Highmark Reimbursement Policy Bulletin

HISTORY VERSION

Bulletin Number:	RP-072		
Subject:	Injection and Infusion Services		
Effective Date:	January 1, 2022	**End Date:**	November 18, 2024
Issue Date:	July 1, 2024	**Revised Date:**	November 18, 2024
Date Reviewed:	June 2024		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Claim Type	**UB**	☒	**1500**	☒				

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The purpose of this policy is to provide direction on injection and infusion services billed with drugs.

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 of quotation from CPT®)

As stated in the CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 12, 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*."

REIMBURSEMENT GUIDELINES:

The chemotherapy and therapeutic administration guidelines identified in this policy are for individuals **18 years of age and older.** The coding of hydration and administration services along with coding of infusions and injections must follow the coding hierarchy guidelines. ("Infusion Hierarchy")

Follow CPT guidelines and hierarchy rules when coding infusion and injections. The Infusion Hierarchy determines initial service. In the doctor's office (place of service 11), the initial code should be the code which best describes the primary reason for the encounter. In the hospital outpatient clinic (place of service 22), the Infusion Hierarchy determines the initial service. The order in which an infusion service is rendered during a visit does not determine the "initial" service. There is only one initial service coded per vascular access site, per encounter per date.

The Infusion Hierarchy is as follows:

1. Chemotherapy services are primary to Therapeutic, Prophylactic and Diagnostic services
2. Therapeutic, Prophylactic and Diagnostic services are primary to hydration. The order is:
    A. Chemotherapy
    B. Therapeutic, prophylactic and diagnostic services
    C. Hydration

3. Infusions are primary to I.V. pushes, which are primary to injections. The order is:
    A. Infusions
    B. I.V. push
    C. Injection

Note: This Infusion Hierarchy does not apply to subQ/IM injections.

Infusions may be concurrent (i.e., multiple drugs are infused simultaneously through the same line) or sequential (infusion of drugs one after another through the same access site).

Note: I.V. infusion differs from an I.V. push which is defined as an infusion lasting 15 minutes or less.

Infusions Start / Stop Time

Selection of the correct CPT code is dependent upon the start and stop time of infusion services. If "stop time" is not documented, only an I.V. push can be billed. Therefore, it is important to use the following guidance:

1. Infusion services are coded based on the length of the infusion, which is a time-based service.
2. The Start and Stop times of each medication administration must be accurately recorded, as this determines the correct CPT code assignment.
3. The first hour of infusion is weighted heavier than subsequent hours to include preparation time, patient education, and patient assessment prior to and after the infusion.
4. The time calculations for the length of the infusion should stop when the infusion is discontinued and restart at the time the infusion resumes.

Time Documented

Time documentation is critical because it drives the assignment and accuracy of the CPT coding of infusion services.

Key Time Ranges

1. 15 minutes or less
    - infusions lasting 15 minutes or less would be coded as an *I.V. push
2. 16 minutes or more
    - infusion can be reported after 16 minutes

***Note**: An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion.

3. 31 minutes to 1 hour
    - hydration infusion must be at least 31 minutes in length to bill the service
4. 16-90 minutes versus more than 90 minutes
5. 16-90 minutes represents the first hour of infusion services
6. 91 minutes or more represents the subsequent hour of infusion, in intervals greater than 30 minutes beyond 1-hour increments
7. 30 minutes since last reported push

Note: Each additional sequential I.V. push of same drug/substance must not be reported if within 30 minutes of each other.

Services Not Included in the Infusion

Supplies for infusion services are not separately payable and should not be separately billed.

Service Included in Infusion

1. Use of local anesthesia;
2. I.V. access;
3. Access to indwelling I.V., subcutaneous catheter or port;
4. Flush at conclusion of infusion;

5. Standard tubing, syringes and supplies; and
6. Preparation of chemotherapy agent(s)

Types of Infusions

1. Initial and sequential infusions:
    A. Bill an I.V. push for intravenous infusions that last 15 minutes or less
    B. If no stop time is documented an I.V. push is the only service that can be billed, regardless of the length of the infusion
    C. CPT code 96413 - Chemo infusion, 1st hour, initial drug
    D. CPT code 96365 - Non-Chemo infusion, 1st hour, initial drug
    E. Requires a new substance or drug

    Sequential infusions are considered to be an infusion or I.V. push of a new substance following a primary or initial service 16 minutes or more.

    Initial infusions for therapy, prophylaxis, or diagnostic (specify substance or drug) are considered an initial service for 16-90 minutes.

2. Concurrent infusions occurs at the same time as the initial infusion:
    A. Add-on CPT code 96368 is listed separately in addition to code for primary procedure
    B. Report only once per encounter
    C. Time does not matter
    D. Drugs given at the same time
    E. Multiple drugs added to one bag of fluids is not a concurrent infusion; it is one infusion
    F. There is no concurrent code for chemotherapy or hydration

3. I.V. push and Additional Hours:
    A. Always secondary to initial infusion code, but always primary to hydration infusion
    B. List each additional sequential I.V. push of a new substance or the same drug separately
    C. Additional pushes of the same drug must be greater than 30 minutes apart
    D. Can never be used alone, must always have a primary infusion/push CPT code
    E. An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion

    Note: An "I.V. push" is considered an injection (or infusion) of a drug of 15 minutes or less.

    Note: "Each Additional Hour" is defined as the same drug, report if more than 31 minutes beyond initial or additional hour.

4. Hydration Infusion

    Assign CPT 96360 – I.V. hydration, initial 31-90 minutes, and CPT 96361 (add on code), used once infusion lasts 91 minutes in length. An intravenous infusion of hydration of 30 minutes or less is not billable. Hydration infusion must be at least 31 minutes in length to bill the service. It is appropriate to charge for hydration provided before and/or after therapeutic infusion, but not the hydration time running at the same time as the therapeutic infusion. Hydration time intervals should be continuous and not added together.

Note: Codes 96360 and 96361 are intended to report a hydration I.V. infusion to consist of a pre-packaged fluid and electrolytes (eg, normal saline, D5-1/2 normal saline + 30 meq KCL/liter) but are not used to report infusion of drugs or other substances.

Key Considerations

1. Saline solution is a hydration service. Saline solution with electrolytes is still a hydration, but electrolytes administered in a bag minus saline are considered drugs.
2. If there is no stop time documented, then the hydration service is not chargeable.
3. Hydration cannot be reported to Keep Vein Open (KVO), i.e. Heplock flush or saline lock, or to flush a line after drug infusion.
4. Hydration cannot be reported if drugs are mixed with fluids and infused in the same bag/syringe.
5. Hydration cannot be reported if a separate bag of fluid is hung and run concurrently with another drug infusion.
6. Novitas Solutions Local Coverage Determination (LCD) L34960 and Article - Billing and Coding Hydration (A56634) requires a covered diagnosis for hydration coverage.
7. Palmetto Local Coverage Article (LCA) A58527-Billing and Coding: Complex Drug Administration Coding and (LCA) A53778- Billing and Coding: Infusion, Injection and Hydration Services.

8. Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage (LCA) Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

9. Per the AMA CPT Manual, Infusion and Injection services within the CPT code range of 96360-96425 and 96521-96523 are not intended to be reported by the physician in the facility setting. Instead physicians should select the most appropriate E/M service. When an E/M service is performed in addition to the infusion and injection service, modifier -25 must be appended to the E/M service to indicate that the service provided was significant and separately identifiable.

Chemotherapy services include:

1. Chemotherapy initiation of prolonged infusion > 8 hours requiring pump
2. Chemotherapy infusions
3. Chemotherapy injections

Injection and Intravenous Infusion Chemotherapy and Other Complex Drug or Highly Complex Biologic Agent Administration:

Note: Also reference the drug table below.

Code	Code Description	Time
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/ drug	16 minutes up to 1 hour. If over an hour and 30 minutes, also assign 96415 +
96415 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional hour (List separately in addition to code for primary procedure)	Add-on code for >61 minutes (i.e., the infusion time must be greater than 30 minutes to 1 hour beyond the initial infusion time of 1 hour)
96417 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug) up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour

96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	15 minutes or less
96411 (Add-on)	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	15 minutes or less

Non-chemotherapy therapeutic, prophylactic and diagnostic injections, and I.V. infusion services include:

1. Initiation of prolonged infusion greater than 8 hours requiring pump
2. Non-Chemo Infusions
3. Non-Chemo Injections

Therapeutic, Prophylactic and Diagnostic Injections, and Infusion (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration):

Note: Also reference the drug table below.

Code	Code Description	Time
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify initial substance or drug) up to 1 hour`	16 minutes up to 1 hour
96366 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	Add-on code after 31 minutes or >61 minutes
96367 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, use 96366 for additional hour(s) of sequential infusion
96368 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, Report only once per encounter
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	15 minutes or less
96375 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	15 minutes or less
96376 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)	Report at intervals >30 minutes

Hydration infusion services include:

1. Hydration Infusions

Code	Code Description	Time
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	31 minutes up to 1 hour
96361 (Add-on)	Intravenous infusion, hydration; each additional hour (list separately in addition to code for primary procedure)	Add-on for each additional hour (after 31 minutes)

Summary of infusion services for chemotherapy, non-chemotherapy and hydration:

Type	Chemotherapy and Other Highly Complex Drug or Biologic Agent	Non-chemotherapy (Therapeutic, Prophylactic & Diagnostic Injections/Infusions)	Hydration
Initial Infusion	96413	96365	96360
Each Additional Hour	96415 (Add-on)	96366 (Add-on)	96361 (Add-on)
Subsequent Infusion	96417 (Add-on)	96367 (Add-on)	N/A
Concurrent Infusion	N/A	96368 (Add-on)	N/A
I.V. Push Initial	96409	96374	N/A
Subsequent I.V. Push – New	96411 (Add-on)	96365	N/A
Subsequent I.V. Push – Same	N/A	96376 (Add-on) Note: Facility only at 30 minutes apart	N/A

Other injection and infusion services:

1. Chemotherapy Administration

Code	Code Description
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g. intrathecal), requiring and including spinal puncture
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions

The drugs listed in the table below must be billed with the appropriate administration type. Refer to the coordinating injection/infusion section of this policy to assign the appropriate CPT code. This list is not all inclusive and subject to change.

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. If a chemotherapy administration code is billed with one of the codes listed below, the administration code will be denied and non-billable to the member. 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 Drug Name	Brand Name	HCPCS
Benralizumab	Fasenra	J0517
Canakinumab	Ilaris	J0638
Certolizumab pegol	Cimzia	J0717
Denosumab	Prolia/Xgeva	J0897
Filgrastim (g-csf) excludes biosimilars	Neupogen	J1442**
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110**
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101**
Luspatercept-aamt	Reblozyl	J0896
Mepolizumab	Nucala	J2182
Octreotide	Sandostatin LAR Depot	J2353
Omalizumab	Xolair	J2357
Pegfilgrastim,excludes biosimilar	Neulasta	J2506*
Pegfilgrastim-apgf, biosimilar	Nyvepria (Neulasta)	Q5122
Pegfilgrastim-bmez, biosimilar	Ziextenzo (Neulasta)	Q5120
Pegfilgrastim-cbqv, biosimilar	Udenyca (Neulasta)	Q5111
Pegfilgrastim-fpgk	Stimufend	Q5127
Pegfilgrastim-jmdb, biosimilar	Fulphila (Neulasta)	Q5108
Pegfilgrastim-pbbk	Fylnetra	Q5130
Rilonacept	Arcalyst	J2793
Secukinumab	Cosentyx	J3247
Tbo-filgrastim	Granix	J1447
Tildrakizumab-asmn	Ilumya	J3245

Note: *Effective January 1, 2018, provider are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

Note: **When billing filgrastim (HCPCS codes J1442, Q5101, or Q5110, append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

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.

Generic Drug Name	Brand Name	HCPCS
Abatacept	Orencia	J0129****

Agalsidase beta	Fabrazyme	J0180
Alglucosidase alfa	Lumizyme	J0221
Alpha 1-proteinase inhibitor (human)	Glassia	J0257
Alpha 1-proteinase inhibitor (human),NOS	Aralast	J0256
Anifrolumab-fnia	Saphnelo	J0491
Belatacept	Nulojix	J0485
Bezlotoxumab	Zinplava	J0565
C1 esterase inhibitor (human)	Berinert	J0597
Eculizumab	Soliris	J1300
Edaravone	Radicava	J1301
Elosulfase alfa	Vimizim	J1322
Filgrastim-(g-csf) excludes biosimilars	Neupogen	J1442***
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110***
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101***
Golimumab	Simponi Aria	J1602
Idursulfase	Elaprase	J1743
Imiglucerase	Cerezyme	J1786
Immune globulin	Cutaquig	J1551
Immune globulin	Bivigam	J1556
Immune globulin	Carimune® NF, Gammagard® S/D	J1566
Immune globulin	Flebogamma	J1572
Immune globulin	Gammagard	J1569
Immune globulin	Gammaplex	J1557
Immune globulin	Gamunex- C	J1561
Immune globulin	Octagam	J1568
Immune globulin	Privigen	J1459
Immune globulin	Asceniv	J1554
Natalizumab	Tysabri	J2323
Mirikizumab-mrkz	Omvoh	J2267
Octreotide	Sandostatin	J2354**
Remdesivir	Veklury	J0248
Reslizumab	Cinqair	J2786
Tocilizumab	Actemra	J3262
Ustekinumab	Stelara	J3358*
Ustekinumab-auub, biosimilar	Wezlana	Q5137
Ustekinumab-auub, biosimilar	Wezlana	Q5138
Vedolizumab	Entyvio	J3380
Velaglucerase alfa	Vpriv	J3385

Note: *Effective September 23, 2016, IV ustekinumab (Stelara®) should be billed with HCPCS code J3590 (OPPS: C9399 for dates of service [DOS] before 4/01/2017; C9487 for DOS from 4/01/2017 to 6/30/2017, Q9989 for DOS from 7/01/2017-12/31/2017 and J3358 for DOS

1/01/2018 and after) for the initial IV dose of Stelara® when used for Crohn's disease and Ulcerative Colitis. Each subsequent subcutaneous dose **must** be billed with J3357. This IV formulation is now FDA approved for Crohn's disease and Ulcerative Colitis. 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.

Note: ** When billing octreotide acetate (HCPCS code J2354), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Note: *** When billing filgrastim (HCPCS codes J1442, Q5101, Q5110), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

Note: **** When billing abatacept (HCPCS code J0129), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Documentation Requirements:

1. Documentation is for the correct beneficiary and date of service.
2. Documentation is complete, legible, signed and dated by the Physician or Clinician.
3. Documentation includes Physician's order for date(s) of service when medication(s) were administered, to include the medication name, dosage, frequency and method of administration.
4. Medication Administration Record for dates of service include the medication name, dosage, method of administration, and start/stop times for infusions (when applicable).
5. Documentation to support the amount of drugs or biologicals discarded (single use packaging) for the relevant beneficiary (when applicable).
6. Medical necessity supported by the medical record (e.g. office/progress notes, history and physical, laboratory test results, etc.)
7. Documentation for the procedures, operative reports and anesthesia reports (when applicable).
8. If billing incident to services, the documentation supports appropriate supervision (billing physician is present in the office suite during the performance of procedure).
9. Documentation meets criteria specified in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).
10. Evidence an Advanced Beneficiary Notice of Non-coverage (ABN) was provided to the beneficiary, if applicable.

RELATED POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-6: Approved Drugs and Biologicals
- I-9: Treatment of Gaucher Disease
- I-14: Immune Globulin Therapy
- I-24: Belatacept (Nulojix)

- I-27: Certolizumab (Cimzia)
- I-30: Denosumab (Prolia, Xgeva)
- I-31: Tocilizumab (Actemra)
- I-35: Golimumab (Simponi, Simponi Aria)
- I-37: Ustekinumab (Stelara)
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme)
- I-58: Alglucosidase alfa (Lumizyme)
- I-85: Natalizumab (Tysabri)
- I-88: Granulocyte Colony-Stimulating Factors
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha 1-Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Complement Inhibitors
- I-138: Elosulfase alfa (Vimizim)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-151: Site of Care
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-210: IL-1 and IL-1b Blockers
- I-214: Luspatercept (Reblozyl)
- I-245: Anifrolumab-fnia (Saphnelo)
- G-16: Chemotherapy Services

Refer to the following Medicare Advantage Medical Policies for additional information:

- I-20: Denosumab (Prolia, Xgeva)
- I-27: Octreotide Acetate for Injectable Suspension (Sandostain® LAR Depot) (WV only)
- I-51: Self-Administered Drug Exclusion List
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme) (WV only)
- I-56: Granulocyte Colony-Stimulating Factors
- I-68: Treatment of Gaucher Disease
- I-85: Natalizumab (Tysabri)
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-98: Immunosuppressive Drugs
- I-103: Intravenous Immune Globulin
- I-105: Billing and Coding: App'd Drugs and Biologicals; Includes Cancer Chemo Agents (PA only)
- I-105: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (DE only)

- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha-1 Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Compliment Inhibitors
- I-132: Agalsidase beta (Fabrazyme)
- I-134: Alglucosidase alfa (Lumizyme) and Avalglucosidase alfa-ngpt (Nexviazyme)
- I-138: Elosulfase alfa (Vimizim)
- I-139: Ustekinumab (Stelara)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin) and Lanreotide (Somatuline Depot)
- I-184: Certolizumab (Cimzia)
- I-194: Tocilizumab (Actemra)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-208: Billing and Coding Chemotherapy (WV only)
- I-210: IL-1 and IL-1b Blockers
- I-218: Golimumab (Simponi, Simponi Aria)
- I-223: Luspatercept (Reblozyl)
- I-252: Anifrolumab-fnia (Saphnelo)
- Y-5: Hydration Therapy (PA & DE only)
- Z-106: Billing and Coding: Complex Drug Administration Coding (WV only)

Refer to the following Reimbursement Policies for additional information:

- RP-003: Drug Wastage and Convenience Kits
- RP-019N: Drugs and Biologicals (This policy is accessible to Network providers only)
- RP-035: Correct Coding Guidelines
- RP-044: Medication Therapy Management

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Highmark Provider Resource Center, Special eBulletin, ATTN: Referring Physicians; Expanded Access to Infused Drug Therapy. Aug.14, 2017. https://content.highmarkprc.com/Files/NewsletterNotices/SpecialBulletins/sb-all-reimbursement-changes-hit-081417.pdf

REFERENCES:

- 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 Non chemotherapy Injections and Infusions, Part D-Chemotherapy Administration https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

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- Social Security Administration, Section 1861(t); Part E. https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

- Novitas Solutions, *Local Coverage Determination (LCD)*; (L34960) Hydration Therapy https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A53049) Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents. https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A59073) Billing and Coding: Complex Drug Administration Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A58527) Billing and Coding: Complex Drug Administration Coding. Article - Billing and Coding: Complex Drug Administration Coding (A58527) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A53778) Billing and Coding: Infusion, Injection and Hydration Services Article - Billing and Coding: Infusion, Injection and Hydration Services (A53778) (cms.gov)

- MEDLEARN Publishing Coding Essentials for Infusion & Injection Therapy Services

POLICY UPDATE HISTORY INFORMATION:

1 / 2022	Implementation
4 /2022	Updated direction for some drugs and eliminated the MA and Commercial variance
5 / 2022	Added note for billing drugs with certain codes. Added medical policy cross references
7 / 2022	Added code J1551
10 / 2022	Removed code J0222 and replaced code J3590 with J0491
4 / 2023	Added codes Q5127 and Q5130
1 / 2024	Updated code description for 96361
7 / 2024	Added codes J2267, J3247, Q5137, and Q5138
11 / 2024	Policy archived

Highmark Reimbursement Policy Bulletin

HIGHMARK.

HISTORY VERSION

Bulletin Number:	RP- 072		
Subject:	Injection and Infusion Services		
Effective Date:	January 1, 2022	**End Date:**	
Issue Date:	July 1, 2024	**Revised Date:**	July 2024
Date Reviewed:	June 2024		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Claim Type	**UB**	☒	**1500**	☒				

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The purpose of this policy is to provide direction on injection and infusion services billed with drugs.

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 of quotation from CPT®)

As stated in the CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 12, 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*."

REIMBURSEMENT GUIDELINES:

The chemotherapy and therapeutic administration guidelines identified in this policy are for individuals **18 years of age and older.** The coding of hydration and administration services along with coding of infusions and injections must follow the coding hierarchy guidelines. ("Infusion Hierarchy")

Follow CPT guidelines and hierarchy rules when coding infusion and injections. The Infusion Hierarchy determines initial service. In the doctor's office (place of service 11), the initial code should be the code which best describes the primary reason for the encounter. In the hospital outpatient clinic (place of service 22), the Infusion Hierarchy determines the initial service. The order in which an infusion service is rendered during a visit does not determine the "initial" service. There is only one initial service coded per vascular access site, per encounter per date.

The Infusion Hierarchy is as follows:

1. Chemotherapy services are primary to Therapeutic, Prophylactic and Diagnostic services
2. Therapeutic, Prophylactic and Diagnostic services are primary to hydration. The order is:
    A. Chemotherapy
    B. Therapeutic, prophylactic and diagnostic services
    C. Hydration

3. Infusions are primary to I.V. pushes, which are primary to injections. The order is:
    A. Infusions
    B. I.V. push
    C. Injection

Note: This Infusion Hierarchy does not apply to subQ/IM injections.

Infusions may be concurrent (i.e., multiple drugs are infused simultaneously through the same line) or sequential (infusion of drugs one after another through the same access site).

