Billing and Coding Article

Article - Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (A53049)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

NOT AN LCD REFERENCE ARTICLE

This article is not in direct support of an LCD. Learn more

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12202 - MAC B	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12301 - MAC A	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12302 - MAC B	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12401 - MAC A	J - L	New Jersey

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Novitas Solutions, Inc.	A and B MAC	12402 - MAC B	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12501 - MAC A	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	Delaware District of Columbia Maryland New Jersey Pennsylvania

Article Information

General Information

Article ID
A53049

Article Title
Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents

Article Type
Billing and Coding

Original Effective Date
10/01/2015

Revision Effective Date
11/02/2023

Revision Ending Date
N/A

Retirement Date
N/A

CMS National Coverage Policy

Internet-Only Manuals (IOMs):

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual,*
  - Chapter 15, Sections 50 Drugs and Biologicals and 60.1 Incident To Physician's Professional Services
  - Chapter 16, Section 10 General Exclusions from Coverage
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual,*
  - Chapter 1, Part 4, Section 280.14 Infusion Pumps
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual,*
  - Chapter 12, Sections 20.3 Bundled Services/Supplies, 30.5 Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions, 30.6.6 Payment for Evaluation and Management Services Provided During Global Period of Surgery and 30.6.7 Payment for Office or Other Outpatient Evaluation and Management (E/M) Visits (Codes 99202-99215)
  - Chapter 17 Drugs and Biologicals
  - Chapter 23, Section 20.9 National Correct Coding Initiative (NCCI)

Social Security Act (Title XVIII) References:

- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.
- Title XVIII of the Social Security Act, Section 1861(t)(1) Drugs and Biologicals.
- Title XVIII of the Social Security Act, Section 1861(v)(1)(A) Reasonable Cost.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment may be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Article Guidance

Article Text

Notice: It is not appropriate to bill Medicare for services that are not covered as if they are covered. When billing for non-covered services, use the appropriate modifier.

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 medically reasonable and 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 medically 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 noncovered immunizations; and

- They have not been determined by the United States (U.S.) Food and Drug Administration (FDA) to be less than effective.

Definition of Drug or Biological

Drugs and biologicals must be determined to meet the statutory definition. Under the statute Section 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 one of the statutorily named compendia. Due to changes in the pharmaceutical reference industry, some of the statutorily named compendia are no longer published. Examples of compendia that are currently in publication include the United States Pharmacopoeia (USP), the United States Pharmacopoeia National Formulary (USP-NF), or the Homeopathic Pharmacopoeia of the United States (HPUS), or the American Dental Association (ADA) Guide to Dental Therapeutics (except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics). 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.

Self-Administered Drugs

Drugs that can be self-administered by the patient, such as those in pill form or in self-injection form, 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, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs.

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. 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.

In the past, Medicare Administrative Contractors (MACs) may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. For example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. **Medicare will no longer pay for such doses.** In addition, **Medicare will no longer pay for any drug when it is administered on an outpatient emergency basis if the drug is excluded because it is usually self-administered by the patient.**

To determine if a drug or biological cannot be self-administered, please refer to the CMS IOM Publication 100-02, Chapter 15, Section 50.2. For additional information, please refer to Local Coverage Articles A53127, Self-Administered Drug Exclusion List.

Incident To Requirements

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 is not usually self-administered, must be furnished by a physician 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.

If a patient purchases a drug and the physician administers it, the physician cannot bill Medicare for the drug. 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 when purchased by the physician.

Whole blood is a biological that cannot be self-administered and is covered when furnished incident to a physician's service. Payment may also be made for blood fractions if all coverage requirements are satisfied.

Approved Use of Drug

Use of the drug or biological must be safe and effective and otherwise medically reasonable and necessary. Drugs or biologicals approved for marketing by the 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 if:

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

Unlabeled Use of Drug

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. The 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 medically reasonable and necessary according to accepted standards of medical practice.

- Not for a 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 medically 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 medically reasonable and necessary for the diagnosis or treatment of an illness or injury).

Payment for Antigens and Immunizations

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.

