Local Coverage Article: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (A53049)

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**Contractor Information**

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**Article Information**

**General Information**

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Article Title
Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents

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Article Guidance

Article Text:

References

IOM Citations:

- CMS IOM Publication 100-02, Medicare Benefit Policy Manual
  - Chapter 1, Section 120
  - Chapter 15, Sections 50, 50.1, 50.2, 50.3, 50.4, 50.4.1, 50.4.2, 50.4.3, 50.4.4, 50.4.4.1, 50.4.4.2, 50.5, 50.5.2.1, 60, 60.1
  - Chapter 16, Sections 10 and 180
- CMS IOM Publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 4, Section 280.14
- CMS IOM Publication 100-04, Medicare Claims Processing Manual
  - Chapter 12, Section 30.5
  - Chapter 17

Change Request References:

- CMS Change Request 9386, issued November 6, 2015
Coverage and/or Medical Necessity

In reading this document, please note that there is a difference between the section of the statute which defines the overall Medicare benefit for coverage of drugs and biologicals, and the section of the statute which states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury. This article gives information about the overall Medicare benefit for coverage of drugs and biologicals. This contractor, when necessary, develops Local Coverage Determinations (LCDs), to define reasonable and medically necessary uses of particular drugs and biologicals.

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals;
- They are of the types that are not usually self-administered by the patients who take them;
- They meet all the general requirements for coverage of items as incident to a physician's services;
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice;
- They are not excluded as immunizations; and
- They have not been determined by the FDA to be less than effective.

Drugs and biologicals must be determined to meet the statutory definition. Under the statute §1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia (USP), the National Formulary (NF), or the United States Homeopathic Pharmacopoeia (HPUS), or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug compendia.

Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium.

Drugs that are usually self-administered by the patient, such as those in pill form, or are used for self-injection, are generally not covered by Part B. However, there are a limited number of self-administered drugs that are covered because the Medicare statute explicitly provides coverage. Examples of drugs that are usually self-administered by the patient and are covered include: blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, and osteoporosis drugs for certain homebound patients.

Generally, when a physician gives a patient pills or other oral medication, these drugs are excluded from coverage since the form of the drug is self-administered. Similarly, if a physician gives a patient an injection that is usually self-injected this drug is excluded from coverage, unless administered to the patient in an emergency situation.
Whole blood is a biological that cannot be self-administered and is covered when furnished incident to a physician's services. Payment may also be made for blood fractions if all coverage requirements are satisfied.

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must be of a form that cannot be self-administered and must be administered by a physician or by auxiliary personnel employed by him/her under his/her personal supervision. To be covered, drugs and biologicals must be an expense to the physician billing for the service. For example, if a patient purchases a drug and the physician administers it, 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.

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals and cancer chemotherapeutic agents 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, payment may be made for an FDA approved drug or biological or cancer chemotherapeutic agent 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.

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 contractor determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. The following guidelines identify three categories in which medications would not be reasonable and necessary according to accepted standards of medical practice.

- 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).
- 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.
- Excessive Medications –– Medications administered for treatment of a disease which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered.

If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the entire charge will be excluded (i.e., for both the drug and its administration). Also excluded from payment is any charge for other services (such as office visits) which are primarily for the purpose of administering a non-covered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury).

Antigens –– Payment may be made for a reasonable supply of antigens (defined as not more than a 12-month supply) that have been prepared for a particular patient at any one time if:

- the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and
- the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen. Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor.

Immunizations –– Vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. In the absence of injury or
A drug that is less than effective is not eligible for reimbursement, i.e., one that the Food and Drug Administration has determined to lack substantial evidence of effectiveness for all labeled indications. Any other drug product that is identical, similar, or related, will also be ineligible.

If a use is identified as not indicated by CMS or the FDA or if a use is specifically identified as not indicated (in one or more of the CMS approved compendia) or if it is determined (based on peer reviewed medical literature) that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered. In this instance, the administration is also not covered.

Several cancer chemotherapeutic agents and regimes have been developed and approved by the Food and Drug Administration (FDA) to treat various types of cancer. The intended mechanism of action is to interfere with or prevent the growth of malignant (cancerous) cells.