Note: I.V. infusion differs from an I.V. push which is defined as an infusion lasting 15 minutes or less.

Infusions Start / Stop Time

Selection of the correct CPT code is dependent upon the start and stop time of infusion services. If "stop time" is not documented, only an I.V. push can be billed. Therefore, it is important to use the following guidance:

1. Infusion services are coded based on the length of the infusion, which is a time-based service.
2. The Start and Stop times of each medication administration must be accurately recorded, as this determines the correct CPT code assignment.
3. The first hour of infusion is weighted heavier than subsequent hours to include preparation time, patient education, and patient assessment prior to and after the infusion.
4. The time calculations for the length of the infusion should stop when the infusion is discontinued and restart at the time the infusion resumes.

Time Documented

Time documentation is critical because it drives the assignment and accuracy of the CPT coding of infusion services.

Key Time Ranges

1. 15 minutes or less
    - infusions lasting 15 minutes or less would be coded as an *I.V. push
2. 16 minutes or more
    - infusion can be reported after 16 minutes

***Note**: An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion.

3. 31 minutes to 1 hour
    - hydration infusion must be at least 31 minutes in length to bill the service
4. 16-90 minutes versus more than 90 minutes
5. 16-90 minutes represents the first hour of infusion services
6. 91 minutes or more represents the subsequent hour of infusion, in intervals greater than 30 minutes beyond 1-hour increments
7. 30 minutes since last reported push

Note: Each additional sequential I.V. push of same drug/substance must not be reported if within 30 minutes of each other.

Services Not Included in the Infusion

Supplies for infusion services are not separately payable and should not be separately billed.

Service Included in Infusion

1. Use of local anesthesia;
2. I.V. access;
3. Access to indwelling I.V., subcutaneous catheter or port;
4. Flush at conclusion of infusion;

5. Standard tubing, syringes and supplies; and
6. Preparation of chemotherapy agent(s)

Types of Infusions

1. Initial and sequential infusions:
    A. Bill an I.V. push for intravenous infusions that last 15 minutes or less
    B. If no stop time is documented an I.V. push is the only service that can be billed, regardless of the length of the infusion
    C. CPT code 96413 - Chemo infusion, 1st hour, initial drug
    D. CPT code 96365 - Non-Chemo infusion, 1st hour, initial drug
    E. Requires a new substance or drug

    Sequential infusions are considered to be an infusion or I.V. push of a new substance following a primary or initial service 16 minutes or more.

    Initial infusions for therapy, prophylaxis, or diagnostic (specify substance or drug) are considered an initial service for 16-90 minutes.

2. Concurrent infusions occurs at the same time as the initial infusion:
    A. Add-on CPT code 96368 is listed separately in addition to code for primary procedure
    B. Report only once per encounter
    C. Time does not matter
    D. Drugs given at the same time
    E. Multiple drugs added to one bag of fluids is not a concurrent infusion; it is one infusion
    F. There is no concurrent code for chemotherapy or hydration

3. I.V. push and Additional Hours:
    A. Always secondary to initial infusion code, but always primary to hydration infusion
    B. List each additional sequential I.V. push of a new substance or the same drug separately
    C. Additional pushes of the same drug must be greater than 30 minutes apart
    D. Can never be used alone, must always have a primary infusion/push CPT code
    E. An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion

    Note: An "I.V. push" is considered an injection (or infusion) of a drug of 15 minutes or less.

    Note: "Each Additional Hour" is defined as the same drug, report if more than 31 minutes beyond initial or additional hour.

4. Hydration Infusion

    Assign CPT 96360 – I.V. hydration, initial 31-90 minutes, and CPT 96361 (add on code), used once infusion lasts 91 minutes in length. An intravenous infusion of hydration of 30 minutes or less is not billable. Hydration infusion must be at least 31 minutes in length to bill the service. It is appropriate to charge for hydration provided before and/or after therapeutic infusion, but not the hydration time running at the same time as the therapeutic infusion. Hydration time intervals should be continuous and not added together.

Note: Codes 96360 and 96361 are intended to report a hydration I.V. infusion to consist of a pre-packaged fluid and electrolytes (eg, normal saline, D5-1/2 normal saline + 30 meq KCL/liter) but are not used to report infusion of drugs or other substances.

Key Considerations

1. Saline solution is a hydration service. Saline solution with electrolytes is still a hydration, but electrolytes administered in a bag minus saline are considered drugs.
2. If there is no stop time documented, then the hydration service is not chargeable.
3. Hydration cannot be reported to Keep Vein Open (KVO), i.e. Heplock flush or saline lock, or to flush a line after drug infusion.
4. Hydration cannot be reported if drugs are mixed with fluids and infused in the same bag/syringe.
5. Hydration cannot be reported if a separate bag of fluid is hung and run concurrently with another drug infusion.
6. Novitas Solutions Local Coverage Determination (LCD) L34960 and Article - Billing and Coding Hydration (A56634) requires a covered diagnosis for hydration coverage.
7. Palmetto Local Coverage Article (LCA) A58527-Billing and Coding: Complex Drug Administration Coding and (LCA) A53778- Billing and Coding: Infusion, Injection and Hydration Services.

8. Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage (LCA) Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

9. Per the AMA CPT Manual, Infusion and Injection services within the CPT code range of 96360-96425 and 96521-96523 are not intended to be reported by the physician in the facility setting. Instead physicians should select the most appropriate E/M service. When an E/M service is performed in addition to the infusion and injection service, modifier -25 must be appended to the E/M service to indicate that the service provided was significant and separately identifiable.

Chemotherapy services include:

1. Chemotherapy initiation of prolonged infusion > 8 hours requiring pump
2. Chemotherapy infusions
3. Chemotherapy injections

Injection and Intravenous Infusion Chemotherapy and Other Complex Drug or Highly Complex Biologic Agent Administration:

Note: Also reference the drug table below.

Code	Code Description	Time
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/ drug	16 minutes up to 1 hour. If over an hour and 30 minutes, also assign 96415 +
96415 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional hour (List separately in addition to code for primary procedure)	Add-on code for >61 minutes (i.e., the infusion time must be greater than 30 minutes to 1 hour beyond the initial infusion time of 1 hour)
96417 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug) up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour

96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	15 minutes or less
96411 (Add-on)	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	15 minutes or less

Non-chemotherapy therapeutic, prophylactic and diagnostic injections, and I.V. infusion services include:

1. Initiation of prolonged infusion greater than 8 hours requiring pump
2. Non-Chemo Infusions
3. Non-Chemo Injections

Therapeutic, Prophylactic and Diagnostic Injections, and Infusion (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration):

Note: Also reference the drug table below.

Code	Code Description	Time
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify initial substance or drug) up to 1 hour`	16 minutes up to 1 hour
96366 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	Add-on code after 31 minutes or >61 minutes
96367 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, use 96366 for additional hour(s) of sequential infusion
96368 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, Report only once per encounter
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	15 minutes or less
96375 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	15 minutes or less
96376 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)	Report at intervals >30 minutes

Hydration infusion services include:

1. Hydration Infusions

Code	Code Description	Time
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	31 minutes up to 1 hour
96361 (Add-on)	Intravenous infusion, hydration; each additional hour (list separately in addition to code for primary procedure)	Add-on for each additional hour (after 31 minutes)

Summary of infusion services for chemotherapy, non-chemotherapy and hydration:

Type	Chemotherapy and Other Highly Complex Drug or Biologic Agent	Non-chemotherapy (Therapeutic, Prophylactic & Diagnostic Injections/Infusions)	Hydration
Initial Infusion	96413	96365	96360
Each Additional Hour	96415 (Add-on)	96366 (Add-on)	96361 (Add-on)
Subsequent Infusion	96417 (Add-on)	96367 (Add-on)	N/A
Concurrent Infusion	N/A	96368 (Add-on)	N/A
I.V. Push Initial	96409	96374	N/A
Subsequent I.V. Push – New	96411 (Add-on)	96365	N/A
Subsequent I.V. Push – Same	N/A	96376 (Add-on) Note: Facility only at 30 minutes apart	N/A

Other injection and infusion services:

1. Chemotherapy Administration

Code	Code Description
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g. intrathecal), requiring and including spinal puncture
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions

The drugs listed in the table below must be billed with the appropriate administration type. Refer to the coordinating injection/infusion section of this policy to assign the appropriate CPT code. This list is not all inclusive and subject to change.

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. If a chemotherapy administration code is billed with one of the codes listed below, the administration code will be denied and non-billable to the member. 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 Drug Name	Brand Name	HCPCS
Benralizumab	Fasenra	J0517
Canakinumab	Ilaris	J0638
Certolizumab pegol	Cimzia	J0717
Denosumab	Prolia/Xgeva	J0897
Filgrastim (g-csf) excludes biosimilars	Neupogen	J1442**
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110**
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101**
Luspatercept-aamt	Reblozyl	J0896
Mepolizumab	Nucala	J2182
Octreotide	Sandostatin LAR Depot	J2353
Omalizumab	Xolair	J2357
Pegfilgrastim,excludes biosimilar	Neulasta	J2506*
Pegfilgrastim-apgf, biosimilar	Nyvepria (Neulasta)	Q5122
Pegfilgrastim-bmez, biosimilar	Ziextenzo (Neulasta)	Q5120
Pegfilgrastim-cbqv, biosimilar	Udenyca (Neulasta)	Q5111
Pegfilgrastim-fpgk	Stimufend	Q5127
Pegfilgrastim-jmdb, biosimilar	Fulphila (Neulasta)	Q5108
Pegfilgrastim-pbbk	Fylnetra	Q5130
Rilonacept	Arcalyst	J2793
Secukinumab	Cosentyx	J3247
Tbo-filgrastim	Granix	J1447
Tildrakizumab-asmn	Ilumya	J3245

Note: *Effective January 1, 2018, provider are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

Note: **When billing filgrastim (HCPCS codes J1442, Q5101, or Q5110, append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

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.

Generic Drug Name	Brand Name	HCPCS
Abatacept	Orencia	J0129****

Agalsidase beta	Fabrazyme	J0180
Alglucosidase alfa	Lumizyme	J0221
Alpha 1-proteinase inhibitor (human)	Glassia	J0257
Alpha 1-proteinase inhibitor (human),NOS	Aralast	J0256
Anifrolumab-fnia	Saphnelo	J0491
Belatacept	Nulojix	J0485
Bezlotoxumab	Zinplava	J0565
C1 esterase inhibitor (human)	Berinert	J0597
Eculizumab	Soliris	J1300
Edaravone	Radicava	J1301
Elosulfase alfa	Vimizim	J1322
Filgrastim-(g-csf) excludes biosimilars	Neupogen	J1442***
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110***
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101***
Golimumab	Simponi Aria	J1602
Idursulfase	Elaprase	J1743
Imiglucerase	Cerezyme	J1786
Immune globulin	Cutaquig	J1551
Immune globulin	Bivigam	J1556
Immune globulin	Carimune® NF, Gammagard® S/D	J1566
Immune globulin	Flebogamma	J1572
Immune globulin	Gammagard	J1569
Immune globulin	Gammaplex	J1557
Immune globulin	Gamunex- C	J1561
Immune globulin	Octagam	J1568
Immune globulin	Privigen	J1459
Immune globulin	Asceniv	J1554
Natalizumab	Tysabri	J2323
Mirikizumab-mrkz	Omvoh	J2267
Octreotide	Sandostatin	J2354**
Remdesivir	Veklury	J0248
Reslizumab	Cinqair	J2786
Tocilizumab	Actemra	J3262
Ustekinumab	Stelara	J3358*
Ustekinumab-auub, biosimilar	Wezlana	Q5137
Ustekinumab-auub, biosimilar	Wezlana	Q5138
Vedolizumab	Entyvio	J3380
Velaglucerase alfa	Vpriv	J3385

Note: *Effective September 23, 2016, IV ustekinumab (Stelara®) should be billed with HCPCS code J3590 (OPPS: C9399 for dates of service [DOS] before 4/01/2017; C9487 for DOS from 4/01/2017 to 6/30/2017, Q9989 for DOS from 7/01/2017-12/31/2017 and J3358 for DOS

1/01/2018 and after) for the initial IV dose of Stelara® when used for Crohn's disease and Ulcerative Colitis. Each subsequent subcutaneous dose **must** be billed with J3357. This IV formulation is now FDA approved for Crohn's disease and Ulcerative Colitis. 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.

Note: ** When billing octreotide acetate (HCPCS code J2354), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Note: *** When billing filgrastim (HCPCS codes J1442, Q5101, Q5110), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

Note: **** When billing abatacept (HCPCS code J0129), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Documentation Requirements:

1. Documentation is for the correct beneficiary and date of service.
2. Documentation is complete, legible, signed and dated by the Physician or Clinician.
3. Documentation includes Physician's order for date(s) of service when medication(s) were administered, to include the medication name, dosage, frequency and method of administration.
4. Medication Administration Record for dates of service include the medication name, dosage, method of administration, and start/stop times for infusions (when applicable).
5. Documentation to support the amount of drugs or biologicals discarded (single use packaging) for the relevant beneficiary (when applicable).
6. Medical necessity supported by the medical record (e.g. office/progress notes, history and physical, laboratory test results, etc.)
7. Documentation for the procedures, operative reports and anesthesia reports (when applicable).
8. If billing incident to services, the documentation supports appropriate supervision (billing physician is present in the office suite during the performance of procedure).
9. Documentation meets criteria specified in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).
10. Evidence an Advanced Beneficiary Notice of Non-coverage (ABN) was provided to the beneficiary, if applicable.

RELATED POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-6: Approved Drugs and Biologicals
- I-9: Treatment of Gaucher Disease
- I-14: Immune Globulin Therapy
- I-24: Belatacept (Nulojix)

- I-27: Certolizumab (Cimzia)
- I-30: Denosumab (Prolia, Xgeva)
- I-31: Tocilizumab (Actemra)
- I-35: Golimumab (Simponi, Simponi Aria)
- I-37: Ustekinumab (Stelara)
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme)
- I-58: Alglucosidase alfa (Lumizyme)
- I-85: Natalizumab (Tysabri)
- I-88: Granulocyte Colony-Stimulating Factors
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha 1-Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Complement Inhibitors
- I-138: Elosulfase alfa (Vimizim)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-151: Site of Care
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-210: IL-1 and IL-1b Blockers
- I-214: Luspatercept (Reblozyl)
- I-245: Anifrolumab-fnia (Saphnelo)
- G-16: Chemotherapy Services

Refer to the following Medicare Advantage Medical Policies for additional information:

- I-20: Denosumab (Prolia, Xgeva)
- I-27: Octreotide Acetate for Injectable Suspension (Sandostain® LAR Depot) (WV only)
- I-51: Self-Administered Drug Exclusion List
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme) (WV only)
- I-56: Granulocyte Colony-Stimulating Factors
- I-68: Treatment of Gaucher Disease
- I-85: Natalizumab (Tysabri)
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-98: Immunosuppressive Drugs
- I-103: Intravenous Immune Globulin
- I-105: Billing and Coding: App'd Drugs and Biologicals; Includes Cancer Chemo Agents (PA only)
- I-105: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (DE only)

- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha-1 Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Compliment Inhibitors
- I-132: Agalsidase beta (Fabrazyme)
- I-134: Alglucosidase alfa (Lumizyme) and Avalglucosidase alfa-ngpt (Nexviazyme)
- I-138: Elosulfase alfa (Vimizim)
- I-139: Ustekinumab (Stelara)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin) and Lanreotide (Somatuline Depot)
- I-184: Certolizumab (Cimzia)
- I-194: Tocilizumab (Actemra)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-208: Billing and Coding Chemotherapy (WV only)
- I-210: IL-1 and IL-1b Blockers
- I-218: Golimumab (Simponi, Simponi Aria)
- I-223: Luspatercept (Reblozyl)
- I-252: Anifrolumab-fnia (Saphnelo)
- Y-5: Hydration Therapy (PA & DE only)
- Z-106: Billing and Coding: Complex Drug Administration Coding (WV only)

Refer to the following Reimbursement Policies for additional information:

- RP-003: Drug Wastage and Convenience Kits
- RP-019N: Drugs and Biologicals (This policy is accessible to Network providers only)
- RP-035: Correct Coding Guidelines
- RP-044: Medication Therapy Management

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Highmark Provider Resource Center, Special eBulletin, ATTN: Referring Physicians; Expanded Access to Infused Drug Therapy. Aug.14, 2017. https://content.highmarkprc.com/Files/NewsletterNotices/SpecialBulletins/sb-all-reimbursement-changes-hit-081417.pdf

REFERENCES:

- 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 Non chemotherapy Injections and Infusions, Part D-Chemotherapy Administration https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

- Current version of AMA CPT Manual. *Current Procedure Terminology Manual* (CPT®) is copyright American Medical Association. All rights Reserved. The AMA assumes no liability for the data contained in this policy.

- Social Security Administration, Section 1861(t); Part E. https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

- Novitas Solutions, *Local Coverage Determination (LCD)*; (L34960) Hydration Therapy https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A53049) Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents. https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A59073) Billing and Coding: Complex Drug Administration Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A58527) Billing and Coding: Complex Drug Administration Coding. Article - Billing and Coding: Complex Drug Administration Coding (A58527) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A53778) Billing and Coding: Infusion, Injection and Hydration Services Article - Billing and Coding: Infusion, Injection and Hydration Services (A53778) (cms.gov)

- MEDLEARN Publishing Coding Essentials for Infusion & Injection Therapy Services

POLICY UPDATE HISTORY INFORMATION:

1 / 2022	Implementation
4 /2022	Updated direction for some drugs and eliminated the MA and Commercial variance
5 / 2022	Added note for billing drugs with certain codes. Added medical policy cross references
7 / 2022	Added code J1551
10 / 2022	Removed code J0222 and replaced code J3590 with J0491
4 / 2023	Added codes Q5127 and Q5130
1 / 2024	Updated code description for 96361
7 / 2024	Added codes J2267, J3247, Q5137, and Q5138

Highmark Reimbursement Policy Bulletin

HIGHMARK.

HISTORY VERSION

Bulletin Number:	RP- 072		
Subject:	Injection and Infusion Services		
Effective Date:	January 1, 2022	**End Date:**	
Issue Date:	January 1, 2024	**Revised Date:**	January 2024
Date Reviewed:	December 2023		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Claim Type	**UB**	☒	**1500**	☒				

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The purpose of this policy is to provide direction on injection and infusion services billed with drugs.

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 of quotation from CPT®)

As stated in the CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 12, 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*."

REIMBURSEMENT GUIDELINES:

The chemotherapy and therapeutic administration guidelines identified in this policy are for individuals **18 years of age and older.** The coding of hydration and administration services along with coding of infusions and injections must follow the coding hierarchy guidelines. ("Infusion Hierarchy")

Follow CPT guidelines and hierarchy rules when coding infusion and injections. The Infusion Hierarchy determines initial service. In the doctor's office (place of service 11), the initial code should be the code which best describes the primary reason for the encounter. In the hospital outpatient clinic (place of service 22), the Infusion Hierarchy determines the initial service. The order in which an infusion service is rendered during a visit does not determine the "initial" service. There is only one initial service coded per vascular access site, per encounter per date.

The Infusion Hierarchy is as follows:

1. Chemotherapy services are primary to Therapeutic, Prophylactic and Diagnostic services
2. Therapeutic, Prophylactic and Diagnostic services are primary to hydration. The order is:
    A. Chemotherapy
    B. Therapeutic, prophylactic and diagnostic services
    C. Hydration

3. Infusions are primary to I.V. pushes, which are primary to injections. The order is:
    A. Infusions
    B. I.V. push
    C. Injection

Note: This Infusion Hierarchy does not apply to subQ/IM injections.

Infusions may be concurrent (i.e., multiple drugs are infused simultaneously through the same line) or sequential (infusion of drugs one after another through the same access site).

Note: I.V. infusion differs from an I.V. push which is defined as an infusion lasting 15 minutes or less.

Infusions Start / Stop Time

Selection of the correct CPT code is dependent upon the start and stop time of infusion services. If "stop time" is not documented, only an I.V. push can be billed. Therefore, it is important to use the following guidance:

1. Infusion services are coded based on the length of the infusion, which is a time-based service.
2. The Start and Stop times of each medication administration must be accurately recorded, as this determines the correct CPT code assignment.
3. The first hour of infusion is weighted heavier than subsequent hours to include preparation time, patient education, and patient assessment prior to and after the infusion.
4. The time calculations for the length of the infusion should stop when the infusion is discontinued and restart at the time the infusion resumes.

Time Documented

Time documentation is critical because it drives the assignment and accuracy of the CPT coding of infusion services.

Key Time Ranges

1. 15 minutes or less
    - infusions lasting 15 minutes or less would be coded as an *I.V. push
2. 16 minutes or more
    - infusion can be reported after 16 minutes

***Note**: An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion.

3. 31 minutes to 1 hour
    - hydration infusion must be at least 31 minutes in length to bill the service
4. 16-90 minutes versus more than 90 minutes
5. 16-90 minutes represents the first hour of infusion services
6. 91 minutes or more represents the subsequent hour of infusion, in intervals greater than 30 minutes beyond 1-hour increments
7. 30 minutes since last reported push

Note: Each additional sequential I.V. push of same drug/substance must not be reported if within 30 minutes of each other.

Services Not Included in the Infusion

Supplies for infusion services are not separately payable and should not be separately billed.

