Certolizumab)	SubQ in-office injection	SubQ home self-administration	Crohn's disease, RA, PsA
Nucala (Mepolizumab)	SubQ by clinician	SubQ autoinjector for home use	Severe eosinophilic asthma
Actemra (Tocilizumab) /Tyenne / Avtozma	IV infusion	SubQ autoinjector or pen	Rheumatoid arthritis, Cytokine Release Syndrome; SubQ forms added to SAD list 2021
Simponi Aria (Golimumab)	IV infusion	Simponi® SubQ monthly autoinjector	RA, PsA; identical active ingredient, different benefit category
Benlysta (Belimumab)	IV infusion	SubQ autoinjector	Systemic Lupus Erythematosus
Procrit / Retacrit (Epoetin alfa biosimilars)	SubQ administered in office	SubQ self-administered	Anemia; switch improves adherence and reduces clinic visits
Alemtuzumab	IV induction therapy	SubQ formulation (transplant protocols)	Solid-organ transplant immunosuppression; MAC-reviewed case basis
Immunoglobulin Therapy	IVIG (clinic or home nursing)	SubQIG: Cuvitru®, Gamunex-C®, Hizentra®, HyQvia®	Replacement therapy for CVID, SubQID, CIDP – home administration reduces systemic AEs.
Adalimumab (Humira®, Amjevita®)	—	SubQ self-administered pen	Autoimmune conditions; long-standing SAD classification
Secukinumab (Cosentyx®)	—	SubQ self-administered	Psoriasis, PsA, AS.
Methotrexate (Otrexup®, Rasuvo®)	SubQ/IM office injection	SubQ autoinjector	RA, Psoriasis; chronic use supports Part D classification
Peginterferon beta-1a (Plegridy®)	—	SubQ self-administered	Multiple Sclerosis
Ustekinumab (Stelara®, Steqeyma®)	IV induction (B)	SubQ maintenance (D)	Psoriasis, Crohn's disease
Mirikizumab-mrkz (Omvoh®)	IV induction	SubQ maintenance	Ulcerative Colitis

Key Considerations:

- **Site of Administration:** The location and the person administering the drug are key factors. Part B covers drugs administered "incident to" a physician's service in a clinical setting. Part D covers drugs the patient gets from a pharmacy and takes themselves.
- **Formulary Status:** The specific SubQ version must be on the patient's Part D plan's formulary (drug list) for coverage. If it's not, the patient may need to request a coverage exception.

Exceptions:[10]

CMS Publication 100-02, Chapter 15 (Covered Medical and Other Health Services), Section 50.2 (Drugs and Biologicals).

The Five Key Statutory Exceptions

This CMS section explicitly details the categories of self-administered drugs (SADs) that must still be covered under Part B:

1. Certain Oral Anti-Cancer Drugs (if the IV form is covered under Part B)
2. Immunosuppressive Drugs (for patients who have received a Medicare-covered organ transplant)
3. Erythropoietin (EPO) (for certain home dialysis patients)
4. Blood Clotting Factors (for hemophilia patients)
5. Certain Osteoporosis Drugs (for limited homebound patients who meet specific criteria)

The existence of these exceptions is why, for the purpose of the Part B-to-D transition, clinicians must **always check the indication** for the drug, **not just the route to determine the correct payer**.

2. VALUE-BASED CARE AND OPERATIONAL STRATEGY

VBC Incentives and Cost Savings

- **High-cost opportunity:**
  - Transitioning eligible biologics from Part B infusions to Part D self-administered subcutaneous (SubQ) forms can produce major system-level savings without compromising efficacy
- **Cost reduction:**
  - Economic models show **~$18,000 annual savings per patient** when switching from IV to SubQ monoclonal antibody therapy[11]
  - Population-level analyses project **~$3 billion in Medicare savings** over four years with 50% SubQ adoption among eligible patients[11]
- **Operational efficiencies:**
  - Frees up **infusion chair capacity** and reduces need for infusion staff and facility time
  - Cuts administrative load from scheduling, monitoring, and billing complexity under Part B
- **VBC alignment:**
  - Shifts spending from medical to pharmacy benefit, lowering total medical cost under shared savings and ACO models
  - Directly supports quality metrics and financial goals tied to cost containment and patient experience

