

Billing and Coding Guidelines for Drugs and Biologics (Non-chemotherapy)

L 34741

Medicare Excerpts:

CMS 100-02, *Medicare Benefit Policy Manual*, Chapter 15- Section 50 - Drugs and Biologics:

50.2 - Determining Self-Administration of Drug or Biological

(Rev. 157, Issued: 06-08-12, Effective: 07-01-12, Implementation: 07-02-12)

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them.

Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

The term “administered” refers only to the physical process by which the drug enters the patient’s body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Injectable drugs, including intravenously administered drugs, are typically eligible for inclusion under the “incident to” benefit. With limited exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are considered to be usually self-administered by the patient.

50.4.1 - Approved Use of Drug

(Rev. 1, 10-01-03)B3-2049.4

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. (See the Medicare Benefit Policy Manual, Chapter 16, “General Exclusions from Coverage,” §20.) Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA approved drug or biological, if:

- *It was injected on or after the date of the FDA’s approval;*
- *It is reasonable and necessary for the individual patient; and*
- *All other applicable coverage requirements are met.*

The carrier, DME MAC will deny coverage for drugs and biologicals, which have not received final marketing approval by the FDA unless it receives instructions from CMS to the contrary.

50.4.2 - Unlabeled Use of Drug

(Rev. 1, 10-01-03) B3-2049.3

An unlabeled use of a drug is a use that is not included as an indication on the drug’s label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in §50.5.

50.4.3 - Examples of Not Reasonable and Necessary

Determinations as to whether medication is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations (i.e., with the advice of medical consultants and with reference to accepted standards of medical practice and the medical circumstances of the individual case). The following guidelines identify three categories with specific examples of situations in which medications would not be reasonable and necessary according to accepted standards of medical practice:

1. Not for Particular Illness

Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations). Charges for medications, e.g., vitamins, given simply for the general good and welfare of the patient and not as accepted therapies for a particular illness are excluded from coverage.

2. Injection Method Not Indicated

Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration. For example, the accepted standard of medical practice for the treatment of certain diseases is to initiate therapy with parenteral penicillin and to complete therapy with oral penicillin. Carriers exclude the entire charge for penicillin injections given after the initiation of therapy if oral penicillin is indicated unless there are special medical circumstances that justify additional injections.

3. Excessive Medications

Medications administered for treatment of a disease and which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered. For example, the accepted standard of medical practice in the maintenance treatment of pernicious anemia is one vitamin B-12 injection per month. Carriers exclude the entire charge for injections given in excess of this frequency unless there are special medical circumstances that justify additional injections.

60.1 - Incident To Physician's Professional Services

(Rev. 1, 10-01-03) B3-2050.1

To be covered, supplies including drugs and biologicals must represent an expense to the physician or legal entity billing for the services or supplies. For example, where a patient purchases a drug and the physician administers it, the cost of the drug is not covered. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.

Coding Guidelines

1. Diagnosis codes must be listed to the most specific number.
2. Use the appropriate J code to report the drug being used.
3. True codes reflect the dosage of the drug; the number of units should indicate the total number of units given in item 24G of the CMS 1500 form. If filing electronically, the total units should be placed in the NSF Format, Record FAO-18.0, ANSI 837 format Segment SV1-05 (3032) or Segment SV2-04 (3052).

Medicare Excerpts

CMS 100-04, *Medicare Benefit Policy Manual*, Chapter 17, Section 40: Discarded Drugs and Biologicals.

4. **JW Modifier** effective January 1, 2017. Please refer to Modifier JW Fact Sheet on WPS GHA website.
 - Claims for discarded drugs or biologicals amount not administered to any patient shall be submitted using the JW modifier. Unused drugs or biologicals from single use vials or single use packages that are opened and the entire dose/quantity is not administered and the

remainder is discarded. (except those provided under the Competitive Acquisition Program (CAP) for Part B drugs and biologicals).

- Providers must document the discarded drugs or biologicals in the patient's medical record.
- This modifier, billed on a separate line, will provide payment for the amount of discarded drugs or biologicals.

See CR 9603

5. **NOC drug billing:**

Office/Clinic:

Providers submit NOC codes in the 2400/SV101-2 data element in the 5010 professional claim transaction (837P). When billing an NOC code, providers are required to provide a description in the 2400/SV101-7 data element. The 5010 TR3 Implementation Guide instructs: "Use SV101-7 to describe non-specific procedure codes." (Do not use the 2400 NTE segment to describe non-specific procedure codes with 5010.) The SV101-7 data element allows for 80 bytes (i.e., characters, including spaces) of information.

In order for WPS GHA to correctly reimburse NOC drugs and biologicals, providers must indicate the following in the 2400/SV101-7 data element, or Item 19 of the CMS 1500 form:

The name of the drug,

The total dosage (plus strength of dosage, if appropriate), and

The method of administration.

Important: List **one** unit of service in the 2400/SV1-04 data element or in item 24G of the CMS 1500 form. Do not quantity-bill NOC drugs and biologicals even if multiple units are provided. Medicare determines the proper payment of NOC drugs and biologicals by the narrative information, not the number of units billed.

Medicare will reject as unprocessable claims for NOC drugs and biologicals if any of the information above is missing, or if the NOC code is billed with more than one unit of service. (Note: The remittance notice will include remark code M123, "Missing/incomplete/invalid name, strength, or dosage of the drug furnished," even if the rejection is due to the number of units billed.)