Service Included in Infusion

1. Use of local anesthesia;
2. I.V. access;
3. Access to indwelling I.V., subcutaneous catheter or port;
4. Flush at conclusion of infusion;

5. Standard tubing, syringes and supplies; and
6. Preparation of chemotherapy agent(s)

Types of Infusions

1. Initial and sequential infusions:
    A. Bill an I.V. push for intravenous infusions that last 15 minutes or less
    B. If no stop time is documented an I.V. push is the only service that can be billed, regardless of the length of the infusion
    C. CPT code 96413 - Chemo infusion, 1st hour, initial drug
    D. CPT code 96365 - Non-Chemo infusion, 1st hour, initial drug
    E. Requires a new substance or drug

    Sequential infusions are considered to be an infusion or I.V. push of a new substance following a primary or initial service 16 minutes or more.

    Initial infusions for therapy, prophylaxis, or diagnostic (specify substance or drug) are considered an initial service for 16-90 minutes.

2. Concurrent infusions occurs at the same time as the initial infusion:
    A. Add-on CPT code 96368 is listed separately in addition to code for primary procedure
    B. Report only once per encounter
    C. Time does not matter
    D. Drugs given at the same time
    E. Multiple drugs added to one bag of fluids is not a concurrent infusion; it is one infusion
    F. There is no concurrent code for chemotherapy or hydration

3. I.V. push and Additional Hours:
    A. Always secondary to initial infusion code, but always primary to hydration infusion
    B. List each additional sequential I.V. push of a new substance or the same drug separately
    C. Additional pushes of the same drug must be greater than 30 minutes apart
    D. Can never be used alone, must always have a primary infusion/push CPT code
    E. An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion

    Note: An "I.V. push" is considered an injection (or infusion) of a drug of 15 minutes or less.

    Note: "Each Additional Hour" is defined as the same drug, report if more than 31 minutes beyond initial or additional hour.

4. Hydration Infusion

    Assign CPT 96360 – I.V. hydration, initial 31-90 minutes, and CPT 96361 (add on code), used once infusion lasts 91 minutes in length. An intravenous infusion of hydration of 30 minutes or less is not billable. Hydration infusion must be at least 31 minutes in length to bill the service. It is appropriate to charge for hydration provided before and/or after therapeutic infusion, but not the hydration time running at the same time as the therapeutic infusion. Hydration time intervals should be continuous and not added together.

Note: Codes 96360 and 96361 are intended to report a hydration I.V. infusion to consist of a pre-packaged fluid and electrolytes (eg, normal saline, D5-1/2 normal saline + 30 meq KCL/liter) but are not used to report infusion of drugs or other substances.

Key Considerations

1. Saline solution is a hydration service. Saline solution with electrolytes is still a hydration, but electrolytes administered in a bag minus saline are considered drugs.
2. If there is no stop time documented, then the hydration service is not chargeable.
3. Hydration cannot be reported to Keep Vein Open (KVO), i.e. Heplock flush or saline lock, or to flush a line after drug infusion.
4. Hydration cannot be reported if drugs are mixed with fluids and infused in the same bag/syringe.
5. Hydration cannot be reported if a separate bag of fluid is hung and run concurrently with another drug infusion.
6. Novitas Solutions Local Coverage Determination (LCD) L34960 and Article - Billing and Coding Hydration (A56634) requires a covered diagnosis for hydration coverage.
7. Palmetto Local Coverage Article (LCA) A58527-Billing and Coding: Complex Drug Administration Coding and (LCA) A53778- Billing and Coding: Infusion, Injection and Hydration Services.

8. Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage (LCA) Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

9. Per the AMA CPT Manual, Infusion and Injection services within the CPT code range of 96360-96425 and 96521-96523 are not intended to be reported by the physician in the facility setting. Instead physicians should select the most appropriate E/M service. When an E/M service is performed in addition to the infusion and injection service, modifier -25 must be appended to the E/M service to indicate that the service provided was significant and separately identifiable.

Chemotherapy services include:

1. Chemotherapy initiation of prolonged infusion > 8 hours requiring pump
2. Chemotherapy infusions
3. Chemotherapy injections

Injection and Intravenous Infusion Chemotherapy and Other Complex Drug or Highly Complex Biologic Agent Administration:

Note: Also reference the drug table below.

Code	Code Description	Time
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/ drug	16 minutes up to 1 hour. If over an hour and 30 minutes, also assign 96415 +
96415 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional hour (List separately in addition to code for primary procedure)	Add-on code for >61 minutes (i.e., the infusion time must be greater than 30 minutes to 1 hour beyond the initial infusion time of 1 hour)
96417 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug) up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour

96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	15 minutes or less
96411 (Add-on)	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	15 minutes or less

Non-chemotherapy therapeutic, prophylactic and diagnostic injections, and I.V. infusion services include:

1. Initiation of prolonged infusion greater than 8 hours requiring pump
2. Non-Chemo Infusions
3. Non-Chemo Injections

Therapeutic, Prophylactic and Diagnostic Injections, and Infusion (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration):

Note: Also reference the drug table below.

Code	Code Description	Time
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify initial substance or drug) up to 1 hour`	16 minutes up to 1 hour
96366 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	Add-on code after 31 minutes or >61 minutes
96367 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, use 96366 for additional hour(s) of sequential infusion
96368 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, Report only once per encounter
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	15 minutes or less
96375 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	15 minutes or less
96376 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)	Report at intervals >30 minutes

Hydration infusion services include:

1. Hydration Infusions

Code	Code Description	Time
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	31 minutes up to 1 hour
96361 (Add-on)	Intravenous infusion, hydration; each additional hour (list separately in addition to code for primary procedure)	Add-on for each additional hour (after 31 minutes)

Summary of infusion services for chemotherapy, non-chemotherapy and hydration:

Type	Chemotherapy and Other Highly Complex Drug or Biologic Agent	Non-chemotherapy (Therapeutic, Prophylactic & Diagnostic Injections/Infusions)	Hydration
Initial Infusion	96413	96365	96360
Each Additional Hour	96415 (Add-on)	96366 (Add-on)	96361 (Add-on)
Subsequent Infusion	96417 (Add-on)	96367 (Add-on)	N/A
Concurrent Infusion	N/A	96368 (Add-on)	N/A
I.V. Push Initial	96409	96374	N/A
Subsequent I.V. Push – New	96411 (Add-on)	96365	N/A
Subsequent I.V. Push – Same	N/A	96376 (Add-on) Note: Facility only at 30 minutes apart	N/A

Other injection and infusion services:

1. Chemotherapy Administration

Code	Code Description
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g. intrathecal), requiring and including spinal puncture
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions

The drugs listed in the table below must be billed with the appropriate administration type. Refer to the coordinating injection/infusion section of this policy to assign the appropriate CPT code. This list is not all inclusive and subject to change.

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. If a chemotherapy administration code is billed with one of the codes listed below, the administration code will be denied and non-billable to the member. 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 Drug Name	Brand Name	HCPCS
Benralizumab	Fasenra	J0517
Canakinumab	Ilaris	J0638
Certolizumab pegol	Cimzia	J0717
Denosumab	Prolia/Xgeva	J0897
Filgrastim (g-csf) excludes biosimilars	Neupogen	J1442**
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110**
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101**
Luspatercept-aamt	Reblozyl	J0896
Mepolizumab	Nucala	J2182
Octreotide	Sandostatin LAR Depot	J2353
Omalizumab	Xolair	J2357
Pegfilgrastim,excludes biosimilar	Neulasta	J2506*
Pegfilgrastim-apgf, biosimilar	Nyvepria (Neulasta)	Q5122
Pegfilgrastim-bmez, biosimilar	Ziextenzo (Neulasta)	Q5120
Pegfilgrastim-cbqv, biosimilar	Udenyca (Neulasta)	Q5111
Pegfilgrastim-fpgk	Stimufend	Q5127
Pegfilgrastim-jmdb, biosimilar	Fulphila (Neulasta)	Q5108
Pegfilgrastim-pbbk	Fylnetra	Q5130
Rilonacept	Arcalyst	J2793
Tbo-filgrastim	Granix	J1447
Tildrakizumab-asmn	Ilumya	J3245

Note: *Effective January 1, 2018, provider are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

Note: **When billing filgrastim (HCPCS codes J1442, Q5101, or Q5110, append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

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.

Generic Drug Name	Brand Name	HCPCS
Abatacept	Orencia	J0129****
Agalsidase beta	Fabrazyme	J0180

Alglucosidase alfa	Lumizyme	J0221
Alpha 1-proteinase inhibitor (human)	Glassia	J0257
Alpha 1-proteinase inhibitor (human),NOS	Aralast	J0256
Anifrolumab-fnia	Saphnelo	J0491
Belatacept	Nulojix	J0485
Bezlotoxumab	Zinplava	J0565
C1 esterase inhibitor (human)	Berinert	J0597
Eculizumab	Soliris	J1300
Edaravone	Radicava	J1301
Elosulfase alfa	Vimizim	J1322
Filgrastim-(g-csf) excludes biosimilars	Neupogen	J1442***
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110***
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101***
Golimumab	Simponi Aria	J1602
Idursulfase	Elaprase	J1743
Imiglucerase	Cerezyme	J1786
Immune globulin	Cutaquig	J1551
Immune globulin	Bivigam	J1556
Immune globulin	Carimune® NF, Gammagard® S/D	J1566
Immune globulin	Flebogamma	J1572
Immune globulin	Gammagard	J1569
Immune globulin	Gammaplex	J1557
Immune globulin	Gamunex- C	J1561
Immune globulin	Octagam	J1568
Immune globulin	Privigen	J1459
Immune globulin	Asceniv	J1554
Natalizumab	Tysabri	J2323
Octreotide	Sandostatin	J2354**
Remdesivir	Veklury	J0248
Reslizumab	Cinqair	J2786
Tocilizumab	Actemra	J3262
Ustekinumab	Stelara	J3358*
Vedolizumab	Entyvio	J3380
Velaglucerase alfa	Vpriv	J3385

Note: *Effective September 23, 2016, IV ustekinumab (Stelara®) should be billed with HCPCS code J3590 (OPPS: C9399 for dates of service [DOS] before 4/01/2017; C9487 for DOS from 4/01/2017 to 6/30/2017, Q9989 for DOS from 7/01/2017-12/31/2017 and J3358 for DOS 1/01/2018 and after) for the initial IV dose of Stelara® when used for Crohn's disease and Ulcerative Colitis. Each subsequent subcutaneous dose **must** be billed with J3357. This IV formulation is now FDA approved for Crohn's disease and Ulcerative Colitis. 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.

Note: ** When billing octreotide acetate (HCPCS code J2354), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Note: *** When billing filgrastim (HCPCS codes J1442, Q5101, Q5110), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

Note: **** When billing abatacept (HCPCS code J0129), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Documentation Requirements:

1. Documentation is for the correct beneficiary and date of service.
2. Documentation is complete, legible, signed and dated by the Physician or Clinician.
3. Documentation includes Physician's order for date(s) of service when medication(s) were administered, to include the medication name, dosage, frequency and method of administration.
4. Medication Administration Record for dates of service include the medication name, dosage, method of administration, and start/stop times for infusions (when applicable).
5. Documentation to support the amount of drugs or biologicals discarded (single use packaging) for the relevant beneficiary (when applicable).
6. Medical necessity supported by the medical record (e.g. office/progress notes, history and physical, laboratory test results, etc.)
7. Documentation for the procedures, operative reports and anesthesia reports (when applicable).
8. If billing incident to services, the documentation supports appropriate supervision (billing physician is present in the office suite during the performance of procedure).
9. Documentation meets criteria specified in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).
10. Evidence an Advanced Beneficiary Notice of Non-coverage (ABN) was provided to the beneficiary, if applicable.

RELATED POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-6: Approved Drugs and Biologicals
- I-9: Treatment of Gaucher Disease
- I-14: Immune Globulin Therapy
- I-24: Belatacept (Nulojix)
- I-27: Certolizumab (Cimzia)
- I-30: Denosumab (Prolia, Xgeva)
- I-31: Tocilizumab (Actemra)

- I-35: Golimumab (Simponi, Simponi Aria)
- I-37: Ustekinumab (Stelara)
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme)
- I-58: Alglucosidase alfa (Lumizyme)
- I-85: Natalizumab (Tysabri)
- I-88: Granulocyte Colony-Stimulating Factors
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha 1-Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Complement Inhibitors
- I-138: Elosulfase alfa (Vimizim)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-151: Site of Care
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-210: IL-1 and IL-1b Blockers
- I-214: Luspatercept (Reblozyl)
- I-245: Anifrolumab-fnia (Saphnelo)
- G-16: Chemotherapy Services

Refer to the following Medicare Advantage Medical Policies for additional information:

- I-20: Denosumab (Prolia, Xgeva)
- I-27: Octreotide Acetate for Injectable Suspension (Sandostain® LAR Depot) (WV only)
- I-51: Self-Administered Drug Exclusion List
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme) (WV only)
- I-56: Granulocyte Colony-Stimulating Factors
- I-68: Treatment of Gaucher Disease
- I-85: Natalizumab (Tysabri)
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-98: Immunosuppressive Drugs
- I-103: Intravenous Immune Globulin
- I-105: Billing and Coding: App'd Drugs and Biologicals; Includes Cancer Chemo Agents (PA only)
- I-105: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (DE only)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha-1 Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)

- I-130: Compliment Inhibitors
- I-132: Agalsidase beta (Fabrazyme)
- I-134: Alglucosidase alfa (Lumizyme) and Avalglucosidase alfa-ngpt (Nexviazyme)
- I-138: Elosulfase alfa (Vimizim)
- I-139: Ustekinumab (Stelara)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin) and Lanreotide (Somatuline Depot)
- I-184: Certolizumab (Cimzia)
- I-194: Tocilizumab (Actemra)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-208: Billing and Coding Chemotherapy (WV only)
- I-210: IL-1 and IL-1b Blockers
- I-218: Golimumab (Simponi, Simponi Aria)
- I-223: Luspatercept (Reblozyl)
- I-252: Anifrolumab-fnia (Saphnelo)
- Y-5: Hydration Therapy (PA & DE only)
- Z-106: Billing and Coding: Complex Drug Administration Coding (WV only)

Refer to the following Reimbursement Policies for additional information:

- RP-003: Drug Wastage and Convenience Kits
- RP-019N: Drugs and Biologicals (This policy is accessible to Network providers only)
- RP-035: Correct Coding Guidelines
- RP-044: Medication Therapy Management

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Highmark Provider Resource Center, Special eBulletin, ATTN: Referring Physicians; Expanded Access to Infused Drug Therapy. Aug.14, 2017. https://content.highmarkprc.com/Files/NewsletterNotices/SpecialBulletins/sb-all-reimbursement-changes-hit-081417.pdf

REFERENCES:

- 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 Non chemotherapy Injections and Infusions, Part D-Chemotherapy Administration https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

- Current version of AMA CPT Manual. *Current Procedure Terminology Manual* (CPT®) is copyright American Medical Association. All rights Reserved. The AMA assumes no liability for the data contained in this policy.

- Social Security Administration, Section 1861(t); Part E. https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

- Novitas Solutions, *Local Coverage Determination (LCD)*; (L34960) Hydration Therapy https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A53049) Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents. https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A59073) Billing and Coding: Complex Drug Administration Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A58527) Billing and Coding: Complex Drug Administration Coding. Article - Billing and Coding: Complex Drug Administration Coding (A58527) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A53778) Billing and Coding: Infusion, Injection and Hydration Services Article - Billing and Coding: Infusion, Injection and Hydration Services (A53778) (cms.gov)

- MEDLEARN Publishing Coding Essentials for Infusion & Injection Therapy Services

POLICY UPDATE HISTORY INFORMATION:

1 / 2022	Implementation
4 /2022	Updated direction for some drugs and eliminated the MA and Commercial variance
5 / 2022	Added note for billing drugs with certain codes. Added medical policy cross references
7 / 2022	Added code J1551
10 / 2022	Removed code J0222 and replaced code J3590 with J0491
4 / 2023	Added codes Q5127 and Q5130
1 / 2024	Updated code description for 96361

Highmark Reimbursement Policy Bulletin

HIGHMARK.

HISTORY VERSION

Bulletin Number:	RP- 072		
Subject:	Injection and Infusion Services		
Effective Date:	January 1, 2022	**End Date:**	
Issue Date:	April 3, 2023	**Revised Date:**	April 2023
Date Reviewed:	March 2023		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Claim Type	**UB**	☒	**1500**	☒				

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The purpose of this policy is to provide direction on injection and infusion services billed with drugs.

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 of quotation from CPT®)

As stated in the CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 12, 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*."

REIMBURSEMENT GUIDELINES:

The chemotherapy and therapeutic administration guidelines identified in this policy are for individuals **18 years of age and older.** The coding of hydration and administration services along with coding of infusions and injections must follow the coding hierarchy guidelines. ("Infusion Hierarchy")

Follow CPT guidelines and hierarchy rules when coding infusion and injections. The Infusion Hierarchy determines initial service. In the doctor's office (place of service 11), the initial code should be the code which best describes the primary reason for the encounter. In the hospital outpatient clinic (place of service 22), the Infusion Hierarchy determines the initial service. The order in which an infusion service is rendered during a visit does not determine the "initial" service. There is only one initial service coded per vascular access site, per encounter per date.

The Infusion Hierarchy is as follows:

1. Chemotherapy services are primary to Therapeutic, Prophylactic and Diagnostic services
2. Therapeutic, Prophylactic and Diagnostic services are primary to hydration. The order is:
    A. Chemotherapy
    B. Therapeutic, prophylactic and diagnostic services
    C. Hydration

3. Infusions are primary to I.V. pushes, which are primary to injections. The order is:
    A. Infusions
    B. I.V. push
    C. Injection

Note: This Infusion Hierarchy does not apply to subQ/IM injections.

Infusions may be concurrent (i.e., multiple drugs are infused simultaneously through the same line) or sequential (infusion of drugs one after another through the same access site).

Note: I.V. infusion differs from an I.V. push which is defined as an infusion lasting 15 minutes or less.

Infusions Start / Stop Time

Selection of the correct CPT code is dependent upon the start and stop time of infusion services. If "stop time" is not documented, only an I.V. push can be billed. Therefore, it is important to use the following guidance:

1. Infusion services are coded based on the length of the infusion, which is a time-based service.
2. The Start and Stop times of each medication administration must be accurately recorded, as this determines the correct CPT code assignment.
3. The first hour of infusion is weighted heavier than subsequent hours to include preparation time, patient education, and patient assessment prior to and after the infusion.
4. The time calculations for the length of the infusion should stop when the infusion is discontinued and restart at the time the infusion resumes

Time Documented

Time documentation is critical because it drives the assignment and accuracy of the CPT coding of infusion services.

Key Time Ranges

1. 15 minutes or less
    - infusions lasting 15 minutes or less would be coded as an *I.V. push
2. 16 minutes or more
    - infusion can be reported after 16 minutes

***Note**: An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion.

3. 31 minutes to 1 hour
    - hydration infusion must be at least 31 minutes in length to bill the service
4. 16-90 minutes versus more than 90 minutes
5. 16-90 minutes represents the first hour of infusion services
6. 91 minutes or more represents the subsequent hour of infusion, in intervals greater than 30 minutes beyond 1-hour increments
7. 30 minutes since last reported push

Note: Each additional sequential I.V. push of same drug/substance must not be reported if within 30 minutes of each other.

Services Not Included in the Infusion

Supplies for infusion services are not separately payable and should not be separately billed.

Service Included in Infusion

1. Use of local anesthesia;
2. I.V. access;
3. Access to indwelling I.V., subcutaneous catheter or port;
4. Flush at conclusion of infusion;
5. Standard tubing, syringes and supplies; and
6. Preparation of chemotherapy agent(s)

Types of Infusions

1. Initial and sequential infusions:
    A. Bill an I.V. push for intravenous infusions that last 15 minutes or less
    B. If no stop time is documented an I.V. push is the only service that can be billed, regardless of the length of the infusion
    C. CPT code 96413 - Chemo infusion, 1st hour, initial drug
    D. CPT code 96365 - Non-Chemo infusion, 1st hour, initial drug
    E. Requires a new substance or drug

    Sequential infusions are considered to be an infusion or I.V. push of a new substance following a primary or initial service 16 minutes or more.

    Initial infusions for therapy, prophylaxis, or diagnostic (specify substance or drug) are considered an initial service for 16-90 minutes.

2. Concurrent infusions occurs at the same time as the initial infusion:
    A. Add-on CPT code 96368 is listed separately in addition to code for primary procedure
    B. Report only once per encounter
    C. Time does not matter
    D. Drugs given at the same time
    E. Multiple drugs added to one bag of fluids is not a concurrent infusion; it is one infusion
    F. There is no concurrent code for chemotherapy or hydration

3. I.V. push and Additional Hours:
    A. Always secondary to initial infusion code, but always primary to hydration infusion
    B. List each additional sequential I.V. push of a new substance or the same drug separately
    C. Additional pushes of the same drug must be greater than 30 minutes apart
    D. Can never be used alone, must always have a primary infusion/push CPT code
    E. An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion

    Note: An "I.V. push" is considered an injection (or infusion) of a drug of 15 minutes or less.

Note: "Each Additional Hour" is defined as the same drug, report if more than 31 minutes beyond initial or additional hour.

4. Hydration Infusion

   Assign CPT 96360 – I.V. hydration, initial 31-90 minutes, and CPT 96361 (add on code), used once infusion lasts 91 minutes in length. An intravenous infusion of hydration of 30 minutes or less is not billable. Hydration infusion must be at least 31 minutes in length to bill the service. It is appropriate to charge for hydration provided before and/or after therapeutic infusion, but not the hydration time running at the same time as the therapeutic infusion. Hydration time intervals should be continuous and not added together.