Please refer to LCDs L36240, Allergen Immunotherapy for reasonable and necessary requirements.

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 direct exposure, preventive immunization (vaccination or inoculation against such diseases as smallpox, polio, diphtheria, etc.) is not covered. However, pneumococcal, hepatitis B, and influenza vaccines are exceptions to this rule.

For additional information, please refer to Billing and Coding Articles A58872, Tetanus Immunization.

Less Than Effective Drug

A drug that is less than effective is not eligible for reimbursement (i.e., a drug that the FDA 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 physician is contemplating the off-label use of an FDA approved drug or biological in an anti-cancer chemotherapeutic regimen, 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.

   Note: Refer to the CMS IOM Publication 100-02, Chapter 15, Section 50.4.5.B for recent revisions to the Compendia List. Authoritative lists of Compendia will be adjusted, as needed, according to the process defined in the CMS IOM Publication 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 off-label use of the chemotherapeutic agent is not listed in any of the compendia or is listed as having insufficient data or as 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 prior to publication. In-house publications of pharmaceutical manufacturing, sales, or distribution companies or abstracts (including meeting abstracts) are excluded from consideration.
   In determining whether an off-label use is supported, the contractor will consider (among other things) the following:
   - Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the

published evidence.
- Whether the administered chemotherapy regimen is adequately represented in the published evidence.
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
- Whether the study is appropriate to address the clinical question.

The contractor will consider:

1. 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);
2. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and
3. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

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*
- *Lancet*
- *Lancet Oncology*
- *Leukemia*
- *The New England Journal of Medicine*
- *Radiation Oncology*

3. When the provider decides to use an FDA approved chemotherapeutic agent off-label, the evidence used to make that decision (information in the compendia, established guidelines [for example, guidelines developed by the NCCN], research studies in approved peer-reviewed medical journals, etc.) must be available upon request. 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 investigational. Abstracts, opinions, or book chapters are not acceptable.
4. If a use is identified as not indicated by the CMS or the FDA, 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-label usage is not supported. Therefore, the drug is

not covered.

Hydration Administration (CPT codes 96360 and 96361)

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

CPT codes 96360 and 96361 are intended to report a hydration intravenous (IV) infusion consisting of a prepackaged fluid and/or electrolyte solutions (e.g., normal saline, D5-1/2 normal saline +30 mEq KC1/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 National Correct Coding Initiative (NCCI) edits.

JW Modifier Requirement

The CMS encourages physicians, hospitals and other providers and suppliers to care for and administer drugs and biologicals to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. According to the Social Security Act (SSA) Section 1861(v)(1)(A), the reasonable cost of any service is the cost actually incurred, excluding any part of an incurred cost found to be unnecessary in the efficient delivery of needed health services. On this basis, the definition of a reasonable cost for a drug or biological is met when the beneficiary is administered the required dose of the drug or biological in an efficient manner.

Effective January 1, 2017, when billing for drugs and biologicals (except those provided under the Competitive Acquisition Program for Part B drugs and biologicals [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 amounts of drugs or biologicals in the patient's medical record.

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

1. The vial/package must be a single-use vial/package.
2. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer/supplier 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.

A situation in which the JW modifier is not permitted is when the actual dose of the drug or biological administered is less than the billing unit. For example, one billing unit for a drug is equal to 10mg of the drug in a single use vial. A 7mg dose is administered to a patient while 3mg of the remaining drug is discarded. The 7mg dose is billed using one billing unit that represents 10mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3mg 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.

JZ Modifier Requirement

Effective 07/01/2023, providers must report the JZ modifier (Zero drug amount discarded/not administered to any patient) when there is no wastage to report. This must be reported on all claims that bill for drugs separately payable under Part B when there is no discarded amount from single-dose containers or single-use packages. For the amount administered, the claim line must include the billing and payment code, the JZ modifier showing no discarded amounts, and the number of units administered in the units' field.

The JW and JZ modifier policy does not apply for drugs that are not separately payable, such as packaged OPPS or ASC drugs, or drugs administered in the FQHC or RHC setting or to drugs assigned status indicator N (Items and Services Packaged into APC Rates) under the OPPS. Similarly, the JW and JZ modifiers do not apply to drugs assigned payment indicator "N1" (ASC).

