Billing and Coding Guidelines for INJ-041

Medicare Excerpts:

50.2 - Determining Self-Administration of Drug or Biological
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.

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, DMERC, or intermediary 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.

60.2 - *Services of Nonphysician Personnel Furnished Incident To Physician's Services*

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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. Coverage of services and supplies incident to the professional services of a physician in private practice is limited to situations in which there is direct physician supervision of auxiliary personnel.

Coding Guidelines

1. ICD-9 codes must be listed to the most specific number. Carry out all ICD-9 codes out to the fifth space where indicated.
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).
4. NOC drug billing:

   Office/Clinic:

   When using a drug NOC code (J3490, or J3590) list the name of the drug, the amount of the drug that is administered and wasted if applicable; method of administration in the electronic narrative that is equivalent to line 19 of the CMS 1500 form. List the units of service as **one** in 2400/SV1-04 data element of the ANSI X12 4010A1 or in item 24G of the CMS 1500 form.

   Occasionally, the strength of the drug will also be needed on NOC claims. If the NOC ASP pricing file lists the name of the drug with its strength it must also be included on line 19. Example: Sodium Bicarbonate 8.4%.

   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. If a

product is compounded and a specific HCPCS code does not exist for the compounded product, the ASC should report an appropriate unlisted code such as J9999 or J3490.

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 it is given in 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. 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. It would not be appropriate to bill for more than one injection for the administration of Xolair ®.

Question:
Is J1642 injection, Heparin sodium, (heparin lock flush) per 10 units payable when I administer it to flush an IV line?

Response: No, it is not separately payable. An intravenous flush is included in an infusion service or an evaluation and management service that is performed on the same day.

Question:
Can we bill the chemotherapy administration code for the administration of EPO™, Neulasta ™ and Leukine™?

Response: EPO™, Neulasta™and Leukine™ are **not** chemotherapy agents. They should be billed with the therapeutic, prophylaxis or diagnostic subcutaneous or intra-muscular injection code. It is not appropriate to bill these administrations with the chemotherapy administration codes.

CPT 96401 is for the administration of antineoplastic chemotherapeutic agents and biologic response modifiers. Traditional antineoplastic chemotherapy agents and the newer biologic response modifiers have a higher patient risk, requiring special knowledge for use and requires longer patient monitoring.

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 carrier 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 carrier 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/Legacy B contractor.

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