   Note: Codes 96360 and 96361 are intended to report a hydration I.V. infusion to consist of a pre-packaged fluid and electrolytes (eg, normal saline, D5-1/2 normal saline + 30 meq KCL/liter) but are not used to report infusion of drugs or other substances.

<u>Key Considerations</u>

1. Saline solution is a hydration service. Saline solution with electrolytes is still a hydration, but electrolytes administered in a bag minus saline are considered drugs.
2. If there is no stop time documented, then the hydration service is not chargeable.
3. Hydration cannot be reported to Keep Vein Open (KVO), i.e. Heplock flush or saline lock, or to flush a line after drug infusion.
4. Hydration cannot be reported if drugs are mixed with fluids and infused in the same bag/syringe.
5. Hydration cannot be reported if a separate bag of fluid is hung and run concurrently with another drug infusion.
6. Novitas Solutions Local Coverage Determination (LCD) L34960 and Article - Billing and Coding Hydration (A56634) requires a covered diagnosis for hydration coverage.
7. Palmetto Local Coverage Article (LCA) A58527-Billing and Coding: Complex Drug Administration Coding and (LCA) A53778- Billing and Coding: Infusion, Injection and Hydration Services.

8. Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage (LCA) <u>Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)</u>

9. Per the AMA CPT Manual, Infusion and Injection services within the CPT code range of 96360-96425 and 96521-96523 are not intended to be reported by the physician in the facility setting. Instead physicians should select the most appropriate E/M service. When an E/M service is performed in addition to the infusion and injection service, modifier -25 must be appended to the E/M service to indicate that the service provided was significant and separately identifiable.

<u>Chemotherapy services include:</u>

1. Chemotherapy initiation of prolonged infusion > 8 hours requiring pump
2. Chemotherapy infusions
3. Chemotherapy injections

Injection and Intravenous Infusion Chemotherapy and Other Complex Drug or Highly Complex Biologic Agent Administration:

Note: Also reference the drug table below.

Code	Code Description	Time
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/ drug	16 minutes up to 1 hour. If over an hour and 30 minutes, also assign 96415 +
96415 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional hour (List separately in addition to code for primary procedure)	Add-on code for >61 minutes (i.e., the infusion time must be greater than 30 minutes to 1 hour beyond the initial infusion time of 1 hour)
96417 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug) up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	15 minutes or less
96411 (Add-on)	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	15 minutes or less

Non-chemotherapy therapeutic, prophylactic and diagnostic injections, and I.V. infusion services include:

1. Initiation of prolonged infusion greater than 8 hours requiring pump
2. Non-Chemo Infusions
3. Non-Chemo Injections

Therapeutic, Prophylactic and Diagnostic Injections, and Infusion (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration):

Note: Also reference the drug table below.

Code	Code Description	Time
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify initial substance or drug) up to 1 hour`	16 minutes up to 1 hour
96366 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	Add-on code after 31 minutes or >61 minutes
96367 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, use 96366 for additional hour(s) of sequential infusion
96368 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, Report only once per encounter
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	15 minutes or less

96375 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	15 minutes or less
96376 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)	Report at intervals >30 minutes

Hydration infusion services include:

1. Hydration Infusions

Code	Code Description	Time
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	31 minutes up to 1 hour
96361 (Add-on)	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	Add-on for each additional hour (after 31 minutes)

Summary of infusion services for chemotherapy, non-chemotherapy and hydration:

Type	Chemotherapy and Other Highly Complex Drug or Biologic Agent	Non-chemotherapy (Therapeutic, Prophylactic & Diagnostic Injections/Infusions)	Hydration
Initial Infusion	96413	96365	96360
Each Additional Hour	96415 (Add-on)	96366 (Add-on)	96361 (Add-on)
Subsequent Infusion	96417 (Add-on)	96367 (Add-on)	N/A
Concurrent Infusion	N/A	96368 (Add-on)	N/A
I.V. Push Initial	96409	96374	N/A
Subsequent I.V. Push – New	96411 (Add-on)	96365	N/A
Subsequent I.V. Push – Same	N/A	96376 (Add-on) Note: Facility only at 30 minutes apart	N/A

Other injection and infusion services:

1. Chemotherapy Administration

Code	Code Description
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g. intrathecal), requiring and including spinal puncture
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions

The drugs listed in the table below must be billed with the appropriate administration type. Refer to the coordinating injection/infusion section of this policy to assign the appropriate CPT code. This list is not all inclusive and subject to change.

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 Drug Name	Brand Name	HCPCS
Benralizumab	Fasenra	J0517
Canakinumab	Ilaris	J0638
Certolizumab pegol	Cimzia	J0717
Denosumab	Prolia/Xgeva	J0897
Filgrastim (g-csf) excludes biosimilars	Neupogen	J1442**
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110**
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101**
Luspatercept-aamt	Reblozyl	J0896
Mepolizumab	Nucala	J2182
Octreotide	Sandostatin LAR Depot	J2353
Omalizumab	Xolair	J2357
Pegfilgrastim,excludes biosimilar	Neulasta	J2506*
Pegfilgrastim-apgf, biosimilar	Nyvepria (Neulasta)	Q5122
Pegfilgrastim-bmez, biosimilar	Ziextenzo (Neulasta)	Q5120
Pegfilgrastim-cbqv, biosimilar	Udenyca (Neulasta)	Q5111
Pegfilgrastim-fpgk	Stimufend	Q5127
Pegfilgrastim-jmdb, biosimilar	Fulphila (Neulasta)	Q5108
Pegfilgrastim-pbbk	Fylnetra	Q5130
Rilonacept	Arcalyst	J2793

Tbo-filgrastim	Granix	J1447
Tildrakizumab-asmn	Ilumya	J3245

Note: *Effective January 1, 2018, provider are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

Note: **When billing filgrastim (HCPCS codes J1442, Q5101, or Q5110, append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

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.

Generic Drug Name	Brand Name	HCPCS
Abatacept	Orencia	J0129****
Agalsidase beta	Fabrazyme	J0180
Alglucosidase alfa	Lumizyme	J0221
Alpha 1-proteinase inhibitor (human)	Glassia	J0257
Alpha 1-proteinase inhibitor (human),NOS	Aralast	J0256
Anifrolumab-fnia	Saphnelo	J0491
Belatacept	Nulojix	J0485
Bezlotoxumab	Zinplava	J0565
C1 esterase inhibitor (human)	Berinert	J0597
Eculizumab	Soliris	J1300
Edaravone	Radicava	J1301
Elosulfase alfa	Vimizim	J1322
Filgrastim-(g-csf) excludes biosimilars	Neupogen	J1442***
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110***
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101***
Golimumab	Simponi Aria	J1602
Idursulfase	Elaprase	J1743
Imiglucerase	Cerezyme	J1786
Immune globulin	Cutaquig	J1551
Immune globulin	Bivigam	J1556
Immune globulin	Carimune® NF, Gammagard® S/D	J1566
Immune globulin	Flebogamma	J1572
Immune globulin	Gammagard	J1569
Immune globulin	Gammaplex	J1557
Immune globulin	Gamunex- C	J1561
Immune globulin	Octagam	J1568
Immune globulin	Privigen	J1459

Immune globulin	Asceniv	J1554
Natalizumab	Tysabri	J2323
Octreotide	Sandostatin	J2354**
Remdesivir	Veklury	J0248
Reslizumab	Cinqair	J2786
Tocilizumab	Actemra	J3262
Ustekinumab	Stelara	J3358*
Vedolizumab	Entyvio	J3380
Velaglucerase alfa	Vpriv	J3385

Note: *Effective September 23, 2016, IV ustekinumab (Stelara®) should be billed with HCPCS code J3590 (OPPS: C9399 for dates of service [DOS] before 4/01/2017; C9487 for DOS from 4/01/2017 to 6/30/2017, Q9989 for DOS from 7/01/2017-12/31/2017 and J3358 for DOS 1/01/2018 and after) for the initial IV dose of Stelara® when used for Crohn's disease and Ulcerative Colitis. Each subsequent subcutaneous dose **must** be billed with J3357. This IV formulation is now FDA approved for Crohn's disease and Ulcerative Colitis. 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.

Note: ** When billing octreotide acetate (HCPCS code J2354), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Note: *** When billing filgrastim (HCPCS codes J1442, Q5101, Q5110), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

Note: **** When billing abatacept (HCPCS code J0129), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Documentation Requirements:

1. Documentation is for the correct beneficiary and date of service.
2. Documentation is complete, legible, signed and dated by the Physician or Clinician.
3. Documentation includes Physician's order for date(s) of service when medication(s) were administered, to include the medication name, dosage, frequency and method of administration.
4. Medication Administration Record for dates of service include the medication name, dosage, method of administration, and start/stop times for infusions (when applicable).
5. Documentation to support the amount of drugs or biologicals discarded (single use packaging) for the relevant beneficiary (when applicable).
6. Medical necessity supported by the medical record (e.g. office/progress notes, history and physical, laboratory test results, etc.)

7. Documentation for the procedures, operative reports and anesthesia reports (when applicable).
8. If billing incident to services, the documentation supports appropriate supervision (billing physician is present in the office suite during the performance of procedure).
9. Documentation meets criteria specified in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).
10. Evidence an Advanced Beneficiary Notice of Non-coverage (ABN) was provided to the beneficiary, if applicable.

RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-6: Approved Drugs and Biologicals
- I-9: Treatment of Gaucher Disease
- I-14: Immune Globulin Therapy
- I-24: Belatacept (Nulojix)
- I-27: Certolizumab (Cimzia)
- I-30: Denosumab (Prolia, Xgeva)
- I-31: Tocilizumab (Actemra)
- I-35: Golimumab (Simponi, Simponi Aria)
- I-37: Ustekinumab (Stelara)
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme)
- I-58: Alglucosidase alfa (Lumizyme)
- I-85: Natalizumab (Tysabri)
- I-88: Granulocyte Colony-Stimulating Factors
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha 1-Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Complement Inhibitors
- I-138: Elosulfase alfa (Vimizim)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-151: Site of Care
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-210: IL-1 and IL-1b Blockers
- I-214: Luspatercept (Reblozyl)
- I-245: Anifrolumab-fnia (Saphnelo)
- G-16: Chemotherapy Services

Refer to the following Medicare Advantage Medical Policies for additional information:

- I-20: Denosumab (Prolia, Xgeva)
- I-27: Octreotide Acetate for Injectable Suspension (Sandostain® LAR Depot) (WV only)
- I-51: Self-Administered Drug Exclusion List
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme) (WV only)
- I-56: Granulocyte Colony-Stimulating Factors
- I-68: Treatment of Gaucher Disease
- I-85: Natalizumab (Tysabri)
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-98: Immunosuppressive Drugs
- I-103: Intravenous Immune Globulin
- I-105: Billing and Coding: App'd Drugs and Biologicals; Includes Cancer Chemo Agents (PA only)
- I-105: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (DE only)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha-1 Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Compliment Inhibitors
- I-132: Agalsidase beta (Fabrazyme)
- I-134: Alglucosidase alfa (Lumizyme) and Avalglucosidase alfa-ngpt (Nexviazyme)
- I-138: Elosulfase alfa (Vimizim)
- I-139: Ustekinumab (Stelara)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin) and Lanreotide (Somatuline Depot)
- I-184: Certolizumab (Cimzia)
- I-194: Tocilizumab (Actemra)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-208: Billing and Coding Chemotherapy (WV only)
- I-210: IL-1 and IL-1b Blockers
- I-218: Golimumab (Simponi, Simponi Aria)
- I-223: Luspatercept (Reblozyl)
- I-252: Anifrolumab-fnia (Saphnelo)
- Y-5: Hydration Therapy (PA & DE only)
- Z-106: Billing and Coding: Complex Drug Administration Coding (WV only)

Refer to the following Reimbursement Policies for additional information:

- RP-003: Drug Wastage and Convenience Kits
- RP-019N: Drugs and Biologicals (This policy is accessible to Network providers only)
- RP-035: Correct Coding Guidelines
- RP-044: Medication Therapy Management

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Highmark Provider Resource Center, Special eBulletin, ATTN: Referring Physicians; Expanded Access to Infused Drug Therapy. Aug.14, 2017. https://content.highmarkprc.com/Files/NewsletterNotices/SpecialBulletins/sb-all-reimbursement-changes-hit-081417.pdf

REFERENCES:

- 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 Non chemotherapy Injections and Infusions, Part D-Chemotherapy Administration https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

- Current version of AMA CPT Manual. *Current Procedure Terminology Manual* (CPT®) is copyright American Medical Association. All rights Reserved. The AMA assumes no liability for the data contained in this policy.

- Social Security Administration, Section 1861(t); Part E. https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

- Novitas Solutions, *Local Coverage Determination (LCD)*; (L34960) Hydration Therapy https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A53049) Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents. https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A59073) Billing and Coding: Complex Drug Administration Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A58527) Billing and Coding: Complex Drug Administration Coding. Article - Billing and Coding: Complex Drug Administration Coding (A58527) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A53778) Billing and Coding: Infusion, Injection and Hydration Services Article - Billing and Coding: Infusion, Injection and Hydration Services (A53778) (cms.gov)

- MEDLEARN Publishing Coding Essentials for Infusion & Injection Therapy Services

POLICY UPDATE HISTORY INFORMATION:

1 / 2022	Implementation
4 /2022	Updated direction for some drugs and eliminated the MA and Commercial variance
5 / 2022	Added note for billing drugs with certain codes. Added medical policy cross references
7 / 2022	Added code J1551
10 / 2022	Removed code J0222 and replaced code J3590 with J0491
4 / 2023	Added codes Q5127 and Q5130

Highmark Reimbursement Policy Bulletin

HIGHMARK.

HISTORY VERSION

Bulletin Number:	RP- 072		
Subject:	Injection and Infusion Services		
Effective Date:	January 1, 2022	**End Date:**	
Issue Date:	October 10, 2022	**Revised Date:**	September 2022
Date Reviewed:	September 2022		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY** ☐
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY** ☐
Applicable Claim Type	**UB**	☒	**1500**	☒			

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The purpose of this policy is to provide direction on injection and infusion services billed with drugs.

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 of quotation from CPT®)

As stated in the CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 12, 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*."

REIMBURSEMENT GUIDELINES:

The chemotherapy and therapeutic administration guidelines identified in this policy are for individuals **18 years of age and older.** The coding of hydration and administration services along with coding of infusions and injections must follow the coding hierarchy guidelines. ("Infusion Hierarchy")

Follow CPT guidelines and hierarchy rules when coding infusion and injections. The Infusion Hierarchy determines initial service. In the doctor's office (place of service 11), the initial code should be the code which best describes the primary reason for the encounter. In the hospital outpatient clinic (place of service 22), the Infusion Hierarchy determines the initial service. The order in which an infusion service is rendered during a visit does not determine the "initial" service. There is only one initial service coded per vascular access site, per encounter per date.

The Infusion Hierarchy is as follows:

1. Chemotherapy services are primary to Therapeutic, Prophylactic and Diagnostic services
2. Therapeutic, Prophylactic and Diagnostic services are primary to hydration. The order is:
    A. Chemotherapy
    B. Therapeutic, prophylactic and diagnostic services
    C. Hydration
3. Infusions are primary to I.V. pushes, which are primary to injections. The order is:
    A. Infusions
    B. I.V. push
    C. Injection

Note: This Infusion Hierarchy does not apply to subQ/IM injections.

Infusions may be concurrent (i.e., multiple drugs are infused simultaneously through the same line) or sequential (infusion of drugs one after another through the same access site).

Note: I.V. infusion differs from an I.V. push which is defined as an infusion lasting 15 minutes or less.

Infusions Start / Stop Time

Selection of the correct CPT code is dependent upon the start and stop time of infusion services. If "stop time" is not documented, only an I.V. push can be billed. Therefore, it is important to use the following guidance:

1. Infusion services are coded based on the length of the infusion, which is a time-based service.
2. The Start and Stop times of each medication administration must be accurately recorded, as this determines the correct CPT code assignment.
3. The first hour of infusion is weighted heavier than subsequent hours to include preparation time, patient education, and patient assessment prior to and after the infusion.
4. The time calculations for the length of the infusion should stop when the infusion is discontinued and restart at the time the infusion resumes

Time Documented

Time documentation is critical because it drives the assignment and accuracy of the CPT coding of infusion services.

Key Time Ranges

1. 15 minutes or less
    - infusions lasting 15 minutes or less would be coded as an *I.V. push
2. 16 minutes or more
    - infusion can be reported after 16 minutes

***Note**: An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion.

3. 31 minutes to 1 hour
    - hydration infusion must be at least 31 minutes in length to bill the service
4. 16-90 minutes versus more than 90 minutes
5. 16-90 minutes represents the first hour of infusion services
6. 91 minutes or more represents the subsequent hour of infusion, in intervals greater than 30 minutes beyond 1-hour increments
7. 30 minutes since last reported push

Note: Each additional sequential I.V. push of same drug/substance must not be reported if within 30 minutes of each other.

Services Not Included in the Infusion

Supplies for infusion services are not separately payable and should not be separately billed.

Service Included in Infusion

1. Use of local anesthesia;
2. I.V. access;
3. Access to indwelling I.V., subcutaneous catheter or port;
4. Flush at conclusion of infusion;
5. Standard tubing, syringes and supplies; and
6. Preparation of chemotherapy agent(s)

Types of Infusions

1. Initial and sequential infusions:
    A. Bill an I.V. push for intravenous infusions that last 15 minutes or less
    B. If no stop time is documented an I.V. push is the only service that can be billed, regardless of the length of the infusion
    C. CPT code 96413 - Chemo infusion, 1st hour, initial drug
    D. CPT code 96365 - Non-Chemo infusion, 1st hour, initial drug
    E. Requires a new substance or drug

    Sequential infusions are considered to be an infusion or I.V. push of a new substance following a primary or initial service 16 minutes or more.

    Initial infusions for therapy, prophylaxis, or diagnostic (specify substance or drug) are considered an initial service for 16-90 minutes.

2. Concurrent infusions occurs at the same time as the initial infusion:
    A. Add-on CPT code 96368 is listed separately in addition to code for primary procedure
    B. Report only once per encounter
    C. Time does not matter
    D. Drugs given at the same time
    E. Multiple drugs added to one bag of fluids is not a concurrent infusion; it is one infusion
    F. There is no concurrent code for chemotherapy or hydration

3. I.V. push and Additional Hours:
    A. Always secondary to initial infusion code, but always primary to hydration infusion
    B. List each additional sequential I.V. push of a new substance or the same drug separately
    C. Additional pushes of the same drug must be greater than 30 minutes apart
    D. Can never be used alone, must always have a primary infusion/push CPT code
    E. An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion

    Note: An "I.V. push" is considered an injection (or infusion) of a drug of 15 minutes or less.

Note: "Each Additional Hour" is defined as the same drug, report if more than 31 minutes beyond initial or additional hour.

4. Hydration Infusion

   Assign CPT 96360 – I.V. hydration, initial 31-90 minutes, and CPT 96361 (add on code), used once infusion lasts 91 minutes in length. An intravenous infusion of hydration of 30 minutes or less is not billable. Hydration infusion must be at least 31 minutes in length to bill the service. It is appropriate to charge for hydration provided before and/or after therapeutic infusion, but not the hydration time running at the same time as the therapeutic infusion. Hydration time intervals should be continuous and not added together.

   Note: Codes 96360 and 96361 are intended to report a hydration I.V. infusion to consist of a pre-packaged fluid and electrolytes (eg, normal saline, D5-1/2 normal saline + 30 meq KCL/liter) but are not used to report infusion of drugs or other substances.

<u>Key Considerations</u>

1. Saline solution is a hydration service. Saline solution with electrolytes is still a hydration, but electrolytes administered in a bag minus saline are considered drugs.
2. If there is no stop time documented, then the hydration service is not chargeable.
3. Hydration cannot be reported to Keep Vein Open (KVO), i.e. Heplock flush or saline lock, or to flush a line after drug infusion.
4. Hydration cannot be reported if drugs are mixed with fluids and infused in the same bag/syringe.
5. Hydration cannot be reported if a separate bag of fluid is hung and run concurrently with another drug infusion.
6. Novitas Solutions Local Coverage Determination (LCD) L34960 and Article - Billing and Coding Hydration (A56634) requires a covered diagnosis for hydration coverage.
7. Palmetto Local Coverage Article (LCA) A58527-Billing and Coding: Complex Drug Administration Coding and (LCA) A53778- Billing and Coding: Infusion, Injection and Hydration Services.

8. Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage (LCA) <u>Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)</u>

9. Per the AMA CPT Manual, Infusion and Injection services within the CPT code range of 96360-96425 and 96521-96523 are not intended to be reported by the physician in the facility setting. Instead physicians should select the most appropriate E/M service. When an E/M service is performed in addition to the infusion and injection service, modifier -25 must be appended to the E/M service to indicate that the service provided was significant and separately identifiable.

<u>Chemotherapy services include:</u>

1. Chemotherapy initiation of prolonged infusion > 8 hours requiring pump
2. Chemotherapy infusions
3. Chemotherapy injections

Injection and Intravenous Infusion Chemotherapy and Other Complex Drug or Highly Complex Biologic Agent Administration:

Note: Also reference the drug table below.

