Local Coverage Article:
Billing and Coding: Complex Drug Administration Coding (A58533)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

Article Information

General Information

Article ID
A58533

Original Effective Date
01/01/2021

Article Title

Revision Effective Date

Billing and Coding: Complex Drug Administration Coding 07/23/2021

Article Type
Billing and Coding

Revision Ending Date
N/A

Retirement Date
N/A

CMS National Coverage Policy

Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy.

Title XVIII of the Social Security Act (SSA):

- Section 1861(t) that these drugs may be paid when they are administered incident to a physician's service and determined to be medically reasonable and necessary
- Section 1861(s) (2) (A) or (B) definition of medical and other health services
- Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member

CMS Publications:

- CMS Publication 100-02 *Medicare Benefit Policy Manual,* Chapter 15-Covered Medical and Other Health Services, Section 50 Drugs and Biologicals and 50.3 Incident-to Requirements
- CMS Publication 100-04 Medicare *Claims Processing Manual,* Chapter 12-Physicians/Nonphysician Practitioners, Section 30.5 Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions, Part D-Chemotherapy Administration
- CMS Publication 100-04 Medicare *Claims Processing Manual,* Chapter 17 – Drugs and Biologicals, Section 40 – Discarded Drugs and Biologicals

Article Guidance

Article Text:

The Medicare Administrative Contractor has determined in review of submitted claims that there is inappropriate use of CPT codes 96401-96549 for chemotherapy and other highly complex drug or highly complex biologic agent administration.

The Current Procedural Terminology (CPT) codebook contains the following information and direction for the Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration CPT® codes: "Chemotherapy Administration codes 96401-96549 apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of non-cancer diagnoses (e.g. cyclophosphamide for auto-immune conditions) or to substances such as certain monoclonal antibody agents, and other biologic response modifiers. The highly complex infusion of chemotherapy or other drug or biologic agents requires physician or other qualified health care professional work and/or clinical staff monitoring well beyond that of therapeutic drug agents (96360-96379) because the incidence of severe adverse patient reactions are typically greater. These services can be provided by any physician or other qualified health care professional. Chemotherapy services are typically highly complex and require direct supervision for any or all purposes of patient assessment, provision of consent, safety oversight, and intraservice supervision of staff. Typically, such chemotherapy services require advanced practice training and competency for staff who provide these services; special considerations for preparation, dosage, or disposal; and commonly, these services entail significant patient risk and frequent monitoring. Examples are frequent changes in the infusion rate, prolonged presence of the nurse administering the solution for patient monitoring and infusion adjustments, and frequent conferring with the physician or other qualified health care professional about these issues. When performed to facilitate the infusion of injection, preparation of chemotherapy agent(s), highly complex agent(s), or other highly complex drugs is included and is not reported separately. To report infusions that do not require this level of complexity, see 96360-96379. Codes 96401-96402, 96409-96425, 96521-96523 are not intended to be reported by the individual physician or other qualified

health care professional in the facility setting."

"The term 'chemotherapy' in 96401-96549 includes other highly complex drugs or highly complex biologic agents." (End quotation from CPT®)

Medicare has determined under Section 1861(t) that these drugs may be paid when they are administered incident to a physician's service and determined to be medically reasonable and necessary. Such determination of reasonable and necessary is currently left to the discretion of the Medicare Administrative Contractors (MACs). The documentation in the patient's medical record must support the drugs as being medically reasonable and necessary.

As stated in the CMS Internet Only Manual Publication 100-04, *Medicare Claims Processing Manual*, Chapter 12-Physicians/Nonphysician Practitioners, Section 30.5 Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions, Part D-Chemotherapy Administration, *"A/B MACs (B) may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare."*

Not Otherwise Classified (NOC) Drug Billing:

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

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

- The name of the drug
- The total dosage (plus strength of dosage, if appropriate), and
- The method of administration.

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

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

See Unclassified Drug Billing When Submitting EMC on our website for further information.

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

JW Modifier

JW Modifier effective January 1, 2017. Claims for discarded drugs or biologicals amount not administered to any patient shall be submitted using the JW modifier.
Unused drugs or biologicals from single use vials or single use packages that are opened, and the entire dose/quantity is not administered, and the remainder is discarded. (Except those provided under the Competitive Acquisition Program (CAP) for Part B drugs and biologicals).
Providers must document the discarded drugs or biologicals in the patient's medical record.
This modifier, billed on a separate line, will provide payment for the amount of discarded drugs or biologicals.

