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| **DEPARTMENT:** Regulatory Compliance Support | **POLICY DESCRIPTION:** BILLING – Outpatient Self-Administered Drugs |
| **PAGE:** 1 of 3 | **REPLACES POLICY DATED:** 4/16/99, 4/1/03, 5/31/04, (GOS.BILL.003), 3/6/06, 3/1/08, 08/1/09, 1/1/13, 4/1/16 |
| **EFFECTIVE DATE:** March 1, 2022 | **REFERENCE NUMBER:** REGS.BILL.003 |
| **APPROVED BY:** Ethics and Compliance Policy Committee | |

**SCOPE:** All Company-affiliated hospitals providing and/or billing outpatient self-administered drugs.

**PURPOSE:** To outline billing requirements for outpatient self-administered drugs.

**POLICY:** Most outpatient self-administered drugs are statutorily excluded from the Medicare program and must not be billed as covered services. Hospitals may discount or waive amounts that Medicare beneficiaries owe for Noncovered self-administered drugs (including Noncovered self-administered drugs that may be covered under Medicare Part D) and any associated administration services charges when certain conditions are met as outlined below.

**PROCEDURE:**

1. Facility personnel must determine if drugs provided to a patient in an outpatient setting which are in a self-administrable form (e.g., pills, syrups, suppositories) are “self-administered” according to the definition in this policy.

   Examples of situations where drugs provided in an outpatient setting would be “self-administered” include, but are not limited to:
   - Drugs given to a patient for their continued use at home after leaving the hospital.
   - Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment**.**
   - Daily routine insulin or hypertension medication given preoperatively to a patient.
   - A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain.
   - A laxative suppository for constipation while the patient waits to receive an unrelated X-ray.

     Note: In addition to the above situations, Medicare Contractors may include on their website a listing of drugs which they have deemed to be self-administered.

2. If a drug provided to a patient in an outpatient setting is determined to be “self-administered,” facility personnel must then determine if the drug or biological is an integral component of a Medicare-covered procedure or is directly related to it. In this case, it is considered to be a packaged supply and must be billed as a covered service to Medicare.

   Examples of situations where “self-administered” drugs provided in an outpatient setting would be considered “packaged” as an integral component of, or directly related to a procedure, include, but are not limited to:
   - Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.
   - Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient

immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre- and postoperatively.
- Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.
- Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.
- Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of the procedure.

3. Facilities must review their chargemasters and billing procedures to confirm that SADs, and SADs that are packaged as integral to a procedure, are appropriately identified.

4. Drugs determined to be "self-administered," but not packaged as integral to a Medicare-covered procedure, and any associated drug administration charges must not be billed as covered services to Medicare.

5. SADs not considered packaged as integral to a procedure may be billed to the patient or other third party payer. However, hospitals may discount or waive amounts that Medicare beneficiaries owe for Noncovered SADs (including Noncovered SADs that may be covered under Medicare Part D) and the associated administration services that the beneficiary receives in outpatient settings, providing the following conditions are met:
   - Beneficiary receives the drug for ingestion or administration in outpatient settings,
   - Hospitals must uniformly apply their policies regarding discounts or waivers on Noncovered SADs (e.g., without regard to a beneficiary's diagnosis or type of treatment,
   - Hospitals must not market or advertise the discounts or waivers; and
   - Hospitals must not claim the discounted or waived amounts as bad debt or otherwise shift the burden of these costs to the Medicare or Medicaid programs, other payers, or individuals.

   Drugs given to a patient for their continued use at home after leaving the hospital do not meet these conditions, are not eligible for discounts or waivers, and must be billed to the beneficiary unless CMS provides additional guidance.

6. Drugs determined **not** to be "self-administered," or determined to be "self-administered" **but** considered packaged as integral to a procedure, must be billed to Medicare as covered services with the appropriate revenue code, provided all other Medicare coverage requirements have been met. Drugs determined to be covered by the Medicare program (including statutorily covered Part B drugs and Medicare-covered drugs as provided in National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs)) must be billed to Medicare as covered services and not be billed to the beneficiary.

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7. Business Office/Service Center personnel must educate all staff associates responsible for billing pharmacy services on the contents of this policy. Facility personnel must educate pharmacy staff responsible for requesting or adding procedure charge codes to the chargemaster on the contents of this policy.

8. Business Office/Service Center personnel must identify Medicare Contractor interpretations which vary from the interpretations in this policy including regular review of Self-administered Drug Exclusion Lists published on Medicare Contractor websites.

9. The Facility Ethics and Compliance Committee is responsible for the implementation of this policy within the facility.

**DEFINITION:**

Self-Administered Drug (SAD): A self-administered drug is a drug or biological furnished to a hospital patient in an outpatient setting for therapeutic purposes which is usually self-administered and is not an integral component of a procedure or directly related to it, i.e., when it facilitates the performance of or recovery from a particular procedure. When it is an integral component of a procedure or directly related to it, the drug or biological is considered to be a packaged supply and may be covered by Medicare. In addition, some drugs and biologicals commonly used in outpatient hospital settings are statutorily covered under Part B and are therefore not considered "self-administered":

- immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a Medicare covered organ transplant,
- oral anti-cancer drugs (and pro-drugs) taken during cancer chemotherapy which have the same active ingredient and are used for the same indications as covered chemotherapy drugs,
- oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen as a full therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration, and
- erythropoietin (EPO) for the treatment of anemia for persons with chronic renal failure who are on dialysis.

**REFERENCES:**


1. Medicare Benefit Policy Manual (Pub. 100-02), Chapter 15, Section 50.2
2. CMS Medicare Prescription Drug Benefit Manual (Pub. 100-18), Chapter 6, Appendix C.
3. OIG Policy Statement Regarding Hospitals That Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings, October 29, 2015. http://oig.hhs.gov/compliance/alerts/guidance/policy-10302015.pdf