Patient Financial Impact – Part B vs. Part D[12-15]

Coverage Type	Out-of-Pocket Cost Structure	Typical Patient Scenario	Key Considerations (2025 and beyond)
Part B (Medical Benefit)	20% coinsurance per infusion (no annual limit)	$5,000 infusion → $1,000 patient coinsurance per visit	• Medicare supplement insurance often covers 100% of Part B coinsurance • No annual out-of-pocket cap • Patients without Medicare supplement insurance may face high recurring costs
Part D (Pharmacy Benefit)	Copay or coinsurance varies by plan tier; subject to annual out-of-pocket cap	Drug filled at specialty pharmacy; paid monthly	• **$2,000 annual cap on out-of-pocket costs** effective in 2025, $2100 in 2026 • Coinsurance based on formulary tier; varies by plan • Out-of-pocket resets annually
Part D with Low-Income Subsidy (LIS / "Extra Help")	Minimal or nominal cost-sharing	Average $72/year for biologics vs. $3,700+ for non-LIS patients	• Best protection for high-cost biologics • Ideal for patients without supplemental Medigap coverage • LIS significantly reduces cost exposure
Part D for Patients with Medicare supplement insurance	Medicare supplement insurance **does not apply** to Part D	Previously paid $0 under Part B; now may owe up to $2,000 annually	• Providers should counsel patients on cost shift • Manufacturer copay cards not allowed; use **charitable or foundation-based assistance**

The transition from Part B to Part D changes how patients pay for their medications. Under Part B, patients owe 20% coinsurance per infusion, though most with Medicare supplement insurance pay little or nothing. When the same drug moves to Part D, Medicare supplement insurance no longer applies, and patients face copays or coinsurance through their pharmacy plan. However, **2025 reforms cap annual Part D out-of-pocket costs at $2,000, offering protection that Part B lacks**.[12, 13]

Those with the Low-Income Subsidy (LIS) pay the least, often under $100 per year, while beneficiaries with Medicare supplement insurance may now owe modest costs they did not previously see. In short, Part D can lower expenses for patients without Medicare supplement insurance or with LIS but may increase costs slightly for others, making proactive financial counseling and benefits review essential before transition.

Operational Best Practices – Implementing A Part B → Part D Transition

"Don't let the patient go it alone."

1. Prior Authorization (PA) and Coverage Coordination

Action Step	Best Practice Guidance
Initiate PA Early	Submit PA **before transition** to avoid treatment gaps. Include patient diagnosis, prior therapy history, and rationale for switching (e.g., "stable on IV form; converting to SubQ for home use")
Use ePA Portals	File PAs through **electronic prior authorization (ePA)** systems to expedite processing and track status
Formulary Exceptions	If the plan prefers a biosimilar or IV/IM alternative, submit a **formulary exception request** for SubQ formulation supported by clinical documentation and rationale.
Coordinate With Specialty Pharmacy	Maintain open communication with the **Part D specialty pharmacy** to confirm PA approval, drug shipment, and delivery timing

2. Patient Transition and Education

Action Step	Best Practice Guidance
Designate a Care Lead	Assign an **RN or clinical pharmacist** to oversee each patient's transition from IV to SubQ therapy.
Provide Injection Training	Conduct or arrange **hands-on or virtual education sessions** on injection technique, storage, site rotation, and sharps disposal.
Supply Written & Visual Aids	Give patients **easy-to-follow instructions** and troubleshooting guides for home reference.
Schedule First-Dose Support	Offer **first-injection observation** (in-person or virtual) to ensure proper administration and patient confidence.