Generally, cancer chemotherapeutic agents are covered only if all of the following requirements are met:

- Documentation is present to support that the drug is safe and effective and is being administered for an approved indication.
- Documentation in the patient’s medical record supports the medical necessity of administering the chemotherapy drug to that individual patient.
- Documentation in the patient’s medical record supports that the chemotherapy drug was administered as billed.

Therefore, payment may be made for an FDA-approved chemotherapeutic 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.

There are many reasons to consider an unlabeled use for a cancer chemotherapy agent. Some of these are:

- Drugs may be effective for many other cancers in addition to the ones that were considered in the primary labeling of the drug.
- Many chemotherapeutic agents are given in combinations. Any one of the drugs in the combination may not have been approved in the initial labeling of the products. In addition the combination of effective chemotherapeutic agents changes over time.
- Cancer chemotherapeutic agents are always changing and improving over time. Oncologists are often left with few approved treatment options if initial treatment regimens have failed.

If a physician is contemplating the use of an FDA-unlabeled anti-cancer drug, non chemotherapeutic drug or biological the subsequent steps should be followed:

1. Initially, one of the CMS approved drug compendia should be consulted to find a list of approved agents and their list of indications. See the Medicare citations above for the updated list of approved compendia and the transparent process for choosing them.

   **Note:** Authoritative lists of Compendia will be adjusted, as needed, according to the process defined in the CMS IOM Pub. 100-02, Chapter 15, Section 50.4.5.1.

   In review of these compendia if the use of the chemotherapeutic agent is supported by any one of these compendia AND the use is NOT listed as "not indicated, unsupported, not recommended" or equivalent terms in any of the other approved compendia, the agent may be approved.
2. In those circumstances when the unlabeled use of the chemotherapeutic agent, nonchemotherapeutic drug or biological is not listed in any of the compendia or is listed as insufficient data or investigational, the use of the drug may be supported by clinical research that appears in peer reviewed medical literature. Peer reviewed medical literature includes scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).

Coverage will be determined based on the results of peer reviewed medical literature published in the regular editions of the following publications, not to include supplement editions privately funded by parties with a vested interest in the recommendations of the authors:

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly The European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
3. Unlabeled uses of cancer chemotherapeutic agents, non chemotherapeutic drugs and biologicals may also be considered medically accepted if determined to be the community standard of care and to be medically accepted as safe and effective for the particular use. In order to determine if a chemotherapeutic agent meets the level of community standard of care, the following may be used:

Peer reviewed medical literature in journals other than those journals cited above also can be used to establish a community level standard of care. Again this literature includes scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts). Furthermore, the level of evidence in each article must be determined.

Levels of evidence as defined below will be used to assess research and to determine a grade of recommendation for a particular medical treatment. These levels are described below:

Level 1: Randomized controlled trials/meta analyses

Level 2: Cohort studies

Level 3: Case controlled studies

Level 4: Cross sectional surveys, case reports, or case series

Level 5: Expert opinion

If the peer-reviewed literature is a Level 1 study, the use of that specific chemotherapeutic agent is considered to be the community standard and the agent is covered. However, if the peer-reviewed literature is a Level 2, 3, or 4 study two or more articles by different authoring groups are required to establish the use of the chemotherapeutic agent as the community standard before the agent will be covered. If the literature is only Level 5 then the chemotherapeutic agent has not been established as a community standard and will not be covered. The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size.

In determining whether there is supportive clinical evidence for a particular use of a drug, the quality of the published evidence must be considered. Such consideration involves the assessment of the following study characteristics:

- The adequacy of the number of subjects;
- The response rate;
- The effect on key status and survival indications. That is, the effect on the patient's well-being and other responses to therapy that indicate effectiveness (e.g., reduction in mortality, morbidity, signs and symptoms);
• The appropriateness of the study design, that is, whether the experimental design in light of the drugs and conditions under investigation is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); and

• The prevalence and life history of the disease when evaluating the adequacy of the number of subjects and the response rate.

Regardless of the evidence supporting coverage for a particular off-label use, payment may only be made if the use is reasonable and necessary for the treatment of illness or injury of the specific patient receiving the drug.