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.

(See MLN Matters Number: MM9603 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf)

Route of Administration Modifier:
The use of the JA and JB modifiers is required for drugs which have one HCPCS Level II (J or Q) code but multiple routes of administration. Drugs that fall under this category must be billed with JA Modifier for the intravenous infusion of the drug or billed with JB Modifier for subcutaneous injection of the drug.

The lists below are not an all-inclusive list and may be subject to further revision.

Subcutaneous and Intramuscular Injection Non-Chemotherapy

The administration of the following drugs should not be billed using a chemotherapy administration code. Instead, the administration of the following drugs in their subcutaneous or intramuscular forms should be billed using CPT code 96372, (therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular).

Generic/Trade Names:

Generic Name	Trade Name	HCPCS Code
benralizumab	Fasenra™	J0517
canakinumab	Ilaris®	J0638
certolizumab pegol*	Cimzia®*	J0717*
filgrastim (g-csf) excludes biosimilars***	Neupogen®***	J1442***
tbo-filgrastim	Granix®	J1447
filgrastim-sndz biosimilar***	Zarxio®***	Q5101***
filgrastim-aafi***	Nivestym®***	Q5110***

luspatercept-aamt	Reblozyl®	J0896
mepolizumab	NUCALA®	J2182
octreotide acetate depot	Sandotstatin LAR depot	J2353
omalizumab	Xolair®	J2357
pegfilgrastim**	Neulasta®**	J2505**
pegfilgfrastim-jmdb, biosimilar	Fulphila®	Q5108
pegfilgrastim-cbqv	Udenyca®	Q5111
pegfilgrastim-bmez	Ziextenzo®	Q5120
pegfilgrastim-apgf, biosimilar	Nyvepri™	Q5122
rilonacept	Arcalyst®	J2793
tildrakizumab-asmn	Ilumya™	J3245

*Note: The self-administration formulation of certolizumab pegol (Cimzia® prefilled syringe as a 200 mg/1 ml unit dose) is not a Medicare benefit. Providers and facilities must bill this formulation with the GY modifier as a statutorily excluded service.

**Note: Effective 01/01/2018 providers are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

***The subcutaneous or intravenous formulation of filgrastim is billed using HCPCS code J1442, Q5101 or Q5110 with the JA (intravenous) or JB (subcutaneous) modifier.

The subcutaneous or intravenous formulation of octreotide acetate is billed using HCPCS code J2354 with the JA (intravenous) or JB (subcutaneous) modifier.

To avoid unnecessary rejections, claims for these types of drugs and their non-chemotherapy administration should be billed as a pair on a separated claim from any chemotherapy.

Infusions Non-Chemotherapy

The administration of the following drugs should not be billed using a chemotherapy administration code. The IV administration of the drugs below should be billed with the appropriate IV injection/infusion CPT code listed under Therapeutic Prophylactic, and Diagnostic Injections and Infusions.

To avoid unnecessary rejections; claims for chemotherapy drugs and their chemotherapy administration should be billed as a pair on a separate claim. In this circumstance, the Medicare Claims Processing System will still allow the add-on codes 96367 and 96368 if billed appropriately on a separate claim from the initial claim for the chemotherapy drug and administration codes with the same date of service.

Generic/Trade Names:

Generic Name	**Trade Name**	**HCPCS Code**
abatacept	Orencia®****	J0129****

belatacept	Nulojix®	J0485
bezlotoxumab	Zinplava™	J0565
eculizumab	Soliris®	J1300
edaravone	Radicava™	J1301
filgrastim (g-csf) excludes biosimilars***	Neupogen®***	J1442***
filgrastim-sndz, biosimiliar***	Zarxio®***	Q5101***
filgrastim-aafi***	Nivestym®***	Q5110**
golimumab	Simponi Aria®	J1602
natalizumab	Tysabri®	J2323
octreotide acetate non-depot**	Sandotstatin®**	J2354**
patisiran	Onpattro™	J0222
reslizumab	Cinqair®	J2786
ustekinumab*	Stelara®*	J3358*
vedolizumab	Entyvio®	J3380

*Effective September 23, 2016, IV ustekinumab (Stelara®) should be billed with HCPCS J3590 (OPPS: C9399 for dates of service (DOS) before 04/01/2017; C9487 for DOS from 04/01/2017 to 06/30/17, Q9989 for DOS from 07/01/2017-12/31/17 and J3358 for DOS 01/01/2018 and after) for the initial IV dose of Stelara® when used for Crohn's disease and Ulcerative Colitis and each subsequent subcutaneous dose **must** be billed with J3357. This IV formulation is now FDA approved for Crohn's disease and Ulcerative Colitis.