Coding Guidance

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

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

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.

Reporting the Appropriate Number of Units

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.

Reporting Not Otherwise Classified (NOC) Code(s)

Please refer to Billing and Coding Articles A59073, Complex Drug Administration Coding for information regarding billing NOC codes.

Reporting Evaluation and Management (E/M) Visit on the Same Day as Drug Administration Services

The E/M service for CPT code 99211 cannot be paid if it is billed with a drug administration service. This includes a chemotherapy or nonchemotherapy drug infusion service, as well as a therapeutic or diagnostic injection code.

When a medically necessary, significant and separately identifiable E/M service (which meets a higher complexity level than CPT code 99211) is performed, in addition to drug administration service(s), the appropriate E/M CPT code should be reported with modifier -25. Documentation should support the level of E/M service billed. For an E/M service provided on the same day, a different diagnosis is not required.

Please refer to the CMS IOM Publication 100-04, Chapter 12, Sections 20.3.B, 30.5.C, D, F, 30.6.6 and 30.6.7.D for additional information on E/M services furnished on the same day as drug administration services.

Please refer to Billing and Coding Articles A59073, Complex Drug Administration Coding for information regarding chemotherapy and nonchemotherapy drug administration codes.

Reporting Multiple Infusions or Injections

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, narcotic 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 the 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.

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.

Reporting Infusion Time(s) and Fluid

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. Time may be documented with start and stop times or with total time.

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 one hour.

Report the additional hour of chemotherapy administration with CPT code 96415 for infusion intervals of greater than 30 minutes beyond one hour increments. Report CPT code 96415 in conjunction with the initial chemotherapy administration CPT code 96413.

The fluid used to administer the drug(s) is considered incidental 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 the initial hydration CPT code 96360 if performed as a concurrent infusion service. Report the additional hour of hydration with 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 the additional hour or additional sequential CPT code 96366, 96367, 96375 or 96376 (as applicable) to identify therapeutic, prophylactic or diagnostic nonchemotherapy drug infusion or injection when provided as a secondary or subsequent service in association with chemotherapy administration CPT code 96413.

Report the additional sequential infusion chemotherapy administration CPT code 96417 in conjunction with the initial chemotherapy administration CPT code 96413. Report CPT code 96417 only once per sequential infusion.

Report irrigation CPT code 96523 if it is the only service provided that day. If there is an E/M 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.

Report CPT code 36593 for declotting a catheter or port.

Please refer to Billing and Coding Articles A59073, Complex Drug Administration Coding for additional information regarding chemotherapy and nonchemotherapy drug administration codes.

Services Not Separately Reportable

If performed to facilitate an infusion or injection of a drug or biological, 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)

Biosimilar Modifiers

Effective on April 1, 2018, providers and suppliers will no longer be required to report modifiers with HCPCS codes for

biosimilars (reference the CMS Transmittal 3966, CR 10454).

Compounded Drugs

Compounded drugs are drugs not reconstituted as labeled in order to create a combination of drugs or vary the concentration/volume. As such, compounded medications do not have a National Drug Code (NDC) number, an average sales price (ASP) or an average wholesale price (AWP). Compounded drugs are contractor priced on invoice.

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 Guidance:

1. Compounded drugs should be reported with HCPCS code J7999 on a single claim line.
2. Place quantity = '1' on the line billed for J7999.
    a. Enter the name, total dose (in mg or mcg) of each drug of the refill, and invoice amount in Box 19 of the CMS 1500 or the appropriate comment loop of electronic claims.
    b. Covered compounded single or combination drugs should be billed on a single detail line.
3. Do not list the drug separately from the dosage, such as morphine bupivacaine baclofen sufentanil 20mg 6mg 4mcg 5mcg. This format will be denied.
4. List each drug with the applicable dosing amount, for example morphine 20mg, bupivacaine 6 mg, baclofen 4 mcg, sufentanil 5 mcg.
5. The ICD-10-CM code used on each detailed line must represent the condition treated by the drug(s) billed on that detail line.
6. Drug doses used in narrative description must be in mgs or mcgs only. Do not report µgs.