4. If the provider decides to use a chemotherapeutic agent, non cancer chemotherapeutic drug or biological or combination that does not have FDA-approved labeling, the evidence used to make that decision (information in the compendia, established guidelines [for example guidelines developed by the National Comprehensive Cancer Network, Association of Community Cancer Center Compendia, American Society of Clinical Oncology], research studies in approved peer-reviewed medical journals, etc.) must be available upon request. In the case of a drug or biological that is administered for an off-label use NOT included in one of the compendia or established guidelines (e.g., National Comprehensive Cancer Network), the KX modifier is reported on the claim to indicate that supporting documentation as described above is available upon request. The KX modifier may not be used to circumvent a non-coverage decision if a contractor policy exists for a specific drug and that policy defines certain non-coverage conditions. Those defined non-covered conditions will remain non-covered whether KX appears on the claim or not.

5. If, however, a use is identified as not indicated by CMS or the FDA, or if a use is specifically identified as not indicated in one or more compendia listed or the contractor determines, based on peer reviewed medical literature that a particular use of a drug is not safe and effective, the off labeled usage is not supported and, therefore, the drug is not covered.

Hydration Administration (CPT codes 96360, 96361)

Medicare currently permits separate payment of hydration therapy provided sequentially (but not concurrently) to chemotherapy infusion.

CPT codes 96360 and 9631 are intended to report a hydration IV infusion consisting of a prepackaged fluid and/or electrolyte solutions (e.g., normal saline, D5-1/2 normal saline +30mEq KCl/liter), but are not used to report infusion of drugs or other substances. Hydration IV infusion typically requires direct physician supervision for purposes of consent, safety oversight or intra-service supervision of staff. Typically such infusions require little special handling to prepare or dispose of, and staff which administer these do not typically require advanced training. After initial set up, infusion typically entails little patient risk and thus little monitoring. Further instructions regarding hydration and its use may be found in the CPT Manual, particularly with regard to facilities. In addition, certain coding combinations are not permissible by the CCI edits.

Please refer to LCD L34960, Hydration Therapy for reasonable and necessary guidelines regarding hydration therapy.

Discarded Drugs and Biologicals

In certain situations, physicians, hospitals and other providers may schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. However, if a physician, hospital or other provider must discard the remainder of a single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded along with the amount administered, up to the amount of the drug or biological as indicated on the vial or package label. Medical record documentation must clearly indicate the amount of drug administered and the amount wasted. When billing drugs, units of service must be billed in multiples of the dosage specified in the full HCPCS descriptor. This descriptor does not always match the dose given. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient.

JW Modifier Requirement:

When billing for Part B drugs and biologicals (except those provided under CAP), the use of the JW modifier to
identify unused drugs or biologicals from single use vials or single use packages that are appropriately discarded is required. The discarded amount shall be billed on a separate claim line using the JW modifier. Providers are required to document the discarded drug or biological in the patient’s medical record.

Additionally, if after administering the prescribed dosage of any given drug, the provider must discard the remainder of a single-use vial or other package, Medicare may cover the amount of the drug discarded along with the amount administered.

The following elements must be followed in order for the discarded amount to be covered.

1. The vial must be a single-use vial.
2. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient.
3. The left-over amount must actually be discarded and may not be used for another patient regardless of whether or not that other patient has Medicare.

The following examples will help illustrate some of these points:

**Example of choice of vial size**

HCPCS for drug A indicates 1 unit = 30 mg

Drug A doses available from the manufacturer: 60 mg vial and 90 mg vial

The amount prescribed for the patient is 48 mg. If the provider uses a 90 mg vial to administer the dose, the provider may only bill 2 units (rather than 3 units) as the doses available from the manufacturer allow the prescribed amount to be administered with a 60 mg vial.

**Example illustrating the billing of wastage when the waste is included in the units reported:**

“If 2.5 milligrams of Zoledronic Acid is administered, it is appropriate to bill for 3 units, as the HCPCS defines the unit for Zoledronic Acid as 1 milligram.” In this example, the wastage is already considered reimbursed in the billing of the 3 units. (2.5 mg given and 0.5mg wasted). The entire 3mg expense to the provider is covered with one detail line by billing the J code multiplied by three. The medical record must document the 2.5 mg injected and the 0.5mg of wastage.