**The subcutaneous or intravenous formulation of octreotide acetate is billed using HCPCS code J2354 with the JA (intravenous) or JB (subcutaneous) modifier.

***The subcutaneous or intravenous formulation of filgrastim is billed using HCPCS code J1442, Q5101 or Q5110 with the JA (intravenous) or JB (subcutaneous) modifier.

****The subcutaneous or intravenous formulation of abatacept is billed using HCPCS code J0129 with the JA (intravenous) or JB (subcutaneous) modifier. The subcutaneous (SQ) form is on A53033 Self-Administered Drug Exclusion List (SAD List).

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

The administration of the following drugs should not be billed using a chemotherapy administration code. Instead, the administration of the following drugs in their subcutaneous or intramuscular forms should be billed using CPT code 96372. For the administration of a drug using an On-Body Injector bill with CPT code 96377.

J0717: The self-administration formulation of certolizumab pegol (Cimzia® prefilled syringe as a 200 mg/1 ml unit dose) is not a Medicare benefit. Providers and facilities must bill this formulation with the GY modifier as a statutorily excluded service.

J2505: Effective 01/01/2018 providers are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

J1442, Q5101 or Q5110: The subcutaneous or intravenous formulation of filgrastim needs to be billed with the JA (intravenous) or JB (subcutaneous) modifier.

J2354: The subcutaneous or intravenous formulation of octreotide acetate needs to be billed with the JA (intravenous) or JB (subcutaneous) modifier.

Group 1 Codes:

CODE	DESCRIPTION
96372	Ther/proph/diag inj sc/im
96377	Applicaton on-body injector
J0517	Inj., benralizumab, 1 mg
J0638	Canakinumab injection
J0717	Certolizumab pegol inj 1mg
J0896	Inj luspatercept-aamt 0.25mg
J0897	Denosumab injection
J1442	Inj filgrastim excl biosimil
J1447	Inj tbo filgrastim 1 microg
J2182	Injection, mepolizumab, 1mg
J2353	Octreotide injection, depot
J2357	Omalizumab injection
J2505	Injection, pegfilgrastim 6mg
J2793	Rilonacept injection
J3245	Inj., tildrakizumab, 1 mg
Q5101	Injection, zarxio
Q5108	Injection, fulphila
Q5110	Nivestym
Q5111	Injection, udenyca 0.5 mg
Q5120	Inj pegfilgrastim-bmez 0.5mg
Q5122	Inj, nyvepria

Group 2 Paragraph:

The administration of the following drugs should not be billed using a chemotherapy administration code. Instead, the IV administration of the drugs should be billed with the following CPT Codes for IV injection/infusion.

J3358: Effective September 23, 2016, IV ustekinumab (Stelara®) should be billed with HCPCS J3590 (OPPS: C9399 for dates of service (DOS) *before* 04/01/2017; C9487 for DOS from 04/01/2017 to 06/30/17, Q9989 for DOS from 07/01/2017-12/31/17 and J3358 for DOS 01/01/2018 and after) for the initial IV dose of Stelara® when used for Crohn's disease and Ulcerative Colitis and each subsequent subcutaneous dose **must** be billed with J3357. This IV formulation is now FDA approved for Crohn's disease and Ulcerative Colitis.

J2354: The subcutaneous or intravenous formulation of octreotide acetate needs to be billed with the JA (intravenous) or JB (subcutaneous) modifier.

J1442, Q5101 or Q5110: The subcutaneous or intravenous formulation of filgrastim needs to billed with the JA (intravenous) or JB (subcutaneous) modifier.

J0129: The subcutaneous or intravenous formulation of abatacept is billed with a JA (intravenous) or JB (subcutaneous) modifier. The SQ form is on A53032 Self-Administered Drug Exclusion List (SAD List).