See NOC Billing/NOC Drug and Biological Codes on our website for further information:

http://www.wpsmedicare.com/j5macpartb/claims/submission/b_nTMoc.shtml

ASC and Hospital Outpatient Departments:

HCPCS code C9399, Unclassified drug or biological, should be used for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned.

6. When billing an intravitreal injection of a pharmacologic agent; eg, Lucentis (Ranibizumab), Eylea (Aflibercept), or Avastin (Bevacizumab) use HCPCS code 67028 Intravitreal injection of a pharmacologic agent (separate procedure) and the appropriate modifier: RT, LT or 50 (bilateral).
7. Part B Biosimilar Biological Product Payment and Required Modifiers
The 2016 Physician Fee Schedule Final Rule, updated the regulation text found at 42 CFR 414.904(j) to make clear that effective January 1, 2016, the payment amount for a biosimilar biological drug product is based on the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code.

CR10454 Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - April 2018 Update. Effective for claims with dates of service on or after April 1, 2018 HCPCS codes Q5103 and Q5104 will be payable for Medicare, HCPCS code Q5102 will no longer be payable, and modifiers that describe the manufacturer of a biosimilar product (for example, ZA, ZB and ZC) will no longer be required on Medicare claims.

If a HCPCS code and corresponding biosimilar modifier(s) do not appear on the quarterly update, then a modifier is not required to appear on claims for the code. New biosimilar products that are not adequately described by an existing unique HCPCS code may be billed under a miscellaneous code or “not otherwise classified” code such as J3590. Similarly, a “not otherwise classified” code may also be used in situations where an existing biosimilar HCPCS code is associated with a corresponding modifier that is not yet in effect in the claims processing system. The manufacturer modifier is not required on claims that use a miscellaneous HCPCS code.

Frequently asked Questions and Answers:

Question:

Xolair comes in a 150 mg vial and it clearly states on the package insert that no more than 150mg is to be injected in any one site. If a patient needs to have 450 mg of Xolair given and we administer three separate injections in three different sites, is it appropriate to bill 3 units of the chemotherapy injection code?

Response:

The drug administration service is for the administration of a drug and is not based on the number of vials or syringes that are used to safely administer the drug. It would not be appropriate to bill for more than one injection for the administration of Xolair ®. The therapeutic, prophylactic or diagnostic injection administration CPT code should be used for the administration of this drug.

Question:

Benadryl and Cimetidine have been added to one bag of normal saline by our Pharmacy. Is it appropriate to bill an administration code for each drug?

Response: No, it is not appropriate to bill an infusion administration code for each drug that is contained within an IV bag. Only one IV bag is being administered and should be billed as one infusion service.

Question:

Can physicians bill their local contractor for drugs as "incident to" the chemotherapy administration provided in the physician's office when the pump used to infuse the drugs is an ambulatory pump and after the drug infusion is initiated, the patient is able to go home with the pump and returns to the physician's office for refills and/or disconnect?

Response: Injectable drugs administered **in a physician's office**, whether with or without a pump, must be billed to the local contractor and not the DME MAC. The drug(s) that is loaded into an ambulatory infusion pump in the physician's office for use in the patient's home must be billed to the DME MAC **if** the pump is billed to the DME MAC. Ambulatory pumps are billed to the DME and implantable pumps are billed to MAC B Contractor.

Revision History:

04/01/2018: Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - April 2018 Update CR 10454. Coding Guidelines: 7: Included updated explanation and removed billing with modifiers explanation. Annual review 03/07/2018; Formatting corrections; Corrections to update IOM references/verbiage.

11/01/2017: Medicare Part B Drug Average Sales Price: Part B Biosimilar Biological Product Payment and Required Modifiers: HCPCS code Q5102 appropriate modifiers: ZB or ZC; added explanation regarding Q5102 modifiers to Group 1 Paragraph, Group 11 Paragraph, CMS National Coverage Policy and Billing & Coding Guidelines.

04/01/2017: annual review 03/09/2017, reformatted without change in coverage, JW Modifier information added to Policy/Billing & Coding Guidelines, added L34741 to Billing & Coding Guideline Title.

08/01/2016: Added Instruction #5: code 67028 & modifier information. Effective date 09/15/2016.

05/01/2016: Annual review completed 04/05/2016. Removed two questions from frequently asked questions section and corrected typos and removed any outdated information. Updated NOC section per the WPS NOC billing website and removed old information.

05/01/2015-Annual Review 04/01/2015; added additional paragraph from the IOM to section 50.2 - Determining Self-Administration of Drug or Biological.

06/01/2014-Update to frequently asked questions for Xolair. Removed statement: The chemotherapy administration codes pay more than the non-chemotherapy administration codes due to the risk and side effects associated with these drugs and the overhead to monitor the patient. Added the therapeutic, prophylactic or diagnostic injection administration CPT code should be used for the administration of this drug. Effective 07/15/2014; added excerpt dates and corrected typo -60.2 changed to 60.1;

05/01/2014-Added reference CMS 100-02, Medicare Benefit Policy Manual, Chapter 15- Section 50 - Drugs and Biologicals above Medicare Excerpts. Changed ICD-9 to dx codes under coding guidelines 1 & removed reference to 5th digit.