**Example of reporting JW modifier on separate claim line:**

A single use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95 unit dose is billed on one line, while the discarded 5 units shall be billed on another line by using the JW modifier. Both line items would be processed for payment.

**NOTE:** The JW modifier is not permitted when the actual dose of the drug or biological administered is less than the billing unit.

**Example of when the actual drug or biological dose administered is less than the billing unit:**

If one billing unit for a drug is equal to 10 mg of the drug in a single use vial and a 7 mg dose is administered to a patient while 3 mg of the remaining drug is discarded, then the 7 mg dose is billed using one billing unit that represents 10 mg on a single line item. Billing another unit on a separate line item with the JW modifier for the discarded 3 mg of drug is not permitted because it would result in overpayment. Therefore, when the billing unit is equal to or greater than the total actual dose and the amount discarded, the use of the JW modifier is not permitted.

As a reminder, drug wastage cannot be billed if none of the drug was administered (such as a missed appointment by the patient).

**NOTE:** Multi-use vials are not subject to payment for discarded amounts of drug or biological.

**NOTE:** The JW modifier is not used on claims for CAP drugs

**Compounded Drugs**

Compounded medications created by a pharmacist in accordance with the Federal Food, Drug and Cosmetic Act
may be covered under Medicare. A compounded drug is defined as a combination of drugs mixed by a pharmacist. This definition does not include a simple reconstitution of a drug as directed by the package insert. Compounded drugs that are self-administered are not a covered Medicare service.

**Coding Guidelines**

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This information does not take precedence over CCI edits. Please refer to CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

If the "J" code descriptor can be multiplied to reflect the dosage being administered, use the J-code, with the appropriate number of units which reflect the dosage given.

It is not appropriate to use the "J" code with a multiplier in the units' field, when there is another "J" code, which more closely describes the amount given.

It is not appropriate to bill for the full amount of a drug when it has been split between two or more patients. Bill only for the amount given to each beneficiary.

NOC codes should only be reported for those drugs that do not have a valid HCPCS code which describes the drug being administered.

When appropriate, the NOC code is selected based upon the therapeutic value of the drug (e.g., J8999 Prescription drug, oral, chemotherapeutic, NOS; J3490 Unclassified drugs, etc.).

When billing with an NOC code, include on the claim, the narrative description reflective of the agent and the dose administered.

Where the sole purpose of an office visit was for the patient to receive an injection, (CPT codes 96372, 96373, 96374, and 96379) payment may be made only for the injection service (if it is covered).

Conversely, injection services (CPT codes 96372, 96373, 96374, and 96379) included in the Medicare Physician Fee Schedule (MPFS) are not paid for separately, if the physician is paid for any other physician fee schedule service furnished at the same time.

Payment for the administration of a chemotherapy injection or infusion, injection or infusion of certain cancer drugs not used to treat cancer, and monoclonal antibodies (CPT codes 96401-96549) may be paid when provided on the same day as an Evaluation and Management (E/M) service, other than 99211, if the E/M service represents a separate and significantly identifiable service. Modifier 25 must be used. A different diagnosis code is not required. The drug is separately payable.

All injection claims must include the specific name of the drug and dosage. Identification of the drug enables proper payment for the services.

Off-label uses of a drug or biological that are NOT supported in one of the compendia or established guidelines (e.g., National Comprehensive Cancer Network) as detailed above, should be reported with the KX modifier as appropriate to indicate that literature supporting the off-label use is available upon request. The KX modifier may not be used to circumvent a non-coverage decision if a contractor policy exists for a specific drug and that policy defines certain non-covered conditions. Supporting documentation must be available upon request.

Services related to non-covered services or drugs are also not covered (e.g., administration services).

When the drug is purchased by the beneficiary, or when the drug was supplied without charge by the manufacturer, it should NOT be billed to Medicare by the provider, even with a submitted charge of $0.00.

The chemotherapy administration codes apply to parenteral administration of non-radionuclide antineoplastic drugs and antineoplastic agents provided for the treatment of non-cancer diagnoses (e.g. cyclophosphamide for autoimmune conditions), or to substances such as monoclonal antibody agents and other biologic response modifiers. Administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is not considered chemotherapy administration. Such services are reported using the following CPT codes as appropriate: codes 96365-96368 and 96372, 96374-96376.