Use of Infusion Pumps

Medicare will consider infusion pumps and associated services medically reasonable and necessary for the conditions listed in the Medicare National Coverage Determination Manual Pub.100-03, Chapter 1, Section, 280.14.

The use of compounded drugs has been especially prevalent in the filling of infusion pumps. The following methods are appropriate when billing for drugs used in infusion pumps:

1. When submitting a claim for compounded drug(s) for a single agent or a combination of agents, providers must use HCPCS code J7999. Even though the compound is similar to or includes a drug with a specific HCPCS code, providers must use HCPCS code J7999, Compounded drug, not otherwise classified, for reimbursement of the compounded drug. **The KD modifier must be appended to indicate the drug will be administered through Durable Medical Equipment (DME) such as an infusion pump**.
2. When a non-compounded drug is used (a true 'off –the –shelf' product without compounding), the specific HCPCS code for the drug may be used.

Note: Compounded drugs and/or combination drugs used in infusion pumps should be reported with HCPCS code J7999 and **appended with modifier KD to indicate the drugs were infused through DME**.

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. 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.
3. 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.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

CPT/HCPCS Modifiers

N/A

ICD-10-CM Codes that Support Medical Necessity

N/A

ICD-10-CM Codes that DO NOT Support Medical Necessity

N/A

ICD-10-PCS Codes

N/A

Additional ICD-10 Information

N/A

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

CODE	DESCRIPTION
999x	Not Applicable

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

Other Coding Information

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
11/02/2023	R21	Article revised and published on 11/16/2023 effective for dates of service on or after 11/2/2023 to correct a typographical error. Under the section Use of Infusion Pumps, #2, the following sentence has been deleted: "Payment for these drugs is reimbursed differently and is not subject to the fee schedule below."
11/02/2023	R20	Article revised and published on 11/02/2023 to include information and coding guidance on Compounded Drugs and JZ modifier requirements, to revise information regarding infusion pumps and to align articles across JH/JL and JN. There have also been formatting changes made to the article.
06/06/2022	R19	Article revised and published on 06/08/2023 in response to the CMS Change Request 13064. The CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Section 30.6.7 Payment for Office or Other Outpatient Evaluation and Management (E/M) Visits (Codes 99201-99215) has been revised to change the name of Section 30.6.7 to 'Payment for Office or Other Outpatient Evaluation and Management (E/M) Visits (Codes 99202-99215)'.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
06/06/2022	R18	Article revised and published on 06/02/2022 in response to the new Billing and Coding Article for Complex Drug Administration Coding (A59073) that becomes effective on 06/06/2022. This article has been updated and overlapping information has been removed. Please refer to the Complex Drug Administration Coding Article for billing and coding information. The following sections have been removed: 'Chemotherapeutic Agents', 'Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen', 'Discarded Drugs and Biologicals', 'Reporting Not Otherwise Classified (NOC) Codes', and 'Reporting Chemotherapy Administration and Related Nonchemotherapy Drug Administration Code(s)'. A 'Documentation Requirements' section was added and the 'Definition of Drug or Biological' section has been revised to reflect current references. Minor formatting changes have been made throughout.
05/13/2021	R17	Article revised and published on 03/24/2022 in response to an inquiry. Language was added to the 'Coding Guidelines' section for 'Reporting Chemotherapy Administration and Related Nonchemotherapy Drug Administration Code(s)' regarding when it is appropriate to use these codes based on the CPT® Codebook.
05/13/2021	R16	Article revised and published on 05/13/2021 to revise the 'Reporting infusion time(s) and fluid' section to add the following statement: Time may be documented with start and stop times or with total time. Minor formatting changes made throughout the coding section.
11/07/2019	R15	Article revised and published on 11/07/2019. Consistent with CMS Change Request 10901 and system changes, the order of the Coding Section has been revised and new sections for CPT/HCPCS Modifiers and Other Coding Information have been added.
04/18/2019	R14	Article revised and published on 04/18/2019. The IOM Citations section was revised to add titles of sections, to delete references that were not applicable and to add a reference to the National Correct Coding Initiative (NCCI) edits. References to the NCCI edits were updated consistent with CMS Change Request 10868.
06/14/2018	R13	Article reviewed for administrative purposes. No changes were made to the Article itself.
06/14/2018	R12	Article revised and published on 06/14/2018. Based on an inquiry, revised the information on reporting an E/M visit on same day as drug administration services per CMS IOM Pub. 100-04, Chapter 12, Sections 30.5.F, 30.6.6, and 30.6.7.D. Per article annual review, updated the IOM citation references, added clarification on the compendia references included in the statutory definition of drugs and biologicals, reformatted the article and placed headers for each category of information, added short descriptive language to identify the CPT codes included in the "Coding Guidelines" section, removed LCDs referenced under the "Other Comments" section, and removed

