



Medicare Coverage of Self-Administered Drugs Given in Outpatient Settings: CMS Guidance to Providers and Beneficiaries

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Medicare's Supplemental Medical Insurance (SMI, or Part B) covers general care received in an hospital outpatient setting, such as an emergency department, observation unit, surgery center, or pain clinic. However, Part B only covers a limited number of drugs or biologicals in these settings such as drugs administered by infusion or injection that are not considered "usually self-administered."

However, during the course of treatment in these outpatient settings, Medicare beneficiaries may need "self-administered drugs," or drugs the patient would usually take on their own – and typically not covered under Medicare Part B. However, with the introduction of Medicare Part D, or the prescription drug benefit in 2006, beneficiaries may be covered for these drugs if they meet certain criteria.

Below is a summary of the Centers for Medicare and Medicaid (CMS) guidance to both providers and patients with regard to potential coverage and reimbursement for "self-administered drugs" given in the outpatient setting.

Medicare Part D will, with proper documentation, cover "self-administered drugs" under the following conditions:

- The drug is on the Part D plan's formulary (or covered by an exception)
- The drug is not routinely filled at out-of-network providers such as a hospital outpatient department.
- In-network pharmacy access was impractical at the time of service.

CMS Guidance for Hospitals

- CMS instructs hospitals to bill Medicare beneficiaries for "self-administered drugs" if the drugs are not covered under Medicare Part A (Hospital Insurance) or Part B.
- In the event that the hospital pharmacy has a contract with the Medicare beneficiaries Part D plan, the hospital may bill the Part D plan as an in-network pharmacy.

CMS Guidance for Medicare beneficiaries

- CMS reminds beneficiaries that since most hospitals do not participate in Medicare Part D as an in-network pharmacy, they are responsible for paying up front and out-of-pocket costs for their “self-administered drugs” and submit claims to their Part D plan for refund should they meet the criteria above.
- Their Part D plan will verify eligibility of the drug for reimbursement under Part D and, if covered, will reimburse only for in-network cost for the drug minus any deductibles, copayments, or coinsurance that would normally be charged for the drug.
- Further, beneficiaries may need to pay the difference between what the hospital charged them for the drug and what the Part D plan will allow.
- In the case that a drug is not covered by the Part D plan (i.e., not on the plan’s formulary), the beneficiary is responsible for paying the hospital charges in full. Beneficiaries are reminded that they are able to file for an exception with their Part D plan.

Additional Information and Resources

- CMS suggests that Medicare beneficiaries bring their drugs, or a list of the drugs they are taking, to the hospital to **show** them to the staff so that staff are aware what drugs a beneficiary is currently taking.
- Affected hospital staff should review this guidance to ensure compliance with applicable CMS rules and how best to respond to Medicare beneficiary questions regarding the coverage of “self-administered drugs.”
- *CMS Tip Sheet for Hospitals*: <http://www.cms.gov/partnerships/downloads/11331-P.pdf>
- *CMS Guidance to Medicare Beneficiaries*: <http://www.medicare.gov/Publications/Pubs/pdf/11333.pdf>
- For general inquiries about Medicare’s coverage of “self-administrated drugs” or the Medicare program in general, please contact Christopher Topoleski, Director of Federal Regulatory Affairs at 301-664-8692 or via e-mail at ctopoleski@ashp.org.

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