The chemotherapy administration codes may be reported when the clinical indication for the drug being administered satisfies the definition above.

Chemotherapy administration codes include confirmation or recalculation of doses based upon the condition of the patient.
the patient on the day of chemotherapy administration.

When administering multiple infusions, injections, or combinations, only one "initial" drug administration service code should be reported per patient per day, unless protocol requires that two separate IV sites must be used. The initial code is the code that best describes the key or the primary reason for the encounter, and is reported irrespective of the order in which the infusions or injections occur.

If an injection or infusion is of a subsequent or concurrent nature, even if it is the first such service within that group of services, the subsequent or concurrent code from the appropriate section should be reported (e.g., the first IV push given subsequent to an initial one-hour infusion is reported using a subsequent IV push code).

Report separate codes for each parenteral method of administration employed when therapy is administered by different techniques. Medications (e.g., antibiotics, steroidal agents, antiemetics, narcotics analgesics) administered independently or sequentially as supportive management of chemotherapy or certain monoclonal antibody administration should be separately reported using CPT codes 96360, 96361, 96365 or 96379 as appropriate. Report the specific service as well as code(s) for the specific substance or drug(s) provided.

There is no code for concurrent administration of chemotherapeutic drugs. Multiple drugs given at the same session are considered to be sequential, rather than concurrent. The services are reported with CPT code 96411 for IV push administration of additional drugs/substances at the same session and CPT code 96417 for IV infusion administration of additional drugs/substances at the same session.

When reporting codes for which infusion time is a factor, use the actual time over which the infusion is administered. Services leading up to the infusion and to conclude the infusion are included in the infusion service and not separately reported. The services include starting the IV and monitoring the patient post-infusion. Standard clinical practice is to document the actual start and stop times in the patient’s medical records. This would ensure that the times are accurate in the event there are interruptions or delays during the infusion process. Flow sheets kept by personnel during infusion services help to identify proper infusion times.

The first hour initial codes are defined as "up to one hour". This eliminates the need to report the 52 modifier to inform Medicare of durations of less than 1 hour.

Report CPT code 96415 for infusion intervals of greater than 30 minutes beyond 1 hour increments. Report CPT code 96415 in conjunction with CPT code 96413.

The fluid used to administer the drug(s) is considered hydration and is not separately reportable. An infusion consisting of three substances in a single bag is not intended to be reported as three separate infusion services.

Do not report CPT code 96360 if performed as a concurrent infusion service. Report CPT code 96361 to identify hydration furnished as a secondary or subsequent service after a different initial service is administered through the same IV access. Report CPT code 96366, 96367, 96375 or 96376, to identify therapeutic, prophylactic or diagnostic drug infusion or injection when provided as a secondary or subsequent service in association with CPT code 96413.

Report CPT code 96417 in conjunction with CPT code 96413. Report CPT code 96417 only once per sequential infusion.

Report CPT code 96523 if it is the only service provided that day. If there is a visit or other drug administration service provided on the same day, payment for CPT code 96523 is included in the payment for the other service.

If performed to facilitate an infusion or injection of a non chemotherapeutic drug, biological or cancer chemotherapy agent, the following are included and are not reported separately:

- Use of local anesthesia
- IV start
- Access to indwelling IV, subcutaneous catheter or port
- Flush at conclusion of infusion
- Standard tubing, syringes and supplies
- Preparation of chemotherapy agent(s)
- Report CPT code 36593 for declotting a catheter or port.

**Modifier EJ – subsequent dose in a series**

To distinguish between the initial dose of a drug and subsequent doses of that same drug used in a sequential
series in the treatment of a condition, the modifier EJ should be used to identify the subsequent doses. Do not report an initial dose of a drug with the –EJ modifier.