Code	Code Description	Time
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/ drug	16 minutes up to 1 hour. If over an hour and 30 minutes, also assign 96415 +
96415 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional hour (List separately in addition to code for primary procedure)	Add-on code for >61 minutes (i.e., the infusion time must be greater than 30 minutes to 1 hour beyond the initial infusion time of 1 hour)
96417 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug) up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	15 minutes or less
96411 (Add-on)	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	15 minutes or less

Non-chemotherapy therapeutic, prophylactic and diagnostic injections, and I.V. infusion services include:

1. Initiation of prolonged infusion greater than 8 hours requiring pump
2. Non-Chemo Infusions
3. Non-Chemo Injections

Therapeutic, Prophylactic and Diagnostic Injections, and Infusion (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration):

Note: Also reference the drug table below.

Code	Code Description	Time
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify initial substance or drug) up to 1 hour`	16 minutes up to 1 hour
96366 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	Add-on code after 31 minutes or >61 minutes
96367 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, use 96366 for additional hour(s) of sequential infusion
96368 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, Report only once per encounter

96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	15 minutes or less
96375 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	15 minutes or less
96376 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)	Report at intervals >30 minutes

Hydration infusion services include:

1. Hydration Infusions

Code	Code Description	Time
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	31 minutes up to 1 hour
96361 (Add-on)	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	Add-on for each additional hour (after 31 minutes)

Summary of infusion services for chemotherapy, non-chemotherapy and hydration:

Type	Chemotherapy and Other Highly Complex Drug or Biologic Agent	Non-chemotherapy (Therapeutic, Prophylactic & Diagnostic Injections/Infusions)	Hydration
Initial Infusion	96413	96365	96360
Each Additional Hour	96415 (Add-on)	96366 (Add-on)	96361 (Add-on)
Subsequent Infusion	96417 (Add-on)	96367 (Add-on)	N/A
Concurrent Infusion	N/A	96368 (Add-on)	N/A
I.V. Push Initial	96409	96374	N/A
Subsequent I.V. Push – New	96411 (Add-on)	96365	N/A
Subsequent I.V. Push – Same	N/A	96376 (Add-on) Note: Facility only at 30 minutes apart	N/A

Other injection and infusion services:

1. Chemotherapy Administration

Code	Code Description
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g. intrathecal), requiring and including spinal puncture

96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions

The drugs listed in the table below must be billed with the appropriate administration type. Refer to the coordinating injection/infusion section of this policy to assign the appropriate CPT code. This list is not all inclusive and subject to change.

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 Drug Name	Brand Name	HCPCS
Benralizumab	Fasenra	J0517
Canakinumab	Ilaris	J0638
Certolizumab pegol	Cimzia	J0717
Denosumab	Prolia/Xgeva	J0897
Filgrastim (g-csf) excludes biosimilars	Neupogen	J1442**
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110**
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101**
Luspatercept-aamt	Reblozyl	J0896
Mepolizumab	Nucala	J2182
Octreotide	Sandostatin LAR Depot	J2353
Omalizumab	Xolair	J2357
Pegfilgrastim,excludes biosimilar	Neulasta	J2506*
Pegfilgrastim-apgf, biosimilar	Nyvepria (Neulasta)	Q5122
Pegfilgrastim-bmez, biosimilar	Ziextenzo (Neulasta)	Q5120
Pegfilgrastim-cbqv, biosimilar	Udenyca (Neulasta)	Q5111
Pegfilgrastim-jmdb, biosimilar	Fulphila (Neulasta)	Q5108

Rilonacept	Arcalyst	J2793
Tbo-filgrastim	Granix	J1447
Tildrakizumab-asmn	Ilumya	J3245

Note: *Effective January 1, 2018, provider are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

Note: **When billing filgrastim (HCPCS codes J1442, Q5101, or Q5110, append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

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.

Generic Drug Name	Brand Name	HCPCS
Abatacept	Orencia	J0129****
Agalsidase beta	Fabrazyme	J0180
Alglucosidase alfa	Lumizyme	J0221
Alpha 1-proteinase inhibitor (human)	Glassia	J0257
Alpha 1-proteinase inhibitor (human),NOS	Aralast	J0256
Anifrolumab-fnia	Saphnelo	J0491
Belatacept	Nulojix	J0485
Bezlotoxumab	Zinplava	J0565
C1 esterase inhibitor (human)	Berinert	J0597
Eculizumab	Soliris	J1300
Edaravone	Radicava	J1301
Elosulfase alfa	Vimizim	J1322
Filgrastim-(g-csf) excludes biosimilars	Neupogen	J1442***
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110***
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101***
Golimumab	Simponi Aria	J1602
Idursulfase	Elaprase	J1743
Imiglucerase	Cerezyme	J1786
Immune globulin	Cutaquig	J1551
Immune globulin	Bivigam	J1556
Immune globulin	Carimune® NF, Gammagard® S/D	J1566
Immune globulin	Flebogamma	J1572
Immune globulin	Gammagard	J1569

Immune globulin	Gammaplex	J1557
Immune globulin	Gamunex- C	J1561
Immune globulin	Octagam	J1568
Immune globulin	Privigen	J1459
Immune globulin	Asceniv	J1554
Natalizumab	Tysabri	J2323
Octreotide	Sandostatin	J2354**
Remdesivir	Veklury	J0248
Reslizumab	Cinqair	J2786
Tocilizumab	Actemra	J3262
Ustekinumab	Stelara	J3358*
Vedolizumab	Entyvio	J3380
Velaglucerase alfa	Vpriv	J3385

Note: *Effective September 23, 2016, IV ustekinumab (Stelara®) should be billed with HCPCS code J3590 (OPPS: C9399 for dates of service [DOS] before 4/01/2017; C9487 for DOS from 4/01/2017 to 6/30/2017, Q9989 for DOS from 7/01/2017-12/31/2017 and J3358 for DOS 1/01/2018 and after) for the initial IV dose of Stelara® when used for Crohn's disease and Ulcerative Colitis. Each subsequent subcutaneous dose **must** be billed with J3357. This IV formulation is now FDA approved for Crohn's disease and Ulcerative Colitis. 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.

Note: ** When billing octreotide acetate (HCPCS code J2354), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Note: *** When billing filgrastim (HCPCS codes J1442, Q5101, Q5110), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

Note: **** When billing abatacept (HCPCS code J0129), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Documentation Requirements:

1. Documentation is for the correct beneficiary and date of service.
2. Documentation is complete, legible, signed and dated by the Physician or Clinician.
3. Documentation includes Physician's order for date(s) of service when medication(s) were administered, to include the medication name, dosage, frequency and method of administration.

4. Medication Administration Record for dates of service include the medication name, dosage, method of administration, and start/stop times for infusions (when applicable).
5. Documentation to support the amount of drugs or biologicals discarded (single use packaging) for the relevant beneficiary (when applicable).
6. Medical necessity supported by the medical record (e.g. office/progress notes, history and physical, laboratory test results, etc.)
7. Documentation for the procedures, operative reports and anesthesia reports (when applicable).
8. If billing incident to services, the documentation supports appropriate supervision (billing physician is present in the office suite during the performance of procedure).
9. Documentation meets criteria specified in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).
10. Evidence an Advanced Beneficiary Notice of Non-coverage (ABN) was provided to the beneficiary, if applicable.

RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information.

- I-6: Approved Drugs and Biologicals
- I-9: Treatment of Gaucher Disease
- I-14: Immune Globulin Therapy
- I-24: Belatacept (Nulojix)
- I-27: Certolizumab (Cimzia)
- I-30: Denosumab (Prolia, Xgeva)
- I-31: Tocilizumab (Actemra)
- I-35: Golimumab (Simponi, Simponi Aria)
- I-37: Ustekinumab (Stelara)
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme)
- I-58: Alglucosidase alfa (Lumizyme)
- I-85: Natalizumab (Tysabri)
- I-88: Granulocyte Colony-Stimulating Factors
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha 1-Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Complement Inhibitors
- I-138: Elosulfase alfa (Vimizim)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-151: Site of Care

- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-210: IL-1 and IL-1b Blockers
- I-214: Luspatercept (Reblozyl)
- I-245: Anifrolumab-fnia (Saphnelo)
- G-16: Chemotherapy Services

Refer to the following Medicare Advantage Medical Policies for additional information:

- I-20: Denosumab (Prolia, Xgeva)
- I-27: Octreotide Acetate for Injectable Suspension (Sandostain® LAR Depot) (WV only)
- I-51: Self-Administered Drug Exclusion List
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme) (WV only)
- I-56: Granulocyte Colony-Stimulating Factors
- I-68: Treatment of Gaucher Disease
- I-85: Natalizumab (Tysabri)
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-98: Immunosuppressive Drugs
- I-103: Intravenous Immune Globulin
- I-105: Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (PA only)
- I-105: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (DE only)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha-1 Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Compliment Inhibitors
- I-132: Agalsidase beta (Fabrazyme)
- I-134: Alglucosidase alfa (Lumizyme) and Avalglucosidase alfa-ngpt (Nexviazyme)
- I-138: Elosulfase alfa (Vimizim)
- I-139: Ustekinumab (Stelara)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin) and Lanreotide (Somatuline Depot)
- I-184: Certolizumab (Cimzia)
- I-194: Tocilizumab (Actemra)

- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-208: Billing and Coding Chemotherapy (WV only)
- I-210: IL-1 and IL-1b Blockers
- I-218: Golimumab (Simponi, Simponi Aria)
- I-223: Luspatercept (Reblozyl)
- I-252: Anifrolumab-fnia (Saphnelo)
- Y-5: Hydration Therapy (PA & DE only)
- Z-106: Billing and Coding: Complex Drug Administration Coding (WV only)

Refer to the following Reimbursement Policies for additional information:

- RP-003: Drug Wastage and Convenience Kits
- RP-019N: Drugs and Biologicals (This policy is accessible to Network providers only)
- RP-035: Correct Coding Guidelines
- RP-044: Medication Therapy Management

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Highmark Provider Resource Center, Special eBulletin, ATTN: Referring Physicians; Expanded Access to Infused Drug Therapy. Aug.14, 2017. https://content.highmarkprc.com/Files/NewsletterNotices/SpecialBulletins/sb-all-reimbursement-changes-hit-081417.pdf

REFERENCES:

- 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 Non chemotherapy Injections and Infusions, Part D-Chemotherapy Administration https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

- Current version of AMA CPT Manual. *Current Procedure Terminology Manual* (CPT®) is copyright American Medical Association. All rights Reserved. The AMA assumes no liability for the data contained in this policy.

- Social Security Administration, Section 1861(t); Part E. https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

- Novitas Solutions, *Local Coverage Determination (LCD)*; (L34960) Hydration Therapy https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A53049) Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents.
  https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A59073) Billing and Coding: Complex Drug Administration
  Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A58527) Billing and Coding: Complex Drug Administration Coding.
  Article - Billing and Coding: Complex Drug Administration Coding (A58527) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A53778) Billing and Coding: Infusion, Injection and Hydration Services
  Article - Billing and Coding: Infusion, Injection and Hydration Services (A53778) (cms.gov)

- MEDLEARN Publishing Coding Essentials for Infusion & Injection Therapy Services

POLICY UPDATE HISTORY INFORMATION:

1 / 2022	Implementation
4 /2022	Updated direction for some drugs and eliminated the MA and Commercial variance
5 / 2022	Added note for billing drugs with certain codes. Added medical policy cross references
7 / 2022	Added code J1551
10 / 2022	Removed code J0222 and replaced code J3590 with J0491

Highmark Reimbursement Policy Bulletin

HIGHMARK.

HISTORY VERSION

Bulletin Number:	RP- 072		
Subject:	Injection and Infusion Services		
Effective Date:	January 1, 2022	**End Date:**	
Issue Date:	July 1, 2022	**Revised Date:**	July 2022
Date Reviewed:	June 2022		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY** ☐
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY** ☐
Applicable Claim Type	**UB**	☒	**1500**	☒			

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The purpose of this policy is to provide direction on injection and infusion services billed with drugs.

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 of quotation from CPT®)

Per 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 Non chemotherapy 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."

"Chemotherapy administration codes apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers. The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumb, gemtuzumab, and trastuzumab. Drugs commonly considered to fall under the category of hormonal antineoplastics include leuprolide acetate and goserelin acetate. The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes. A/B MACs (B) may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare."

"The administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is not considered chemotherapy administration."

Medicare has determined under Social Security Section 1861(t) which 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.

REIMBURSEMENT GUIDELINES:

The chemotherapy and therapeutic administration guidelines identified in this policy are for individuals **18 years of age and older.** The coding of hydration and administration services along with coding of infusions and injections must follow the coding hierarchy guidelines. ("Infusion Hierarchy")

Follow CPT guidelines and hierarchy rules when coding infusion and injections. The Infusion Hierarchy determines initial service. In the doctor's office (place of service 11), the initial code should be the code which best describes the primary reason for the encounter. In the hospital outpatient clinic (place of service 22), the Infusion Hierarchy determines the initial service. The order in which an infusion service is rendered during a visit does not determine the "initial" service. There is only one initial service coded per vascular access site, per encounter per date.

The Infusion Hierarchy is as follows:

1. Chemotherapy services are primary to Therapeutic, Prophylactic and Diagnostic services

2. Therapeutic, Prophylactic and Diagnostic services are primary to hydration. The order is:
    A. Chemotherapy
    B. Therapeutic, prophylactic and diagnostic services
    C. Hydration

3. Infusions are primary to I.V. pushes, which are primary to injections. The order is:
    A. Infusions
    B. I.V. push
    C. Injection

Note: This Infusion Hierarchy does not apply to subQ/IM injections.

Infusions may be concurrent (i.e., multiple drugs are infused simultaneously through the same line) or sequential (infusion of drugs one after another through the same access site).

Note: I.V. infusion differs from an I.V. push which is defined as an infusion lasting 15 minutes or less.

Infusions Start / Stop Time

Selection of the correct CPT code is dependent upon the start and stop time of infusion services. If "stop time" is not documented, only an I.V. push can be billed. Therefore, it is important to use the following guidance:

1. Infusion services are coded based on the length of the infusion, which is a time-based service.
2. The Start and Stop times of each medication administration must be accurately recorded, as this determines the correct CPT code assignment.
3. The first hour of infusion is weighted heavier than subsequent hours to include preparation time, patient education, and patient assessment prior to and after the infusion.
4. The time calculations for the length of the infusion should stop when the infusion is discontinued and restart at the time the infusion resumes

Time Documented

Time documentation is critical because it drives the assignment and accuracy of the CPT coding of infusion services.

Key Time Ranges

1. 15 minutes or less
    - infusions lasting 15 minutes or less would be coded as an *I.V. push
2. 16 minutes or more
    - infusion can be reported after 16 minutes

***Note**: An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and

interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion.

3. 31 minutes to 1 hour
    - hydration infusion must be at least 31 minutes in length to bill the service
4. 16-90 minutes versus more than 90 minutes
5. 16-90 minutes represents the first hour of infusion services
6. 91 minutes or more represents the subsequent hour of infusion, in intervals greater than 30 minutes beyond 1-hour increments
7. 30 minutes since last reported push

Note: Each additional sequential I.V. push of same drug/substance must not be reported if within 30 minutes of each other.

Services Not Included in the Infusion

Supplies for infusion services are not separately payable and should not be separately billed.

Service Included in Infusion

1. Use of local anesthesia;
2. I.V. access;
3. Access to indwelling I.V., subcutaneous catheter or port;
4. Flush at conclusion of infusion;
5. Standard tubing, syringes and supplies; and
6. Preparation of chemotherapy agent(s)

Types of Infusions

1. Initial and sequential infusions:
    A. Bill an I.V. push for intravenous infusions that last 15 minutes or less
    B. If no stop time is documented an I.V. push is the only service that can be billed, regardless of the length of the infusion
    C. CPT code 96413 - Chemo infusion, 1st hour, initial drug
    D. CPT code 96365 - Non-Chemo infusion, 1st hour, initial drug
    E. Requires a new substance or drug

    Sequential infusions are considered to be an infusion or I.V. push of a new substance following a primary or initial service 16 minutes or more.

    Initial infusions for therapy, prophylaxis, or diagnostic (specify substance or drug) are considered an initial service for 16-90 minutes.

2. Concurrent infusions occurs at the same time as the initial infusion:
    A. Add-on CPT code 96368 is listed separately in addition to code for primary procedure
    B. Report only once per encounter

C. Time does not matter
D. Drugs given at the same time
E. Multiple drugs added to one bag of fluids is not a concurrent infusion; it is one infusion
F. There is no concurrent code for chemotherapy or hydration

3. I.V. push and Additional Hours:
   A. Always secondary to initial infusion code, but always primary to hydration infusion
   B. List each additional sequential I.V. push of a new substance or the same drug separately
   C. Additional pushes of the same drug must be greater than 30 minutes apart
   D. Can never be used alone, must always have a primary infusion/push CPT code
   E. An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion

   Note: An "I.V. push" is considered an injection (or infusion) of a drug of 15 minutes or less.

   Note: "Each Additional Hour" is defined as the same drug, report if more than 31 minutes beyond initial or additional hour.

4. Hydration Infusion

   Assign CPT 96360 – I.V. hydration, initial 31-90 minutes, and CPT 96361 (add on code), used once infusion lasts 91 minutes in length. An intravenous infusion of hydration of 30 minutes or less is not billable. Hydration infusion must be at least 31 minutes in length to bill the service. It is appropriate to charge for hydration provided before and/or after therapeutic infusion, but not the hydration time running at the same time as the therapeutic infusion. Hydration time intervals should be continuous and not added together.

   Note: Codes 96360 and 96361 are intended to report a hydration I.V. infusion to consist of a pre-packaged fluid and electrolytes (eg, normal saline, D5-1/2 normal saline + 30 meq KCL/liter) but are not used to report infusion of drugs or other substances.

<u>Key Considerations</u>

1. Saline solution is a hydration service. Saline solution with electrolytes is still a hydration, but electrolytes administered in a bag minus saline are considered drugs.
2. If there is no stop time documented, then the hydration service is not chargeable.
3. Hydration cannot be reported to Keep Vein Open (KVO), i.e. Heplock flush or saline lock, or to flush a line after drug infusion.
4. Hydration cannot be reported if drugs are mixed with fluids and infused in the same bag/syringe.
5. Hydration cannot be reported if a separate bag of fluid is hung and run concurrently with another drug infusion.
6. Novitas Solutions Local Coverage Determination (LCD) L34960 and Article - Billing and Coding Hydration (A56634) requires a covered diagnosis for hydration coverage.
7. Palmetto Local Coverage Article (LCA) A58527-Billing and Coding: Complex Drug Administration Coding and (LCA) A53778- Billing and Coding: Infusion, Injection and Hydration Services.

8. Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage (LCA) Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

9. Per the AMA CPT Manual, Infusion and Injection services within the CPT code range of 96360-96425 and 96521-96523 are not intended to be reported by the physician in the facility setting. Instead physicians should select the most appropriate E/M service. When an E/M service is performed in addition to the infusion and injection service, modifier -25 must be appended to the E/M service to indicate that the service provided was significant and separately identifiable.

Chemotherapy services include:

1. Chemotherapy initiation of prolonged infusion > 8 hours requiring pump
2. Chemotherapy infusions
3. Chemotherapy injections

Injection and Intravenous Infusion Chemotherapy and Other Complex Drug or Highly Complex Biologic Agent Administration:

Note: Also reference the drug table below.

Code	Code Description	Time
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/ drug	16 minutes up to 1 hour. If over an hour and 30 minutes, also assign 96415 +
96415 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional hour (List separately in addition to code for primary procedure)	Add-on code for >61 minutes (i.e., the infusion time must be greater than 30 minutes to 1 hour beyond the initial infusion time of 1 hour)
96417 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug) up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	15 minutes or less
96411 (Add-on)	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	15 minutes or less

Non-chemotherapy therapeutic, prophylactic and diagnostic injections, and I.V. infusion services include:

1. Initiation of prolonged infusion greater than 8 hours requiring pump
2. Non-Chemo Infusions
3. Non-Chemo Injections

Therapeutic, Prophylactic and Diagnostic Injections, and Infusion (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration):

Note: Also reference the drug table below.

Code	Code Description	Time
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify initial substance or drug) up to 1 hour`	16 minutes up to 1 hour
96366 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	Add-on code after 31 minutes or >61 minutes
96367 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, use 96366 for additional hour(s) of sequential infusion
96368 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	16 minutes up to 1 hour. Report only once per encounter
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	15 minutes or less
96375 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	15 minutes or less
96376 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)	Report at intervals >30 minutes

Hydration infusion services include:

1. Hydration Infusions

Code	Code Description	Time
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	31 minutes up to 1 hour
96361 (Add-on)	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	Add-on for each additional hour (after 31 minutes)

Summary of infusion services for chemotherapy, non-chemotherapy and hydration:

Type	Chemotherapy and Other Highly Complex Drug or Biologic Agent	Non-chemotherapy (Therapeutic, Prophylactic & Diagnostic Injections/Infusions)	Hydration
Initial Infusion	96413	96365	96360
Each Additional Hour	96415 (Add-on)	96366 (Add-on)	96361 (Add-on)
Subsequent Infusion	96417 (Add-on)	96367 (Add-on)	N/A
Concurrent Infusion	N/A	96368 (Add-on)	N/A
I.V. Push Initial	96409	96374	N/A

Subsequent I.V. Push – New	96411 (Add-on)	96365	N/A
Subsequent I.V. Push – Same	N/A	96376 (Add-on) Note: Facility only at 30 minutes apart	N/A

Other injection and infusion services:

1. Chemotherapy Administration

Code	Code Description
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g. intrathecal), requiring and including spinal puncture
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions

The drugs listed in the table below must be billed with the appropriate administration type. Refer to the coordinating injection/infusion section of this policy to assign the appropriate CPT code. This list is not all inclusive and subject to change.