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		the "Documentation Information" section as it was duplicative to information located in other areas of the article. Bill Types will not be included in the article as there are many that would apply to these services. Therefore, Bill Type 074x was removed with this revision and replaced with 999x Not applicable.
04/01/2018	R11	Article revised and published on 04/12/2018, effective for dates of service on or after 04/01/2018, per TN 3966 CR 10454, added that providers and suppliers will no longer be required to report modifiers with HCPCS codes for biosimilars. Removed the previous biosimilar modifier reporting information from the article text.
09/14/2017	R10	Article revised and published on 09/14/2017. In the "Coverage and/or Medical Necessity" section, updated the hyperlink to the Novitas webpage for self-administered drug information and added reference to A53127 Self-Administered Drug Exclusion List. Under the header "Hydration Administration", added reference to LCD L34960 Hydration Therapy. Under the header "Biosimilar Modifiers", added information to clarify CR 9284 for reporting biosimilar products and corresponding biosimilar modifiers in certain circumstances. Added hyperlink to the CMS.gov webpage for Part B Biosimilar Biological Product Payment and Required Modifiers. In the "Associated Documents" section, added hyperlinks to Related Local Coverage Documents: L35112 Implantable Infusion Pump, A54100 Compounded Drugs Used in an Implantable Infusion Pump, L34960 Hydration Therapy, A53127 Self-Administered Drug Exclusion List, and Related National Coverage Document: NCD 280.14 for Infusion Pumps.
01/01/2017	R9	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.
01/01/2016	R8	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 CR9284. Updated language pertaining to CMS approved compendia per CMS CR9386 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.
10/01/2015	R7	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.
10/01/2015	R6	Article revised and published 01/23/2015 to correct the publication date of the annual

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		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.
10/01/2015	R5	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; J2271; 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; J2704; J3121; J3145; J7181; J7182; J7200; J7201; J7327; J7336; J9267 and J9301. These changes are within a code range.
10/01/2015	R4	Corrected LCD to L35112.
10/01/2015	R3	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.
10/01/2015	R2	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)
10/01/2015	R1	Article revised to provide definition of a reasonable supply of allergy antigen consistent with CR 8665 issued April 16, 2014 effective for dates of service on or after January 1, 2001. JW modifier information inserted. LCD also revised to provide clarification regarding drug wastage for single dose vials based on a reconsideration request. (Article updated 06/12/2014)

Associated Documents

Related Local Coverage Documents

Articles

A59073 - Billing and Coding: Complex Drug Administration Coding

A58872 - Billing and Coding: Tetanus Immunization

A53127 - Self-Administered Drug Exclusion List:

LCDs

L36240 - Allergen Immunotherapy

Related National Coverage Documents

NCDs

280.14 - Infusion Pumps

Statutory Requirements URLs

N/A

Rules and Regulations URLs

N/A

CMS Manual Explanations URLs

N/A

Other URLs

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		
11/09/2023	11/02/2023 - N/A	Currently in Effect (This Version)
10/27/2023	11/02/2023 - N/A	Superseded
06/02/2023	06/06/2022 - 11/01/2023	Superseded
05/27/2022	06/06/2022 - N/A	Superseded

Keywords

N/A