**Biosimilar Modifiers**

Effective January 1, 2016 with an implementation date of January 4, 2016, Per CR9284, Medicare Part B claims for biosimilar biological products that are paid separately (that is, not paid as part of a bundle or package of services) and are assigned to a Healthcare Common Procedure Coding System (HCPCS) code will be required to include a modifier that identifies the manufacturer of the specific product. Once CMS has assigned biosimilar modifiers to a HCPCS code that describes biosimilar biological products, and has disseminated the modifier assignments through the appropriate process, the use of a biosimilar modifier on a claim for the associated HCPCS code will become mandatory. Updates to the assignment of HCPCS codes and biosimilar modifiers will be done quarterly. 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.
• **Part B Billing for certain new biosimilar biological products before the modifier is implemented:**

In situations where a HCPCS code is already associated with one or more biosimilar modifiers and a new biosimilar biological product becomes available before its corresponding manufacturer’s modifier becomes effective, a Not Otherwise Classified (NOC) code without a modifier may be used to bill for the new biosimilar product. Another acceptable alternative would be to hold submission of the claim until the effective date of the HCPCS code and appropriate corresponding biosimilar modifier. For additional information, please visit the “Part B Biosimilar Product Payment and Required Modifiers” webpage located at: [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html)

• **Part B Billing for biosimilar biological products when the existing corresponding biosimilar modifier(s) are not appropriate:**

When billing for a biosimilar product HCPCS code for which the existing corresponding biosimilar modifier(s) do not appropriately describe the product, providers are instructed to include information on the claim that identifies the product and state that the product’s manufacturer is not currently associated with a corresponding biosimilar HCPCS code.
Reporting Compounded Drugs

Compounded drugs are reported as J7999. Please refer to Local coverage Article A54100, for information on reporting compounded drugs.

Special Instructions for the use of Implantable pumps

Compounded drugs and/or combination drugs used in the refilling of implantable infusion pumps are reported as J7999KD. The modifier -KD must be appended to J7999, in this case to indicate infused through Durable Medical Equipment (DME).

The National Coverage decision, 280.14, regarding infusion pumps, will govern the coverage of services related to implantable infusion pumps. (Please refer to LCD, L35112, Implantable Infusion Pump for additional information regarding coverage.) All criteria must be fulfilled in order to be considered for coverage. The medical record for the initial infusion billed to the Contractor must contain the diagnosis, why other therapies failed, a record or the response of the patient to temporary infusion and the reason the pump was implanted. This must be available to the Contractor upon request. Subsequent repetitive infusions for the same patient for the same diagnosis and the same therapy should be billed with an EJ modifier appended to the subsequent infusion drug code(s). Report J7999KD for NOC drugs administered through an implanted infusion pump. The KD modifier must be used to identify drugs being infused through Durable Medical Equipment (DME), as above. Refer to LCD L35112, Implantable Infusion Pump, for Reasonable and Necessary guidance.

Other Information

Other Comments

Please refer to LCD L35112, Implantable Infusion Pump, for additional information.

Please refer to LCD L35093, for reasonable and necessary guidelines regarding Intravenous Immune Globulin (IVIG).

Please refer to LCD L34822, for reasonable and necessary guidelines regarding Luteinizing Hormone-Releasing Hormone (LHRH) Analogs

Please refer to LCD L35428, for reasonable and necessary guidelines regarding Thrombolytic Agents.

Documentation Information

Documentation must be maintained in the patient’s medical record and made available to the contractor upon request.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.

The submitted medical record must support the use of the selected ICD-10-CM code(s).

The submitted CPT/HCPCS code must describe the service performed.

When a portion of the drug is discarded, the medical record must clearly document the amount administered and the amount wasted. The documentation must include the date, time, amount of medication wasted, and the reason for the wastage.

Effective January 1, 2017, the JW modifier is required to be reported to identify drug wastage.

The EJ modifier should be used to identify subsequent claims for a defined course of therapy (e.g., EPO, sodium hyaluronate, infliximab).

Physicians or suppliers are expected to be able to produce copies of relevant supporting full-text articles, guidelines, and/or supporting literature when an unlabeled use does not appear in at least one of the approved compendia, or the unlabeled use is listed in the compendia as having insufficient data or as considered investigational. Abstracts, opinions, or book chapters are not acceptable. Availability of this documentation is indicated by use of the KX modifier on the submitted claim. This material is to be submitted whenever requested.

The KD modifier must be used to identify drugs being administered through Durable Medical Equipment.

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Coding Information

Bill Type Codes:

Bill Type Code | Bill Type Description
--- | ---
074x | Clinic - Outpatient Rehabilitation Facility (ORF)

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:
This Article is applicable to all drugs and biological CPT and HCPCS codes.