Group 2 Codes:

CODE	DESCRIPTION
96365	Ther/proph/diag iv inf init
96366	Ther/proph/diag iv inf addon
96367	Tx/proph/dg addl seq iv inf
96368	Ther/diag concurrent inf
96374	Ther/proph/diag inj iv push
96375	Tx/pro/dx inj new drug addon
96376	Tx/pro/dx inj same drug adon
96379	Ther/prop/diag inj/inf proc
J0129	Abatacept injection
J0222	Inj., patisiran, 0.1 mg
J0485	Belatacept injection
J0565	Inj, bezlotoxumab, 10 mg
J1300	Eculizumab injection
J1301	Injection, edaravone, 1 mg
J1442	Inj filgrastim excl biosimil
J1602	Golimumab for iv use 1mg
J2323	Natalizumab injection

CODE	DESCRIPTION
J2354	Octreotide inj, non-depot
J2786	Injection, reslizumab, 1mg
J3358	Ustekinumab, iv inject, 1 mg
J3380	Injection, vedolizumab
Q5101	Injection, zarxio
Q5110	Nivestym

CPT/HCPCS Modifiers

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
GY	ITEM OR SERVICE STATUTORILY EXCLUDED, DOES NOT MEET THE DEFINITION OF ANY MEDICARE BENEFIT OR, FOR NON-MEDICARE INSURERS, IS NOT A CONTRACT BENEFIT
JA	ADMINISTERED INTRAVENOUSLY
JB	ADMINISTERED SUBCUTANEOUSLY
JW	DRUG AMOUNT DISCARDED/NOT ADMINISTERED TO ANY PATIENT

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 policy does not apply to that Bill Type.Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

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 policy, 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 policy 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
07/23/2021	R5	Under Route of Administration Modifier the first sentence was updated to require the use of JA and JB modifiers for drugs which have HCPCS Level II (J or Q) codes that have multiple routes of administration. In the Article Text under the Infusion Non-Chemotherapy table, the asterisked statement regarding the FDA approval of Stelara® for Ulcerative Colitis was revised to be consistent with other MACs as well as in the Group2 Paragraph under J3338.
02/18/2021	R4	J1447 - tbo-filgrastim (Granix®) was removed in error. Added back into the **Subcutaneous and Intramuscular Injection Non-Chemotherapy** table in Article Text and the Group 1 CPT/HCPCS Codes table.
02/18/2021	R3	In the Article Text the statement, "The subcutaneous or intravenous formulation of abatacept is billed using HCPCS code J1029 with the JA (intravenous) or JB (subcutaneous) modifier"; was corrected to change J1029 to J0129. Corrected the article number to A53033 in the statement; "The subcutaneous (SQ) form is on A53032 Self-Administered Drug Exclusion List (SAD List in the Article Text.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
02/18/2021	R2	Added Q5122-pegfilgrastim-apgf, biosimilar (Nyvepria®) to Subcutaneous and Intramuscular Injection Non-Chemotherapy Generic/Trade Names Table in the Article Text; and Group 1 Codes. Added the statement "...and Ulcerative Colitis was approved on 10/21/2019" to the asterisked section for Stelara and removed the statement "On and after July 31, 2017, both the drug and administration should be billed on the same claim with no other drugs or administration to prevent inappropriate claim rejection." underneath the Infusions Non-Chemotherapy Generic/Trade Name Table in the Article Text and the Group 2 Paragraph effective 01/01/2021. Removed J0894 - decitabine injection (Dacogen®) from Infusions Non-Chemotherapy Generic/Trade Table in the Article Text, Group 2 Paragraph and Codes and removed J1447 - tbo-filgrastim (Granix®) throughout the Article text and tables; from Group 1 Paragraph and Codes sections; and Group 2 Paragraph and Codes section effective 01/10/2021. Corrected grammatical errors throughout the article.
01/01/2021	R1	Corrected the link to the CMS Publication 100-02 Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, Section 50 Drugs and Biologicals and 50.3 Incident to Requirements in the first CMS Manual Explanations URLs section listed below under Associated Documents.

Associated Documents

Related Local Coverage Document(s)

N/A

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

CMS Publication 100-02 Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, Section 50 Drugs and Biologicals and 50.3 Incident-to Requirements

CMS Publication 100-04 Medicare Claims Processing Manual, Chapter 12-Physicians/Nonphysician Practitioners, Section 30.5. Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions, Part D-Chemotherapy Administration

CMS Publication 100-04 Medicare Claims Processing Manual, Chapter 17 – Drugs and Biologicals, Section 40 – Discarded Drugs and Biologicals

Other URL(s)

Unclassified Drug Billing When Submitting EMC

JW Modifier

Public Version(s)

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