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 Drug Name	Brand Name	HCPCS
Benralizumab	Fasenra	J0517
Canakinumab	Ilaris	J0638
Certolizumab pegol	Cimzia	J0717
Denosumab	Prolia/Xgeva	J0897

Filgrastim (g-csf) excludes biosimilars	Neupogen	J1442**
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110**
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101**
Luspatercept-aamt	Reblozyl	J0896
Mepolizumab	Nucala	J2182
Octreotide	Sandostatin LAR Depot	J2353
Omalizumab	Xolair	J2357
Pegfilgrastim,excludes biosimilar	Neulasta	J2506*
Pegfilgrastim-apgf, biosimilar	Nyvepria (Neulasta)	Q5122
Pegfilgrastim-bmez, biosimilar	Ziextenzo (Neulasta)	Q5120
Pegfilgrastim-cbqv, biosimilar	Udenyca (Neulasta)	Q5111
Pegfilgrastim-jmdb, biosimilar	Fulphila (Neulasta)	Q5108
Rilonacept	Arcalyst	J2793
Tbo-filgrastim	Granix	J1447
Tildrakizumab-asmn	Ilumya	J3245

Note: *Effective January 1, 2018, provider are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

Note: **When billing filgrastim (HCPCS codes J1442, Q5101, or Q5110, append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

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.

Generic Drug Name	Brand Name	HCPCS
Abatacept	Orencia	J0129****
Agalsidase beta	Fabrazyme	J0180
Alglucosidase alfa	Lumizyme	J0221
Alpha 1-proteinase inhibitor (human)	Glassia	J0257
Alpha 1-proteinase inhibitor (human),NOS	Aralast	J0256
Anifrolumab-fnia	Saphnelo	J3590
Belatacept	Nulojix	J0485
Bezlotoxumab	Zinplava	J0565
C1 esterase inhibitor (human)	Berinert	J0597
Eculizumab	Soliris	J1300
Edaravone	Radicava	J1301
Elosulfase alfa	Vimizim	J1322

Filgrastim-(g-csf) excludes biosimilars	Neupogen	J1442***
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110***
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101***
Golimumab	Simponi Aria	J1602
Idursulfase	Elaprase	J1743
Imiglucerase	Cerezyme	J1786
Immune globulin	Cutaquig	J1551
Immune globulin	Bivigam	J1556
Immune globulin	Carimune® NF, Gammagard® S/D	J1566
Immune globulin	Flebogamma	J1572
Immune globulin	Gammagard	J1569
Immune globulin	Gammaplex	J1557
Immune globulin	Gamunex- C	J1561
Immune globulin	Octagam	J1568
Immune globulin	Privigen	J1459
Immune globulin	Asceniv	J1554
Natalizumab	Tysabri	J2323
Octreotide	Sandostatin	J2354**
Patisiran	Onpratto	J0222
Remdesivir	Veklury	J0248
Reslizumab	Cinqair	J2786
Tocilizumab	Actemra	J3262
Ustekinumab	Stelara	J3358*
Vedolizumab	Entyvio	J3380
Velaglucerase alfa	Vpriv	J3385

Note: *Effective September 23, 2016, IV ustekinumab (Stelara®) should be billed with HCPCS code J3590 (OPPS: C9399 for dates of service [DOS] before 4/01/2017; C9487 for DOS from 4/01/2017 to 6/30/2017, Q9989 for DOS from 7/01/2017-12/31/2017 and J3358 for DOS 1/01/2018 and after) for the initial IV dose of Stelara® when used for Crohn's disease and Ulcerative Colitis. Each subsequent subcutaneous dose **must** be billed with J3357. This IV formulation is now FDA approved for Crohn's disease and Ulcerative Colitis. 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.

Note: ** When billing octreotide acetate (HCPCS code J2354), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Note: *** When billing filgrastim (HCPCS codes J1442, Q5101, Q5110), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

Note: **** When billing abatacept (HCPCS code J0129), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Documentation Requirements:

1. Documentation is for the correct beneficiary and date of service.
2. Documentation is complete, legible, signed and dated by the Physician or Clinician.
3. Documentation includes Physician's order for date(s) of service when medication(s) were administered, to include the medication name, dosage, frequency and method of administration.
4. Medication Administration Record for dates of service include the medication name, dosage, method of administration, and start/stop times for infusions (when applicable).
5. Documentation to support the amount of drugs or biologicals discarded (single use packaging) for the relevant beneficiary (when applicable).
6. Medical necessity supported by the medical record (e.g. office/progress notes, history and physical, laboratory test results, etc.)
7. Documentation for the procedures, operative reports and anesthesia reports (when applicable).
8. If billing incident to services, the documentation supports appropriate supervision (billing physician is present in the office suite during the performance of procedure).
9. Documentation meets criteria specified in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).
10. Evidence an Advanced Beneficiary Notice of Non-coverage (ABN) was provided to the beneficiary, if applicable.

RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-6: Approved Drugs and Biologicals
- I-9: Treatment of Gaucher Disease
- I-14: Immune Globulin Therapy
- I-24: Belatacept (Nulojix)
- I-27: Certolizumab (Cimzia)
- I-30: Denosumab (Prolia, Xgeva)
- I-31: Tocilizumab (Actemra)
- I-35: Golimumab (Simponi, Simponi Aria)
- I-37: Ustekinumab (Stelara)
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme)
- I-58: Alglucosidase alfa (Lumizyme)
- I-85: Natalizumab (Tysabri)
- I-88: Granulocyte Colony-Stimulating Factors

- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha 1-Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Complement Inhibitors
- I-138: Elosulfase alfa (Vimizim)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-151: Site of Care
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-210: IL-1 and IL-1b Blockers
- I-214: Luspatercept (Reblozyl)
- I-245: Anifrolumab-fnia (Saphnelo)
- G-16: Chemotherapy Services

Refer to the following Medicare Advantage Medical Policies for additional information:

- I-20: Denosumab (Prolia, Xgeva)
- I-27: Octreotide Acetate for Injectable Suspension (Sandostain® LAR Depot) (WV only)
- I-51: Self-Administered Drug Exclusion List
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme) (WV only)
- I-56: Granulocyte Colony-Stimulating Factors
- I-68: Treatment of Gaucher Disease
- I-85: Natalizumab (Tysabri)
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-98: Immunosuppressive Drugs
- I-103: Intravenous Immune Globulin
- I-105: Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (PA only)
- I-105: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (DE only)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha-1 Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Compliment Inhibitors
- I-132: Agalsidase beta (Fabrazyme)

- I-134: Alglucosidase alfa (Lumizyme) and Avalglucosidase alfa-ngpt (Nexviazyme)
- I-138: Elosulfase alfa (Vimizim)
- I-139: Ustekinumab (Stelara)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin) and Lanreotide (Somatuline Depot)
- I-184: Certolizumab (Cimzia)
- I-194: Tocilizumab (Actemra)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-208: Billing and Coding Chemotherapy (WV only)
- I-210: IL-1 and IL-1b Blockers
- I-218: Golimumab (Simponi, Simponi Aria)
- I-223: Luspatercept (Reblozyl)
- I-252: Anifrolumab-fnia (Saphnelo)
- Y-5: Hydration Therapy (PA & DE only)
- Z-106: Billing and Coding: Complex Drug Administration Coding (WV only)

Refer to the following Reimbursement Policies for additional information:

- RP-003: Drug Wastage and Convenience Kits
- RP-019N: Drugs and Biologicals (This policy is accessible to Network providers only)
- RP-035: Correct Coding Guidelines
- RP-044: Medication Therapy Management

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Highmark Provider Resource Center, Special eBulletin, ATTN: Referring Physicians; Expanded Access to Infused Drug Therapy. Aug.14, 2017. https://content.highmarkprc.com/Files/NewsletterNotices/SpecialBulletins/sb-all-reimbursement-changes-hit-081417.pdf

REFERENCES:

- 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 Non chemotherapy Injections and Infusions, Part D-Chemotherapy Administration https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

- Current version of AMA CPT Manual. *Current Procedure Terminology Manual* (CPT®) is copyright American Medical Association. All rights Reserved. The AMA assumes no liability for the data contained in this policy.

- Social Security Administration, Section 1861(t); Part E. https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

- Novitas Solutions, *Local Coverage Determination (LCD)*; (L34960) Hydration Therapy https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A53049) Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents. https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A59073) Billing and Coding: Complex Drug Administration Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A58527) Billing and Coding: Complex Drug Administration Coding. Article - Billing and Coding: Complex Drug Administration Coding (A58527) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A53778) Billing and Coding: Infusion, Injection and Hydration Services Article - Billing and Coding: Infusion, Injection and Hydration Services (A53778) (cms.gov)

- MEDLEARN Publishing Coding Essentials for Infusion & Injection Therapy Services

POLICY UPDATE HISTORY INFORMATION:

1 / 2022	Implementation
4 /2022	Updated direction for some drugs and eliminated the MA and Commercial variance
5 / 2022	Added note for billing drugs with certain codes. Added medical policy cross references.
7 / 2022	Added code J1551

Highmark Reimbursement Policy Bulletin

HIGHMARK.

HISTORY VERSION

Bulletin Number:	RP- 072		
Subject:	Injection and Infusion Services		
Effective Date:	January 1, 2022	**End Date:**	
Issue Date:	May 30, 2022	**Revised Date:**	May 2022
Date Reviewed:	May 2022		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY** ☐
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY** ☐
Applicable Claim Type	**UB**	☒	**1500**	☒			

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The purpose of this policy is to provide direction on injection and infusion services billed with drugs.

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 of quotation from CPT®)

Per 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 Non chemotherapy 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."

"Chemotherapy administration codes apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers. The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumb, gemtuzumab, and trastuzumab. Drugs commonly considered to fall under the category of hormonal antineoplastics include leuprolide acetate and goserelin acetate. The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes. A/B MACs (B) may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare."

"The administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is not considered chemotherapy administration."

Medicare has determined under Social Security Section 1861(t) which 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.

REIMBURSEMENT GUIDELINES:

The chemotherapy and therapeutic administration guidelines identified in this policy are for individuals **18 years of age and older.** The coding of hydration and administration services along with coding of infusions and injections must follow the coding hierarchy guidelines. ("Infusion Hierarchy")

Follow CPT guidelines and hierarchy rules when coding infusion and injections. The Infusion Hierarchy determines initial service. In the doctor's office (place of service 11), the initial code should be the code which best describes the primary reason for the encounter. In the hospital outpatient clinic (place of service 22), the Infusion Hierarchy determines the initial service. The order in which an infusion service is rendered during a visit does not determine the "initial" service. There is only one initial service coded per vascular access site, per encounter per date.

The Infusion Hierarchy is as follows:

1. Chemotherapy services are primary to Therapeutic, Prophylactic and Diagnostic services

2. Therapeutic, Prophylactic and Diagnostic services are primary to hydration. The order is:
    A. Chemotherapy
    B. Therapeutic, prophylactic and diagnostic services
    C. Hydration

3. Infusions are primary to I.V. pushes, which are primary to injections. The order is:
    A. Infusions
    B. I.V. push
    C. Injection

Note: This Infusion Hierarchy does not apply to subQ/IM injections.

Infusions may be concurrent (i.e., multiple drugs are infused simultaneously through the same line) or sequential (infusion of drugs one after another through the same access site).

Note: I.V. infusion differs from an I.V. push which is defined as an infusion lasting 15 minutes or less.

Infusions Start / Stop Time

Selection of the correct CPT code is dependent upon the start and stop time of infusion services. If "stop time" is not documented, only an I.V. push can be billed. Therefore, it is important to use the following guidance:

1. Infusion services are coded based on the length of the infusion, which is a time-based service.
2. The Start and Stop times of each medication administration must be accurately recorded, as this determines the correct CPT code assignment.
3. The first hour of infusion is weighted heavier than subsequent hours to include preparation time, patient education, and patient assessment prior to and after the infusion.
4. The time calculations for the length of the infusion should stop when the infusion is discontinued and restart at the time the infusion resumes

Time Documented

Time documentation is critical because it drives the assignment and accuracy of the CPT coding of infusion services.

Key Time Ranges

1. 15 minutes or less
    - infusions lasting 15 minutes or less would be coded as an *I.V. push
2. 16 minutes or more
    - infusion can be reported after 16 minutes

***Note**: An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and

interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion.

3. 31 minutes to 1 hour
    - hydration infusion must be at least 31 minutes in length to bill the service
4. 16-90 minutes versus more than 90 minutes
5. 16-90 minutes represents the first hour of infusion services
6. 91 minutes or more represents the subsequent hour of infusion, in intervals greater than 30 minutes beyond 1-hour increments
7. 30 minutes since last reported push

Note: Each additional sequential I.V. push of same drug/substance must not be reported if within 30 minutes of each other.

Services Not Included in the Infusion

Supplies for infusion services are not separately payable and should not be separately billed.

Service Included in Infusion

1. Use of local anesthesia;
2. I.V. access;
3. Access to indwelling I.V., subcutaneous catheter or port;
4. Flush at conclusion of infusion;
5. Standard tubing, syringes and supplies; and
6. Preparation of chemotherapy agent(s)

Types of Infusions

1. Initial and sequential infusions:
    A. Bill an I.V. push for intravenous infusions that last 15 minutes or less
    B. If no stop time is documented an I.V. push is the only service that can be billed, regardless of the length of the infusion
    C. CPT code 96413 - Chemo infusion, 1st hour, initial drug
    D. CPT code 96365 - Non-Chemo infusion, 1st hour, initial drug
    E. Requires a new substance or drug

    Sequential infusions are considered to be an infusion or I.V. push of a new substance following a primary or initial service 16 minutes or more.

    Initial infusions for therapy, prophylaxis, or diagnostic (specify substance or drug) are considered an initial service for 16-90 minutes.

2. Concurrent infusions occurs at the same time as the initial infusion:
    A. Add-on CPT code 96368 is listed separately in addition to code for primary procedure
    B. Report only once per encounter

C. Time does not matter
D. Drugs given at the same time
E. Multiple drugs added to one bag of fluids is not a concurrent infusion; it is one infusion
F. There is no concurrent code for chemotherapy or hydration

3. I.V. push and Additional Hours:
   A. Always secondary to initial infusion code, but always primary to hydration infusion
   B. List each additional sequential I.V. push of a new substance or the same drug separately
   C. Additional pushes of the same drug must be greater than 30 minutes apart
   D. Can never be used alone, must always have a primary infusion/push CPT code
   E. An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion

   An "I.V. push" is considered an injection (or infusion) of a drug of 15 minutes or less.

   "Each Additional Hour" is defined as the same drug, report if more than 31 minutes beyond initial or additional hour.

4. Hydration Infusion

   Assign CPT 96360 – I.V. hydration, initial 31-90 minutes, and CPT 96361 (add on code), used once infusion lasts 91 minutes in length. An intravenous infusion of hydration of 30 minutes or less is not billable. Hydration infusion must be at least 31 minutes in length to bill the service. It is appropriate to charge for hydration provided before and/or after therapeutic infusion, but not the hydration time running at the same time as the therapeutic infusion. Hydration time intervals should be continuous and not added together.

   Note: Codes 96360 and 96361 are intended to report a hydration I.V. infusion to consist of a pre-packaged fluid and electrolytes (eg, normal saline, D5-1/2 normal saline + 30 meq KCL/liter) but are not used to report infusion of drugs or other substances.

<u>Key Considerations</u>

1. Saline solution is a hydration service. Saline solution with electrolytes is still a hydration, but electrolytes administered in a bag minus saline are considered drugs.
2. If there is no stop time documented, then the hydration service is not chargeable.
3. Hydration cannot be reported to Keep Vein Open (KVO), i.e. Heplock flush or saline lock, or to flush a line after drug infusion.
4. Hydration cannot be reported if drugs are mixed with fluids and infused in the same bag/syringe.
5. Hydration cannot be reported if a separate bag of fluid is hung and run concurrently with another drug infusion.
6. Novitas Solutions Local Coverage Determination (LCD) L34960 and Article - Billing and Coding Hydration (A56634) requires a covered diagnosis for hydration coverage.

7. Palmetto Local Coverage Article (LCA) A58527-Billing and Coding: Complex Drug Administration Coding and (LCA) A53778- Billing and Coding: Infusion, Injection and Hydration Services.

8. Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage (LCA) Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

9. Per the AMA CPT Manual, Infusion and Injection services within the CPT code range of 96360-96425 and 96521-96523 are not intended to be reported by the physician in the facility setting. Instead physicians should select the most appropriate E/M service. When an E/M service is performed in addition to the infusion and injection service, modifier -25 must be appended to the E/M service to indicate that the service provided was significant and separately identifiable.

Chemotherapy services include:

1. Chemotherapy initiation of prolonged infusion > 8 hours requiring pump
2. Chemotherapy infusions
3. Chemotherapy injections

Injection and Intravenous Infusion Chemotherapy and Other Complex Drug or Highly Complex Biologic Agent Administration:

Note: Also reference the drug table below.

Code	Code Description	Time
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/ drug	16 minutes up to 1 hour. If over an hour and 30 minutes, also assign 96415 +
96415 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional hour (List separately in addition to code for primary procedure)	Add-on code for >61 minutes (i.e., the infusion time must be greater than 30 minutes to 1 hour beyond the initial infusion time of 1 hour)
96417 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug) up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	15 minutes or less
96411 (Add-on)	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	15 minutes or less

Non-chemotherapy therapeutic, prophylactic and diagnostic injections, and I.V. infusion services include:

1. Initiation of prolonged infusion greater than 8 hours requiring pump
2. Non-Chemo Infusions
3. Non-Chemo Injections

Therapeutic, Prophylactic and Diagnostic Injections, and Infusion (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration):

Note: Also reference the drug table below.

Code	Code Description	Time
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify initial substance or drug) up to 1 hour`	16 minutes up to 1 hour
96366 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	Add-on code after 31 minutes or >61 minutes
96367 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, use 96366 for additional hour(s) of sequential infusion
96368 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, Report only once per encounter
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	15 minutes or less
96375 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	15 minutes or less
96376 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)	Report at intervals >30 minutes

Hydration infusion services include:

1. Hydration Infusions

Code	Code Description	Time
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	31 minutes up to 1 hour
96361 (Add-on)	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	Add-on for each additional hour (after 31 minutes)

Summary of infusion services for chemotherapy, non-chemotherapy and hydration:

Type	Chemotherapy and Other Highly Complex Drug or Biologic Agent	Non-chemotherapy (Therapeutic, Prophylactic & Diagnostic Injections/Infusions)	Hydration
Initial Infusion	96413	96365	96360
Each Additional Hour	96415 (Add-on)	96366 (Add-on)	96361 (Add-on)
Subsequent Infusion	96417 (Add-on)	96367 (Add-on)	N/A

Concurrent Infusion	N/A	96368 (Add-on)	N/A
I.V. Push Initial	96409	96374	N/A
Subsequent I.V. Push – New	96411 (Add-on)	96365	N/A
Subsequent I.V. Push – Same	N/A	96376 (Add-on) Note: Facility only at 30 minutes apart	N/A

Other injection and infusion services:

1. Chemotherapy Administration

Code	Code Description
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g. intrathecal), requiring and including spinal puncture
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions

The drugs listed in the table below must be billed with the appropriate administration type. Refer to the coordinating injection/infusion section of this policy to assign the appropriate CPT code. This list is not all inclusive and subject to change.

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 Drug Name	Brand Name	HCPCS
Benralizumab	Fasenra	J0517

Canakinumab	Ilaris	J0638
Certolizumab pegol	Cimzia	J0717
Denosumab	Prolia/Xgeva	J0897
Filgrastim (g-csf) excludes biosimilars	Neupogen	J1442**
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110**
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101**
Luspatercept-aamt	Reblozyl	J0896
Mepolizumab	Nucala	J2182
Octreotide	Sandostatin LAR Depot	J2353
Omalizumab	Xolair	J2357
Pegfilgrastim,excludes biosimilar	Neulasta	J2506*
Pegfilgrastim-apgf, biosimilar	Nyvepria (Neulasta)	Q5122
Pegfilgrastim-bmez, biosimilar	Ziextenzo (Neulasta)	Q5120
Pegfilgrastim-cbqv, biosimilar	Udenyca (Neulasta)	Q5111
Pegfilgrastim-jmdb, biosimilar	Fulphila (Neulasta)	Q5108
Rilonacept	Arcalyst	J2793
Tbo-filgrastim	Granix	J1447
Tildrakizumab-asmn	Ilumya	J3245

Note: *Effective January 1, 2018, provider are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

Note: **When billing filgrastim (HCPCS codes J1442, Q5101, or Q5110, append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

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.