Group 1 Codes: N/A

Group 1 CPT/HCPCS Code Group 1 CPT/HCPCS Code Description

ICD-10 Codes that are Covered N/A
ICD-10 Codes that are Not Covered N/A

Revision History Information

<table>
<thead>
<tr>
<th>Revision History Date</th>
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<th>Revision History Explanation</th>
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<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision HistoryExplanation</th>
</tr>
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<tbody>
<tr>
<td>01/01/2016</td>
<td>R8</td>
<td>Article revised and published on 01/12/2017 effective for dates of service on and after 01/01/2017. Information on reporting the JW modifier has been revised per CR 9603 effective 01/01/2017. The Documentation Information section has been updated to align with the Novitas LCD Documentation requirements.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R7</td>
<td>Article revised and published on 01/28/2016 effective for dates of service on and after 01/01/2016 to reflect the annual CPT/HCPCS code updates. Removed reference to Q9977 and replaced with J7999. Removed the list of CPT/HCPCS codes from the Coding information section as the direction provided by this Article is for all drugs and biologicals, therefore individual codes will not be listed. Removed Bill Type codes and the Revenue code from the coding section. Added information pertaining to implementation of biosimilar claim modifiers per CMS CR 99284. Updated language pertaining to CMS approved compendia per CMS CR 99386 and SSA 1861(t)(1). Removed reference to LCD L33115 which has retired and added reference to LCD L35112 which is current. Article A53049 has been consolidated for JH and JL with no change to content other than as noted in this revision history. Article A53048 for JH will be retired with this consolidation.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R6</td>
<td>Article revised and published on 09/11/2015 to change compounded drug from unspecified J3490 and J7799 codes to HCPCS code Q9977. Added reference to LCD L33115 for Implantable Infusion Pump for Reasonable and Necessary Guidance.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R5</td>
<td>Article revised and published 01/23/2015 to correct the publication date of the annual CPT/HCPCS code updates incorrectly listed as 01/22/2015 in revision history below. The code updates remain as listed in the revision history below.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R4</td>
<td>Article revised and published on 01/22/2015 to reflect the annual CPT/HCPCS code updates. For the following CPT/HCPCS code(s) either the short description and/or the long description was changed. Depending on which description is used in this article, there may not be any change in how the code displays in the document: J7195; J7301; J7302. The following codes have been deleted: J0150; J0151; J0900; J1060; J1070; J1080; J1271; J2275; J3120; J3130; J3140; J3150; J7335 and J9265. The following codes have been added: J0153; J0571; J0572; J0573; J0574; J0575; J0887; J0888; J1071; J1322; J1439; J2274; J3704; J3121; J3145; J7181; J7182; J7200; J7201; J7327; J7336; J9267 and J9301. These changes are within a code range.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R3</td>
<td>Corrected LCD to L35112.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R2</td>
<td>Article revised to provide clarification regarding the proper billing for compounded drugs that are administered via an implantable infusion pump, consistent with LCD, L33115, Implantable Infusion Pump. Typographical errors corrected and duplicative language removed.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>Article revised to correct typographical error in Revision History Number R1 below. The sentence LCD also revised to provide clarification regarding drug wastage for single dose vials based on a reconsideration request should read Article also revised to provide clarification regarding drug wastage for single dose vials based on a reconsideration request. (Article updated 06/26/2014)</td>
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**Related Local Coverage Document(s)** Article(s) A54100 - Compounded Drugs Used in an Implantable Infusion Pump A53127 - Self-Administered Drug Exclusion List LCD(s) L34960 - Hydration Therapy L35112 - Implantable Infusion Pump

**Related National Coverage Document(s)** NCD(s) 280.14 - Infusion Pumps

**Statutory Requirements URL(s)** N/A

**Rules and Regulations URL(s)** N/A

**CMS Manual Explanations URL(s)** N/A

**Other URL(s)** N/A

**Public Version(s)** Updated on 09/08/2017 with effective dates 09/14/2017 - N/A Updated on 01/06/2017 with effective dates 01/01/2017 - N/A Updated on 01/22/2016 with effective dates 01/01/2016 - N/A Some older

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Keywords

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