3. Specialty Pharmacy and Refill Management

Action Step	Best Practice Guidance
Enroll in Mail-Order Programs	Use **manufacturer or plan-supported mail-order options** for reliable, temperature-controlled home delivery.
Verify Refill Scheduling	Ensure patients understand **refill timelines** and how to request replacements to avoid therapy lapses.
Monitor for Delays	Proactively track shipping and refill requests; address barriers promptly through plan liaison or case management.

4. Ongoing Monitoring and Follow-Up

Action Step	Best Practice Guidance
Short-Term Follow-Up	Conduct a **1–2 week post-switch call or visit** to assess adherence, injection comfort, and early adverse effects.
Long-Term Monitoring	Integrate **patient-reported outcomes (PROs)** and adherence tracking into follow-up visits or digital health tools
Document Progress	Capture improvements in convenience, QoL, and adherence for internal VBC reporting.
Continuous Support	Encourage patients to use **manufacturer nurse lines or tele-support** if they experience difficulties

Success Factors

1. Clear and Consistent Communication

Audience	Focus Area	Guidance
Patients	Cost and access education	Provide clear information on new coverage pathways, potential cost differences (Medicare Supp Insurance vs. LIS), and steps to obtain medications under Part D. Include written materials + helpline support
Providers	Clinical workflow updates	Ensure prescribers understand updated coverage rules, authorization processes, and documentation requirements to prevent therapy delays.
Health Plans	Member transition assistance	Maintain transparent outreach from **Part D sponsors** to guide beneficiaries on switching to covered drugs or submitting formulary exception requests

2. Effective Transition Process

Goal	Best Practice
Ensure Timely Access	Prevent coverage gaps by confirming authorization and dispensing pathways before transition. Pharmacy counter delays must be proactively avoided
Use Grace Periods	Apply **CMS-approved transition periods (e.g., 90 days)** to allow time for education and coverage alignment
Streamline Exceptions	Standardize formulary exception and appeal workflows for rapid turnaround; prioritize cases with urgent medical need

3. Proactive Stakeholder Management

Audience	Engagement Focus	Implementation Tip
Patients and Caregivers	Financial and access variability	Identify those at risk for increased costs (e.g., Medicare Supp Insurance holders) and provide proactive counseling
Advocacy Organizations	Equity and safety	Collaborate with patient advocacy groups to ensure safe self-administration and equitable access for vulnerable populations
Pharmacies/Home Infusion Providers	Supply chain coordination	Maintain communication for home delivery, training logistics, and refill tracking to prevent treatment interruptions

4.Benefit and Formulary Strategy

Objective	Operational Focus
Use Regulatory Flexibility	Apply MTM and risk-stratification programs to support adherence and manage costs under VBC models
Optimize Formularies	Meet CMS minimum standards (≥2 drugs per class) while avoiding unnecessary utilization barriers (e.g., redundant prior auths). Protectively scan for SubQ formulations to add to the health plan formulary
Continuous Monitoring	Evaluate adherence, patient satisfaction, and cost outcomes quarterly; refine plan design based on real-world performance

Conclusion

Transitioning eligible Part B drugs to Part D self-administration is a promising strategy at the intersection of clinical innovation and value-based care. It leverages pharmacological advances (SubQ formulations with hyaluronidase) to maintain efficacy and safety while substantially improving the patient experience. From a policy perspective, Medicare is clearly defining which drugs belong under Part D, and forward-thinking practices are adapting by identifying patients who can benefit from home therapy.

The potential rewards are significant: patients gain convenience and autonomy, payers and providers see reduced costs, and infusion capacity is freed up for those who truly need in-clinic care. However, success requires careful execution, appropriate patient selection, proactive navigation of Part D rules, and intensive patient education are all critical. When done thoughtfully, Part B-to-D drug transitions can exemplify high-value care: achieving the same or better health outcomes at a lower cost and with higher patient satisfaction.

As Medicare and healthcare systems continue to push for **“the right care at the right place,”** the shift of injectable therapies into the home setting will likely expand, making the strategies outlined above increasingly essential in routine practice.

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