Generic Drug Name	**Brand Name**	**HCPCS**
Abatacept	Orencia	J0129****
Agalsidase beta	Fabrazyme	J0180
Alglucosidase alfa	Lumizyme	J0221
Alpha 1-proteinase inhibitor (human)	Glassia	J0257
Alpha 1-proteinase inhibitor (human),NOS	Aralast	J0256
Anifrolumab-fnia	Saphnelo	J3590
Belatacept	Nulojix	J0485

Bezlotoxumab	Zinplava	J0565
C1 esterase inhibitor (human)	Berinert	J0597
Eculizumab	Soliris	J1300
Edaravone	Radicava	J1301
Elosulfase alfa	Vimizim	J1322
Filgrastim-(g-csf) excludes biosimilars	Neupogen	J1442***
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110***
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101***
Golimumab	Simponi Aria	J1602
Idursulfase	Elaprase	J1743
Imiglucerase	Cerezyme	J1786
Immune globulin	Bivigam	J1556
Immune globulin	Carimune® NF, Gammagard® S/D	J1566
Immune globulin	Flebogamma	J1572
Immune globulin	Gammagard	J1569
Immune globulin	Gammaplex	J1557
Immune globulin	Gamunex- C	J1561
Immune globulin	Octagam	J1568
Immune globulin	Privigen	J1459
Immune globulin	Asceniv	J1554
Natalizumab	Tysabri	J2323
Octreotide	Sandostatin	J2354**
Patisiran	Onpratto	J0222
Remdesivir	Veklury	J0248
Reslizumab	Cinqair	J2786
Tocilizumab	Actemra	J3262
Ustekinumab	Stelara	J3358*
Vedolizumab	Entyvio	J3380
Velaglucerase alfa	Vpriv	J3385

Note: *Effective September 23, 2016, IV ustekinumab (Stelara®) should be billed with HCPCS code J3590 (OPPS: C9399 for dates of service [DOS] before 4/01/2017; C9487 for DOS from 4/01/2017 to 6/30/2017, Q9989 for DOS from 7/01/2017-12/31/2017 and J3358 for DOS 1/01/2018 and after) for the initial IV dose of Stelara® when used for Crohn's disease and Ulcerative Colitis. Each subsequent subcutaneous dose **must** be billed with J3357. This IV formulation is now FDA approved for Crohn's disease and Ulcerative Colitis. 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.

Note: ** When billing octreotide acetate (HCPCS code J2354), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Note: *** When billing filgrastim (HCPCS codes J1442, Q5101, Q5110), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

Note: **** When billing abatacept (HCPCS code J0129), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Documentation Requirements:

1. Documentation is for the correct beneficiary and date of service.
2. Documentation is complete, legible, signed and dated by the Physician or Clinician.
3. Documentation includes Physician's order for date(s) of service when medication(s) were administered, to include the medication name, dosage, frequency and method of administration.
4. Medication Administration Record for dates of service include the medication name, dosage, method of administration, and start/stop times for infusions (when applicable).
5. Documentation to support the amount of drugs or biologicals discarded (single use packaging) for the relevant beneficiary (when applicable).
6. Medical necessity supported by the medical record (e.g. office/progress notes, history and physical, laboratory test results, etc.)
7. Documentation for the procedures, operative reports and anesthesia reports (when applicable).
8. If billing incident to services, the documentation supports appropriate supervision (billing physician is present in the office suite during the performance of procedure).
9. Documentation meets criteria specified in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).
10. Evidence an Advanced Beneficiary Notice of Non-coverage (ABN) was provided to the beneficiary, if applicable.

RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-6: Approved Drugs and Biologicals
- I-9: Treatment of Gaucher Disease
- I-14: Immune Globulin Therapy
- I-24: Belatacept (Nulojix)
- I-27: Certolizumab (Cimzia)
- I-30: Denosumab (Prolia, Xgeva)
- I-31: Tocilizumab (Actemra)

- I-35: Golimumab (Simponi, Simponi Aria)
- I-37: Ustekinumab (Stelara)
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme)
- I-58: Alglucosidase alfa (Lumizyme)
- I-85: Natalizumab (Tysabri)
- I-88: Granulocyte Colony-Stimulating Factors
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha 1-Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Complement Inhibitors
- I-138: Elosulfase alfa (Vimizim)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-151: Site of Care
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-210: IL-1 and IL-1b Blockers
- I-214: Luspatercept (Reblozyl)
- I-245: Anifrolumab-fnia (Saphnelo)
- G-16: Chemotherapy Services

- Refer to the following Medicare Advantage Medical Policies for additional information:

- I-20: Denosumab (Prolia, Xgeva)
- I-27: Octreotide Acetate for Injectable Suspension (Sandostain® LAR Depot) (WV only)
- I-51: Self-Administered Drug Exclusion List
- I-53: Omalizumab (Xolair)
- I-55: Agalsidase beta (Fabrazyme) (WV only)
- I-56: Granulocyte Colony-Stimulating Factors
- I-68: Treatment of Gaucher Disease
- I-85: Natalizumab (Tysabri)
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-98: Immunosuppressive Drugs
- I-103: Intravenous Immune Globulin

- I-105: Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (PA only)
- I-105: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (DE only)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha-1 Proteinase Inhibitors
- I-129: Vedolizumab (Entyvio)
- I-130: Compliment Inhibitors
- I-132: Agalsidase beta (Fabrazyme)
- I-134: Alglucosidase alfa (Lumizyme) and Avalglucosidase alfa-ngpt (Nexviazyme)
- I-138: Elosulfase alfa (Vimizim)
- I-139: Ustekinumab (Stelara)
- I-146: Monoclonal Antibodies for the Treatment of Asthma and Eosinophilic Conditions
- I-165: Bezlotoxumab (Zinplava)
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin) and Lanreotide (Somatuline Depot)
- I-184: Certolizumab (Cimzia)
- I-194: Tocilizumab (Actemra)
- I-199: Tildrakizumab-asmn (Ilumya)
- I-201: Treatment of Hereditary Amyloidosis
- I-208: Billing and Coding Chemotherapy (WV only)
- I-210: IL-1 and IL-1b Blockers
- I-218: Golimumab (Simponi, Simponi Aria)
- I-223: Luspatercept (Reblozyl)
- I-252: Anifrolumab-fnia (Saphnelo)
- Y-5: Hydration Therapy (PA & DE only)
- Z-106: Billing and Coding: Complex Drug Administration Coding (WV only)

Refer to the following Reimbursement Policies for additional information:

- RP-003: Drug Wastage and Convenience Kits
- RP-019N: Drugs and Biologicals (This policy is accessible to Network providers only)
- RP-035: Correct Coding Guidelines
- RP-044: Medication Therapy Management

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Highmark Provider Resource Center, Special eBulletin, ATTN: Referring Physicians; Expanded Access to Infused Drug Therapy. Aug.14, 2017. https://content.highmarkprc.com/Files/NewsletterNotices/SpecialBulletins/sb-all-reimbursement-changes-hit-081417.pdf

REFERENCES:

- 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 Non chemotherapy Injections and Infusions, Part D-Chemotherapy Administration
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

- Current version of AMA CPT Manual. *Current Procedure Terminology Manual* (CPT®) is copyright American Medical Association. All rights Reserved. The AMA assumes no liability for the data contained in this policy.

- Social Security Administration, Section 1861(t); Part E.
https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

- Novitas Solutions, *Local Coverage Determination (LCD)*; (L34960) Hydration Therapy
https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A53049) Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents.
https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A59073) Billing and Coding: Complex Drug Administration
Article - Billing and Coding: Complex Drug Administration Coding (A59073) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A58527) Billing and Coding: Complex Drug Administration Coding.
Article - Billing and Coding: Complex Drug Administration Coding (A58527) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A53778) Billing and Coding: Infusion, Injection and Hydration Services
Article - Billing and Coding: Infusion, Injection and Hydration Services (A53778) (cms.gov)

- MEDLEARN Publishing Coding Essentials for Infusion & Injection Therapy Services

POLICY UPDATE HISTORY INFORMATION:

1 / 2022	Implementation
4 /2022	Updated direction for some drugs and eliminated the MA and Commercial variance
5 / 2022	Added note for billing drugs with certain codes. Added medical policy cross references.

Highmark Reimbursement Policy Bulletin

HIGHMARK.

HISTORY VERSION

Bulletin Number:	RP- 072		
Subject:	Injection and Infusion Services		
Effective Date:	January 1, 2022	**End Date:**	
Issue Date:	April 11, 2022	**Revised Date:**	April 2022
Date Reviewed:	March 2022		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Claim Type	**UB**	☒	**1500**	☒				

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The purpose of this policy is to provide direction on injection and infusion services billed with drugs.

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."

Per 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 Non chemotherapy 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."

"Chemotherapy administration codes apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers. The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumb, gemtuzumab, and trastuzumab. Drugs commonly considered to fall under the category of hormonal antineoplastics include leuprolide acetate and goserelin acetate. The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes. A/B MACs (B) may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare."

"The administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is not considered chemotherapy administration."

Medicare has determined under Social Security Section 1861(t) which 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.

REIMBURSEMENT GUIDELINES:

The chemotherapy and therapeutic administration guidelines identified in this policy are for individuals **18 years of age and older.** The coding of hydration and administration services along with coding of infusions and injections must follow the coding hierarchy guidelines. ("Infusion Hierarchy")

Follow CPT guidelines and hierarchy rules when coding infusion and injections. The Infusion Hierarchy determines initial service. In the doctor's office (place of service 11), the initial code should be the code which best describes the primary reason for the encounter. In the hospital outpatient clinic (place of service 22), the Infusion Hierarchy determines the initial service. The order in which an infusion service is rendered during a visit does not determine the "initial" service. There is only one initial service coded per vascular access site, per encounter per date.

The Infusion Hierarchy is as follows:

1. Chemotherapy services are primary to Therapeutic, Prophylactic and Diagnostic services

2. Therapeutic, Prophylactic and Diagnostic services are primary to hydration. The order is:
    A. Chemotherapy
    B. Therapeutic, prophylactic and diagnostic services
    C. Hydration

3. Infusions are primary to I.V. pushes, which are primary to injections. The order is:
    A. Infusions
    B. I.V. push
    C. Injection

Note: This Infusion Hierarchy does not apply to subQ/IM injections.

Infusions may be concurrent (i.e., multiple drugs are infused simultaneously through the same line) or sequential (infusion of drugs one after another through the same access site).

Note: I.V. infusion differs from an I.V. push which is defined as an infusion lasting 15 minutes or less.

Infusions Start / Stop Time

Selection of the correct CPT code is dependent upon the start and stop time of infusion services. If "stop time" is not documented, only an I.V. push can be billed. Therefore, it is important to use the following guidance:

1. Infusion services are coded based on the length of the infusion, which is a time-based service.
2. The Start and Stop times of each medication administration must be accurately recorded, as this determines the correct CPT code assignment.
3. The first hour of infusion is weighted heavier than subsequent hours to include preparation time, patient education, and patient assessment prior to and after the infusion.
4. The time calculations for the length of the infusion should stop when the infusion is discontinued and restart at the time the infusion resumes

Time Documented

Time documentation is critical because it drives the assignment and accuracy of the CPT coding of infusion services.

Key Time Ranges

1. 15 minutes or less
    - infusions lasting 15 minutes or less would be coded as an *I.V. push
2. 16 minutes or more
    - infusion can be reported after 16 minutes

***Note**: An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and

interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion.

3. 31 minutes to 1 hour
    - hydration infusion must be at least 31 minutes in length to bill the service
4. 16-90 minutes versus more than 90 minutes
5. 16-90 minutes represents the first hour of infusion services
6. 91 minutes or more represents the subsequent hour of infusion, in intervals greater than 30 minutes beyond 1-hour increments
7. 30 minutes since last reported push

Note: Each additional sequential I.V. push of same drug/substance must not be reported if within 30 minutes of each other.

Services Not Included in the Infusion

Supplies for infusion services are not separately payable and should not be separately billed.

Service Included in Infusion

1. Use of local anesthesia;
2. I.V. access;
3. Access to indwelling I.V., subcutaneous catheter or port;
4. Flush at conclusion of infusion;
5. Standard tubing, syringes and supplies; and
6. Preparation of chemotherapy agent(s)

Types of Infusions

1. Initial and sequential infusions:
    A. Bill an I.V. push for intravenous infusions that last 15 minutes or less
    B. If no stop time is documented an I.V. push is the only service that can be billed, regardless of the length of the infusion
    C. CPT code 96413 - Chemo infusion, 1st hour, initial drug
    D. CPT code 96365 - Non-Chemo infusion, 1st hour, initial drug
    E. Requires a new substance or drug

    Sequential infusions are considered to be an infusion or I.V. push of a new substance following a primary or initial service 16 minutes or more.

    Initial infusions for therapy, prophylaxis, or diagnostic (specify substance or drug) are considered an initial service for 16-90 minutes.

2. Concurrent infusions occurs at the same time as the initial infusion:
    A. Add-on CPT code 96368 is listed separately in addition to code for primary procedure
    B. Report only once per encounter

C. Time does not matter
D. Drugs given at the same time
E. Multiple drugs added to one bag of fluids is not a concurrent infusion; it is one infusion
F. There is no concurrent code for chemotherapy or hydration

3. I.V. push and Additional Hours:
   A. Always secondary to initial infusion code, but always primary to hydration infusion
   B. List each additional sequential I.V. push of a new substance or the same drug separately
   C. Additional pushes of the same drug must be greater than 30 minutes apart
   D. Can never be used alone, must always have a primary infusion/push CPT code
   E. An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion

   An "I.V. push" is considered an injection (or infusion) of a drug of 15 minutes or less.

   "Each Additional Hour" is defined as the same drug, report if more than 31 minutes beyond initial or additional hour.

4. Hydration Infusion

   Assign CPT 96360 – I.V. hydration, initial 31-90 minutes, and CPT 96361 (add on code), used once infusion lasts 91 minutes in length. An intravenous infusion of hydration of 30 minutes or less is not billable. Hydration infusion must be at least 31 minutes in length to bill the service. It is appropriate to charge for hydration provided before and/or after therapeutic infusion, but not the hydration time running at the same time as the therapeutic infusion. Hydration time intervals should be continuous and not added together.

   Note: Codes 96360 and 96361 are intended to report a hydration I.V. infusion to consist of a pre-packaged fluid and electrolytes (eg, normal saline, D5-1/2 normal saline + 30 meq KCL/liter) but are not used to report infusion of drugs or other substances.

<u>Key Considerations</u>

1. Saline solution is a hydration service. Saline solution with electrolytes is still a hydration, but electrolytes administered in a bag minus saline are considered drugs.
2. If there is no stop time documented, then the hydration service is not chargeable.
3. Hydration cannot be reported to Keep Vein Open (KVO), i.e. Heplock flush or saline lock, or to flush a line after drug infusion.
4. Hydration cannot be reported if drugs are mixed with fluids and infused in the same bag/syringe.
5. Hydration cannot be reported if a separate bag of fluid is hung and run concurrently with another drug infusion.
6. Novitas Solutions Local Coverage Determination (LCD) L34960 and Article - Billing and Coding Hydration (A56634) requires a covered diagnosis for hydration coverage.

7. Palmetto Local Coverage Article (LCA) A58527-Billing and Coding: Complex Drug Administration Coding and (LCA) A53778- Billing and Coding: Infusion, Injection and Hydration Services.

8. Per the AMA CPT Manual, Infusion and Injection services within the CPT code range of 96360-96425 and 96521-96523 are not intended to be reported by the physician in the facility setting. Instead physicians should select the most appropriate E/M service. When an E/M service is performed in addition to the infusion and injection service, modifier -25 must be appended to the E/M service to indicate that the service provided was significant and separately identifiable.

Chemotherapy services include:

1. Chemotherapy initiation of prolonged infusion > 8 hours requiring pump
2. Chemotherapy infusions
3. Chemotherapy injections

Injection and Intravenous Infusion Chemotherapy and Other Complex Drug or Highly Complex Biologic Agent Administration:

Note: Also reference the drug table below.

Code	Code Description	Time
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/ drug	16 minutes up to 1 hour. If over an hour and 30 minutes, also assign 96415 +
96415 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional hour (List separately in addition to code for primary procedure)	Add-on code for >61 minutes (i.e., the infusion time must be greater than 30 minutes to 1 hour beyond the initial infusion time of 1 hour)
96417 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug) up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	15 minutes or less
96411 (Add-on)	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	15 minutes or less

Non-chemotherapy therapeutic, prophylactic and diagnostic injections, and I.V. infusion services include:

1. Initiation of prolonged infusion greater than 8 hours requiring pump
2. Non-Chemo Infusions
3. Non-Chemo Injections

Therapeutic, Prophylactic and Diagnostic Injections, and Infusion (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration):

Note: Also reference the drug table below.

Code	Code Description	Time
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify initial substance or drug) up to 1 hour`	16 minutes up to 1 hour
96366 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	Add-on code after 31 minutes or >61 minutes
96367 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, use 96366 for additional hour(s) of sequential infusion
96368 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, Report only once per encounter
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	15 minutes or less
96375 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	15 minutes or less
96376 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)	Report at intervals >30 minutes

Hydration infusion services include:

1. Hydration Infusions

Code	Code Description	Time
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	31 minutes up to 1 hour
96361 (Add-on)	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	Add-on for each additional hour (after 31 minutes)

Summary of infusion services for chemotherapy, non-chemotherapy and hydration:

Type	Chemotherapy and Other Highly Complex Drug or Biologic Agent	Non-chemotherapy (Therapeutic, Prophylactic & Diagnostic Injections/Infusions)	Hydration
Initial Infusion	96413	96365	96360
Each Additional Hour	96415 (Add-on)	96366 (Add-on)	96361 (Add-on)
Subsequent Infusion	96417 (Add-on)	96367 (Add-on)	N/A

Concurrent Infusion	N/A	96368 (Add-on)	N/A
I.V. Push Initial	96409	96374	N/A
Subsequent I.V. Push – New	96411 (Add-on)	96365	N/A
Subsequent I.V. Push – Same	N/A	96376 (Add-on) Note: Facility only at 30 minutes apart	N/A

Other injection and infusion services:

1. Chemotherapy Administration

Code	Code Description
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g. intrathecal), requiring and including spinal puncture
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions

The drugs listed in the table below must be billed with the appropriate administration type. Refer to the coordinating injection/infusion section of this policy to assign the appropriate CPT code. This list is not all inclusive and subject to change.

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 Drug Name	Brand Name	HCPCS
Canakinumab	Ilaris	J0638
Filgrastim	Neupogen	J1442**

Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110**
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101**
Luspatercept	Reblozyl	J0896
Octreotide	Sandostatin Depot	J2353
Pegfilgrastim	Neulasta	J2506
Pegfilgrastim-apgf, biosimilar	Nyvepria (Neulasta)	Q5122
Pegfilgrastim-bmez, biosimilar	Ziextenzo (Neulasta)	Q5120
Pegfilgrastim-cbqv, biosimilar	Udenyca (Neulasta)	Q5111
Pegfilgrastim-jmdb, biosimilar	Fulphila (Neulasta)	Q5108
Rilonacept	Arcalyst	J2793
Tbo-filgrastim	Granix	J1447

Note: **When billing filgrastim (HCPCS codes J1442, Q5101, or Q5110, append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

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.

Generic Drug Name	**Brand Name**	**HCPCS**
Abatacept	Orencia	J0129****
Agalsidase beta	Fabrazyme	J0180
Alglucosidase alfa	Lumizyme	J0221
Alpha 1-proteinase inhibitor (human)	Glassia	J0257
Alpha 1-proteinase inhibitor (human),NOS	Aralast	J0256
Belatacept	Nulojix	J0485
C1 esterase inhibitor (human)	Berinert	J0597
Edaravone	Radicava	J1301
Elosulfase alfa	Vimizim	J1322
Filgrastim	Neupogen	J1442***
Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110***
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101***
Idursulfase	Elaprase	J1743
Imiglucerase	Cerezyme	J1786
Immune globulin	Bivigam	J1556
Immune globulin	Carimune® NF, Gammagard® S/D	J1566
Immune globulin	Flebogamma	J1572
Immune globulin	Gammagard	J1569
Immune globulin	Gammaplex	J1557
Immune globulin	Gamunex- C	J1561

Immune globulin	Octagam	J1568
Immune globulin	Privigen	J1459
Immune globulin	Asceniv	J1554
Octreotide	Sandostatin	J2354**
Patisiran	Onpratto	J0222
Tocilizumab	Actemra	J3262
Velaglucerase alfa	Vpriv	J3385

Note: ** When billing octreotide acetate (HCPCS code J2354), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Note: *** When billing filgrastim (HCPCS codes J1442, Q5101, Q5110), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation.

Note: **** When billing abatacept (HCPCS code J0129), append the JA modifier for the IV formulation or the JB modifier for the subcutaneous formulation. The subcutaneous (SQ) form is on the Self-Administered Drug Exclusion List (SAD List).

Note: Effective January 1, 2018, provider are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

Documentation Requirements:

1. Documentation is for the correct beneficiary and date of service.
2. Documentation is complete, legible, signed and dated by the Physician or Clinician.
3. Documentation includes Physician's order for date(s) of service when medication(s) were administered, to include the medication name, dosage, frequency and method of administration.
4. Medication Administration Record for dates of service include the medication name, dosage, method of administration, and start/stop times for infusions (when applicable).
5. Documentation to support the amount of drugs or biologicals discarded (single use packaging) for the relevant beneficiary (when applicable).
6. Medical necessity supported by the medical record (e.g. office/progress notes, history and physical, laboratory test results, etc.)
7. Documentation for the procedures, operative reports and anesthesia reports (when applicable).
8. If billing incident to services, the documentation supports appropriate supervision (billing physician is present in the office suite during the performance of procedure).
9. Documentation meets criteria specified in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).
10. Evidence an Advanced Beneficiary Notice of Non-coverage (ABN) was provided to the beneficiary, if applicable.

RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-9: Treatment of Gaucher Disease
- I-14: Immune Globulin Therapy
- I-24: Belatacept (Nulojix)
- I-31: Tocilizumab (Actemra)
- I-51: Self-Administered Drug Exclusion List
- I-55: Agalsidase beta (Fabrazyme)
- I-58: Alglucosidase alfa (Lumizyme)
- I-88: Granulocyte Colony-Stimulating Factors
- I-90: Abatacept (Orencia)
- I-93: Idursulfase (Elaprase)
- I-122: Treatment of Hereditary Angioedema (HAE)
- I-126: Alpha 1-Proteinase Inhibitors
- I-138: Elosulfase alfa (Vimizim)
- I-151: Site of Care
- I-173: Edaravone (Radicava)
- I-175: Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
- I-210: IL-1 and IL-1b Blockers
- I-214: Luspatercept (Reblozyl)
- G-16: Chemotherapy Services

Refer to the following Reimbursement Policies for additional information:

- RP-003: Drug Wastage and Convenience Kits
- RP-019N: Drugs and Biologicals (This policy is accessible to Network providers only)
- RP-035: Correct Coding Guidelines
- RP-044: Medication Therapy Management

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Highmark Provider Resource Center, Special eBulletin, ATTN: Referring Physicians; Expanded Access to Infused Drug Therapy. Aug.14, 2017. https://content.highmarkprc.com/Files/NewsletterNotices/SpecialBulletins/sb-all-reimbursement-changes-hit-081417.pdf

REFERENCES:

- 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 Non chemotherapy Injections and Infusions, Part D-Chemotherapy Administration https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

- Current version of AMA CPT Manual. *Current Procedure Terminology Manual* (CPT®) is copyright American Medical Association. All rights Reserved. The AMA assumes no liability for the data contained in this policy.

- Social Security Administration, Section 1861(t); Part E. https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

- Novitas Solutions, *Local Coverage Determination (LCD)*; (L34960) Hydration Therapy https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)and Article updates*; Local Coverage Article (LCA) (A53049) Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents. https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Palmetto, Local Coverage Article (LCA) (A58527) Billing and Coding: Complex Drug Administration Coding. Article - Billing and Coding: Complex Drug Administration Coding (A58527) (cms.gov)

- Palmetto, Local Coverage Article (LCA) (A53778) Billing and Coding: Infusion, Injection and Hydration Services Article - Billing and Coding: Infusion, Injection and Hydration Services (A53778) (cms.gov)

- MEDLEARN Publishing Coding Essentials for Infusion & Injection Therapy Services

POLICY UPDATE HISTORY INFORMATION:

1 / 2022	Implementation
4 /2022	Updated direction for some drugs and eliminated the MA and Commercial variance

Highmark Reimbursement Policy Bulletin

Bulletin Number:	RP- 072		
Subject:	Injection and Infusion Services		
Effective Date:	January 1, 2022	**End Date:**	
Issue Date:	October 1, 2021	**Revised Date:**	
Date Reviewed:			
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☐
Applicable Claim Type	**UB**	☒	**1500**	☒				

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The purpose of this policy is to provide direction on injection and infusion services billed with drugs.

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."

Per 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 Non chemotherapy 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."

"Chemotherapy administration codes apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers. The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumb, gemtuzumab, and trastuzumab. Drugs commonly considered to fall under the category of hormonal antineoplastics include leuprolide acetate and goserelin acetate. The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes. A/B MACs (B) may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare."

"The administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is not considered chemotherapy administration."

Medicare has determined under Social Security Section 1861(t) which 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.

REIMBURSEMENT GUIDELINES:

The chemotherapy and therapeutic administration guidelines identified in this policy are for individuals **18 years of age and older.** The coding of hydration and administration services along with coding of infusions and injections must follow the coding hierarchy guidelines. ("Infusion Hierarchy")

Follow CPT guidelines and hierarchy rules when coding infusion and injections. The Infusion Hierarchy determines initial service. In the doctor's office (place of service 11), the initial code should be the code which best describes the primary reason for the encounter. In the hospital outpatient clinic (place of service 22), the Infusion Hierarchy determines the initial service. The order in which an infusion service is rendered during a visit does not determine the "initial" service. There is only one initial service coded per vascular access site, per encounter per date.

The Infusion Hierarchy is as follows:

1. Chemotherapy services are primary to Therapeutic, Prophylactic and Diagnostic services

2. Therapeutic, Prophylactic and Diagnostic services are primary to hydration. The order is:
    A. Chemotherapy
    B. Therapeutic, prophylactic and diagnostic services
    C. Hydration

3. Infusions are primary to I.V. pushes, which are primary to injections. The order is:
    A. Infusions
    B. I.V. push
    C. Injection

Note: This Infusion Hierarchy does not apply to subQ/IM injections.

Infusions may be concurrent (i.e., multiple drugs are infused simultaneously through the same line) or sequential (infusion of drugs one after another through the same access site).

Note: I.V. infusion differs from an I.V. push which is defined as an infusion lasting 15 minutes or less.

Infusions Start / Stop Time

Selection of the correct CPT code is dependent upon the start and stop time of infusion services. If "stop time" is not documented, only an I.V. push can be billed. Therefore, it is important to use the following guidance:

1. Infusion services are coded based on the length of the infusion, which is a time-based service.
2. The Start and Stop times of each medication administration must be accurately recorded, as this determines the correct CPT code assignment.
3. The first hour of infusion is weighted heavier than subsequent hours to include preparation time, patient education, and patient assessment prior to and after the infusion.
4. The time calculations for the length of the infusion should stop when the infusion is discontinued and restart at the time the infusion resumes

Time Documented

Time documentation is critical because it drives the assignment and accuracy of the CPT coding of infusion services.

Key Time Ranges

1. 15 minutes or less
    - infusions lasting 15 minutes or less would be coded as an *I.V. push
2. 16 minutes or more
    - infusion can be reported after 16 minutes

***Note**: An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and

interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion.

3. 31 minutes to 1 hour
    - hydration infusion must be at least 31 minutes in length to bill the service
4. 16-90 minutes versus more than 90 minutes
5. 16-90 minutes represents the first hour of infusion services
6. 91 minutes or more represents the subsequent hour of infusion, in intervals greater than 30 minutes beyond 1-hour increments
7. 30 minutes since last reported push

Note: Each additional sequential I.V. push of same drug/substance must not be reported if within 30 minutes of each other.

Services Not Included in the Infusion

Supplies for infusion services are not separately payable and should not be separately billed.

Service Included in Infusion

1. Use of local anesthesia;
2. I.V. access;
3. Access to indwelling I.V., subcutaneous catheter or port;
4. Flush at conclusion of infusion;
5. Standard tubing, syringes and supplies; and
6. Preparation of chemotherapy agent(s)

Types of Infusions

1. Initial and sequential infusions:
    A. Bill an I.V. push for intravenous infusions that last 15 minutes or less
    B. If no stop time is documented an I.V. push is the only service that can be billed, regardless of the length of the infusion
    C. CPT code 96413 - Chemo infusion, 1st hour, initial drug
    D. CPT code 96365 - Non-Chemo infusion, 1st hour, initial drug
    E. Requires a new substance or drug

    Sequential infusions are considered to be an infusion or I.V. push of a new substance following a primary or initial service 16 minutes or more.

    Initial infusions for therapy, prophylaxis, or diagnostic (specify substance or drug) are considered an initial service for 16-90 minutes.

2. Concurrent infusions occurs at the same time as the initial infusion:
    A. Add-on CPT code 96368 is listed separately in addition to code for primary procedure
    B. Report only once per encounter

C. Time does not matter
D. Drugs given at the same time
E. Multiple drugs added to one bag of fluids is not a concurrent infusion; it is one infusion
F. There is no concurrent code for chemotherapy or hydration

3. I.V. push and Additional Hours:
   A. Always secondary to initial infusion code, but always primary to hydration infusion
   B. List each additional sequential I.V. push of a new substance or the same drug separately
   C. Additional pushes of the same drug must be greater than 30 minutes apart
   D. Can never be used alone, must always have a primary infusion/push CPT code
   E. An I.V. push is an I.V. push regardless of the time recorded for administration of the drug. Do not confuse the rule for billing an I.V. infusion of less than or equal to 15 minutes as an I.V. push and interpret this to mean that a slow I.V. push of a drug for 16 or more minutes is billable as an intravenous infusion

   An "I.V. push" is considered an injection (or infusion) of a drug of 15 minutes or less.

   "Each Additional Hour" is defined as the same drug, report if more than 31 minutes beyond initial or additional hour.

4. Hydration Infusion

   Assign CPT 96360 – I.V. hydration, initial 31-90 minutes, and CPT 96361 (add on code), used once infusion lasts 91 minutes in length. An intravenous infusion of hydration of 30 minutes or less is not billable. Hydration infusion must be at least 31 minutes in length to bill the service. It is appropriate to charge for hydration provided before and/or after therapeutic infusion, but not the hydration time running at the same time as the therapeutic infusion. Hydration time intervals should be continuous and not added together.

   Note: Codes 96360 and 96361 are intended to report a hydration I.V. infusion to consist of a pre-packaged fluid and electrolytes (eg, normal saline, D5-1/2 normal saline + 30 meq KCL/liter) but are not used to report infusion of drugs or other substances.

<u>Key Considerations</u>

1. Saline solution is a hydration service. Saline solution with electrolytes is still a hydration, but electrolytes administered in a bag minus saline are considered drugs.
2. If there is no stop time documented, then the hydration service is not chargeable.
3. Hydration cannot be reported to Keep Vein Open (KVO), i.e. Heplock flush or saline lock, or to flush a line after drug infusion.
4. Hydration cannot be reported if drugs are mixed with fluids and infused in the same bag/syringe.
5. Hydration cannot be reported if a separate bag of fluid is hung and run concurrently with another drug infusion.
6. Novitas Solutions Local Coverage Determination (LCD) L34960 and Article - Billing and Coding Hydration (A56634) requires a covered diagnosis for hydration coverage.

7. Per the AMA CPT Manual, Infusion and Injection services within the CPT code range of 96360-96425 and 96521-96523 are not intended to be reported by the physician in the facility setting. Instead physicians should select the most appropriate E/M service. When an E/M service is performed in addition to the infusion and injection service, modifier -25 must be appended to the E/M service to indicate that the service provided was significant and separately identifiable.

Chemotherapy services include:

1. Chemotherapy initiation of prolonged infusion > 8 hours requiring pump
2. Chemotherapy infusions
3. Chemotherapy injections

Injection and Intravenous Infusion Chemotherapy and Other Complex Drug or Highly Complex Biologic Agent Administration:

Note: Also reference the drug table below.

Code	Code Description	Time
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/ drug	16 minutes up to 1 hour. If over an hour and 30 minutes, also assign 96415 +
96415 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional hour (List separately in addition to code for primary procedure)	Add-on code for >61 minutes (i.e., the infusion time must be greater than 30 minutes to 1 hour beyond the initial infusion time of 1 hour)
96417 (Add-on)	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug) up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	15 minutes or less
96411 (Add-on)	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	15 minutes or less

Non-chemotherapy therapeutic, prophylactic and diagnostic injections, and I.V. infusion services include:

1. Initiation of prolonged infusion greater than 8 hours requiring pump
2. Non-Chemo Infusions
3. Non-Chemo Injections

Therapeutic, Prophylactic and Diagnostic Injections, and Infusion (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration):

Note: Also reference the drug table below.

Code	Code Description	Time
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify initial substance or drug) up to 1 hour`	16 minutes up to 1 hour

96366 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	Add-on code after 31 minutes or >61 minutes
96367 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, use 96366 for additional hour(s) of sequential infusion
96368 (Add-on)	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)	16 minutes up to 1 hour, Report only once per encounter
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	15 minutes or less
96375 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	15 minutes or less
96376 (Add-on)	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)	Report at intervals >30 minutes

Hydration infusion services include:

1. Hydration Infusions

Code	Code Description	Time
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	31 minutes up to 1 hour
96361 (Add-on)	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	Add-on for each additional hour (after 31 minutes)

Summary of infusion services for chemotherapy, non-chemotherapy and hydration:

Type	Chemotherapy and Other Highly Complex Drug or Biologic Agent	Non-chemotherapy (Therapeutic, Prophylactic & Diagnostic Injections/Infusions)	Hydration
Initial Infusion	96413	96365	96360
Each Additional Hour	96415 (Add-on)	96366 (Add-on)	96361 (Add-on)
Subsequent Infusion	96417 (Add-on)	96367 (Add-on)	N/A
Concurrent Infusion	N/A	96368 (Add-on)	N/A
I.V. Push Initial	96409	96374	N/A

Subsequent I.V. Push – New	96411 (Add-on)	96365	N/A
Subsequent I.V. Push – Same	N/A	96376 (Add-on) Note: Facility only at 30 minutes apart	N/A

Other injection and infusion services:

1. Chemotherapy Administration

Code	Code Description
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter
96450	Chemotherapy administration, into CNS (e.g. intrathecal), requiring and including spinal puncture
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	Chemotherapy administration; intralesional, more than 7 lesions

The drugs listed in the table below must be billed with the appropriate administration type (Chemotherapy or Therapeutic) as identified for Medicare Advantage and Commercial business. Refer to the coordinating injection/infusion section of this policy to assign the appropriate CPT code. This list in not all inclusive and subject to change.

Generic Drug Name	Brand Name	Code	Medicare Advantage Billing	Commercial Billing
Abatacept	Orencia	J0129	Therapeutic	Therapeutic
Agalsidase beta	Fabrazyme	J0180	Chemotherapy	Therapeutic
Alglucosidase alfa	Lumizyme	J0221	Chemotherapy	Therapeutic
Alpha 1-proteinase inhibitor (human)	Glassia	J0257	Chemotherapy	Therapeutic
Alpha 1-proteinase inhibitor (human),NOS	Aralast	J0256	Chemotherapy	Therapeutic
Belatacept	Nulojix	J0485	Therapeutic	Therapeutic
Belimumab	BenLysta	J0490	Chemotherapy	Therapeutic
Benralizumab	Fasenra	J0517	Chemotherapy	Therapeutic
Bezlotoxumab	Zinplava	J0565	Chemotherapy	Therapeutic
C1 esterase inhibitor (human)	Berinert	J0597	Chemotherapy	Therapeutic
Canakinumab	Ilaris	J0638	Chemotherapy	Therapeutic
Certolizumab	Cimzia	J0717	Chemotherapy	Therapeutic
Denosumab	Prolia/Xgeva	J0897	Chemotherapy	Therapeutic
Eculizumab	Solaris	J1300	Chemotherapy	Therapeutic
Edaravone	Radicava	J1301	Therapeutic	Therapeutic
Elosulfase alfa	Vimizim	J1322	Chemotherapy	Therapeutic
Filgrastim	Neupogen	J1442	Therapeutic	Therapeutic
Filgrastim-sndz,biosimilar	Zarxio (Neupogen)	Q5101	Therapeutic	Therapeutic

Filgrastim-aafi, biosimilar	Nivestym (Neupogen)	Q5110	Therapeutic	Therapeutic
Golimumab	Simponi	J1602	Chemotherapy	Therapeutic
Guselkumab	Tremfya	J1628	Chemotherapy	Therapeutic
Idursulfase	Elaprase	J1743	Chemotherapy	Therapeutic
Imiglucerase	Cerezyme	J1786	Chemotherapy	Therapeutic
Immune globulin	Asceniv	J1554	Chemotherapy	Therapeutic
Immune globulin	Bivigam	J1556	Chemotherapy	Therapeutic
Immune globulin	Carimune® NF, Gammagard® S/D	J1566	Chemotherapy	Therapeutic
Immune globulin	Flebogamma	J1572	Chemotherapy	Therapeutic
Immune globulin	Gammagard	J1569	Chemotherapy	Therapeutic
Immune globulin	Gammaplex	J1557	Chemotherapy	Therapeutic
Immune globulin	Gamunex- C	J1561	Chemotherapy	Therapeutic
Immune globulin	Octagam	J1568	Chemotherapy	Therapeutic
Immune globulin	Privigen	J1459	Chemotherapy	Therapeutic
Infliximab	Remicade	J1745	Chemotherapy	Therapeutic
Infliximab-dyyb, biosimilar	Inflectra (Remicade)	Q5103	Chemotherapy	Therapeutic
Infliximab -abda, biosimilar	Renflexis (Remicade)	Q5104	Chemotherapy	Therapeutic
Infliximab-qbtx, biosimilar	Ixifi (Remicade)	Q5109	Chemotherapy	Therapeutic
Infliximab-axxq,biosimilar	Avsola (Remicade)	Q5121	Chemotherapy	Therapeutic
Mepolizumab	Nucala	J2182	Chemotherapy	Therapeutic
Octreotide	Sandostatin	J2354	Therapeutic	Therapeutic
Octreotide	Sandostatin Depot	J2353	Therapeutic	Therapeutic
Patisiran	Onpratto	J0222	Therapeutic	Therapeutic
Pegfilgrastim	Neulasta	J2505	Therapeutic	Therapeutic
Pegfilgrastim-jmdb, biosimilar	Fulphila (Neulasta)	Q5108	Therapeutic	Therapeutic
Pegfilgrastim-cbqv, biosimilar	Udenyca (Neulasta)	Q5111	Therapeutic	Therapeutic
Pegfilgrastim-bmez, biosimilar	Ziextenzo (Neulasta)	Q5120	Therapeutic	Therapeutic
Pegfilgrastim-apgf, biosimilar	Nyvepria (Neulasta)	Q5122	Therapeutic	Therapeutic
Rilonacept	Arcalyst	J2793	Therapeutic	Therapeutic
Tildrakizumab	Ilumya	J3245	Chemotherapy	Therapeutic
Tocilizumab	Actemra	J3262	Chemotherapy	Therapeutic
Ustekinumab	Stelara	J3357	Chemotherapy	Therapeutic
Ustekinumab	Stelara	J3358	Chemotherapy	Therapeutic
Vedolizumab	Entyvio	J3380	Chemotherapy	Therapeutic
Velaglucerase alfa	Vpriv	J3385	Chemotherapy	Therapeutic

Note: Effective January 1, 2018, provider are instructed to use 96377 for the on-body application injector for Neulasta® Onpro Kit.

Documentation Requirements:

1. Documentation is for the correct beneficiary and date of service.
2. Documentation is complete, legible, signed and dated by the Physician or Clinician.

3. Documentation includes Physician's order for date(s) of service when medication(s) were administered, to include the medication name, dosage, frequency and method of administration.
4. Medication Administration Record for dates of service include the medication name, dosage, method of administration, and start/stop times for infusions (when applicable).
5. Documentation to support the amount of drugs or biologicals discarded (single use packaging) for the relevant beneficiary (when applicable).
6. Medical necessity supported by the medical record (e.g. office/progress notes, history and physical, laboratory test results, etc.)
7. Documentation for the procedures, operative reports and anesthesia reports (when applicable).
8. If billing incident to services, the documentation supports appropriate supervision (billing physician is present in the office suite during the performance of procedure).
9. Documentation meets criteria specified in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).
10. Evidence an Advanced Beneficiary Notice of Non-coverage (ABN) was provided to the beneficiary, if applicable.

RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-90: Abatacept (Orencia)
- I-55: Agalsidase beta (Fabrazyme)
- I-58: Alglucosidase alfa (Lumizyme)
- I-126: Alpha 1-Proteinase Inhibitors
- I-24: Belatacept (Nulojix)
- I-33: Belimumab (Benlysta)
- I-165: Bezlotoxumab (Zinplava)
- I-27: Certolizumab (Cimzia)
- G-16: Chemotherapy Services
- I-30: Denosumab (Prolia, Xgeva)
- I-130: Eculizumab (Solaris) and Ravulizumab (Ultomiris)
- I-173: Edaravone (Radicava)
- I-138: Elosulfase alfa (Vimizim)
- I-35: Golimumab (Simponi, Simponi Aria)
- I-88: Granulocyte Colony-Stimulating Factors
- I-93: Idursulfase (Elaprase)
- I-210: IL-1 and IL-1b Blockers
- I-14: Immune Globulin Therapy
- I-28: Infliximab
- I-175: Octreotide acetate (Sandostatin, Sandostatin LAR) and Lanreotide (Somatuline Depot)
- I-151: Site of Care
- I-199: Tildrakizumab-asmn (Illumya)

- I-31: Tocilizumab (Actemra)
- I-37: Ustekinumab (Stelara)
- I-129: Vedolizumab (Entyvio)

Refer to the following Reimbursement Policies for additional information:

- RP-003: Drug Wastage and Convenience Kits
- RP-044: Medication Therapy Management
- RP-019N: Drugs and Biologicals (This policy is accessible to Network providers only)
- RP-035: Correct Coding Guidelines

ADDITIONAL BILLING INFORMATION AND GUIDELINES:

- Highmark Provider Resource Center, Special eBulletin, ATTN: Referring Physicians; Expanded Access to Infused Drug Therapy. Aug.14, 2017. https://content.highmarkprc.com/Files/NewsletterNotices/SpecialBulletins/sb-all-reimbursement-changes-hit-081417.pdf

REFERENCES:

- 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 Non chemotherapy Injections and Infusions, Part D-Chemotherapy Administration https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

- Current version of AMA CPT Manual. *Current Procedure Terminology Manual* (CPT®) is copyright American Medical Association. All rights Reserved. The AMA assumes no liability for the data contained in this policy.

- Social Security Administration, Section 1861(t); Part E. https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

- Novitas Solutions, *Local Coverage Determination (LCD)*; (L34960) Hydration Therapy https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

- Novitas Solutions, *Local Coverage Determination (LCD)*; (A53049) Billing and Coding: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents. https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00006151

POLICY UPDATE HISTORY INFORMATION:

1 / 2022	Implementation