Corporate Medical Policy: Place of Service for Medical Infusions

Related Corporate Medical Policies with Applicable Restricted Product(s):

- Abatacept (Orencia®)
- ADAMTS13, recombinant-krhn (Adzynma®)
- Alpha 1-Antitrypsin Inhibitor Therapy
- Anifrolumab-fnia (Saphnelo™)
- Belimumab (Benlysta®)
- Beremagene geperpavec-svdt (Vyjuvek™)
- Burosumab-twza (Crysvita®)
- Canakinumab (Ilaris®)
- Certolizumab pegol (Cimzia®)
- Crizanlizumab-tmca (Adakveo®)
- Eculizumab (Soliris®)
- Edaravone (Radicava®)
- Enzyme Replacement Therapy (ERT) for Lysosomal Storage Disorders
- Eptinezumab-jjmr (Vyepti™)
- Evinacumab-dgnb (Evkeeza™)
- Fosdenopterin (Nulibry™)
- Givosiran (Givlaari®)
- Golimumab (Simponi Aria®)
- Guselkumab (Tremfya®)
- Ibalizumab-uiyk (Trogarzo®)
- Immunoglobulin Therapy
- Inclisiran (Leqvio®)
- Inebilizumab-cdon (Uplizna™)
- Infliximab (Remicade®) and Infliximab Biosimilars
- Interleukin-5 Antagonists
- Letermovir (Prevymis™)
- Lumasiran (Oxlumo™)

- Luspatercept-aamt (Reblozyl®)
- Natalizumab (Tysabri®) and Natalizumab Biosimilars
- Nedosiran (Rivfloza™)
- Ocrelizumab (Ocrevus®)
- Omalizumab (Xolair®)
- Patisiran (Onpattro®)
- Pegcetacoplan (Empaveli™)
- Plasminogen, human-tvmh (Ryplazim®)
- Pozelimab-bbfg (Veopoz™)
- Ravulizumab-cwvz (Ultomiris®)
- Romiplostim (NPlate®)
- Romosozumab-aqqg (Evenity™)
- Secukinumab (Cosentyx®)
- Somatostatin Analogs
- Sutimlimab (Enjaymo™)
- Teprotumumab-trbw (Tepezza™)
- Tezepelumab-ekko (Tezspire™)
- Tildrakizumab-asmn (Ilumya®)
- Tocilizumab (Actemra®)
- Treatment of Hereditary Angioedema
- Ublituximab-xiiy (Briumvi™)
- Ustekinumab (Stelara®)
- Vedolizumab (Entyvio®)
- Vutrisiran (Amvuttra™)

**NOTE: A comprehensive list of the individual restricted products that are applicable to this policy is included below in the “Restricted Product(s) Applicable to Policy” table.

Other Related Corporate Medical Policies:

- Infusion Therapy in the Home

- Private Duty Nursing Services

Rationale:

- Inpatient hospital and outpatient facilities are uniquely equipped to handle and support emergency medical situations. It is appropriate for patients, who are medically unstable and in danger of needing medical services only available in an outpatient hospital setting, to have access to medical injections or infusions in these facilities.
- For those patients who are considered medically stable, drug injections or infusions may be administered in settings that would be considered less intensive, yet safe and effective alternatives. Acceptable alternative sites of care include non-hospital outpatient centers, physician/professional offices, infusion suites/ambulatory infusion centers, and infusions administered at home.
- Alternative places of service may be more convenient for the patient, less expensive, and lessen risk of exposure to hospital acquired infections.
- Guidelines and agencies support first injections or infusions of most drugs in well-controlled, hospital-based settings. This is to ensure emergency access to care to address serious infusion-associated adverse reactions, such as anaphylaxis or severe hypotension. Research has shown the safety and efficacy of administering subsequent injections or infusions in a less intensive environment, including the home setting.
- **Please note, this policy specifically applies to the injection or infusion drugs that are addressed separately in individual medical policies as referenced above in the “Restricted Product(s)” section.

Criteria for Medical Necessity:

Medical injection or infusion therapy of the restricted product(s) in an inpatient or outpatient hospital setting is considered medically necessary when the following criteria are met:

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if ONE of the following criteria are met:
    a. History of a severe adverse event following that injection or infusion (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**

c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
f. Re-initiation of therapy, defined as ONE of the following:
    i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
    ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
g. Requirement of a change in the requested restricted product formulation; **AND**

3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
Abatacept (Orencia®)	abatacept (Orencia®) intravenous (IV) infusion or subcutaneous (SC) injection	J0129
ADAMTS13, recombinant-krhn (Adzynma®)	ADAMTS13, recombinant-krhn (Adzynma®) intravenous (IV) infusion	C9399* J3490* J3590*
Alpha 1-Antitrypsin Inhibitor Therapy	alpha1-proteinase inhibitor (human) (Aralast NP™) intravenous (IV) infusion	J0256
	alpha1-proteinase inhibitor (human) (Glassia®) intravenous (IV) infusion	J0257

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
	alpha1-proteinase inhibitor (human) (Prolastin®-C) intravenous (IV) infusion	J0256
	alpha1-proteinase inhibitor (human) (Zemaira®) intravenous (IV) infusion	J0256
Anifrolumab-fnia (Saphnelo™)	anifrolumab-fnia (Saphnelo™) intravenous (IV) infusion	J0491
Belimumab (Benlysta®)	belimumab (Benlysta®) intravenous (IV) infusion or subcutaneous (SC) injection	J0490
Beremagene geperpavec-svdt (Vyjuvek™)	Beremagene geperpavec-svdt (Vyjuvek™) biological suspension mixed with excipient gel for topical application	J3401
Burosumab-twza (Crysvita®)	burosumab-twza (Crysvita®) subcutaneous (SC) injection	J0584
Canakinumab (Ilaris®)	canakinumab (Ilaris®) subcutaneous (SC) injection	J0638
Certolizumab pegol (Cimzia®)	certolizumab pegol (Cimzia®) subcutaneous (SC) injection	J0717

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
Crizanlizumab-tmca (Adakveo®)	crizanlizumab-tmca (Adakveo®) intravenous (IV) infusion	J0791
Eculizumab (Soliris®)	eculizumab (Soliris®) intravenous (IV) infusion	J1300
Edaravone (Radicava®)	edaravone (Radicava®) intravenous (IV) infusion	J1301
Enzyme Replacement Therapy (ERT) for Lysosomal Storage Disorders	laronidase (Aldurazyme®) intravenous (IV) infusion	J1931
	imiglucerase (Cerezyme®) intravenous (IV) infusion	J1786
	idursulfase (Elaprase®) intravenous (IV) infusion	J1743
	taliglucerase alfa (Elelyso®) intravenous (IV) infusion	J3060
	pegunigalsidase alfa-iwxj (Elfabrio®) intravenous (IV) infusion)	J2508

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
	agalsidase beta (Fabrazyme®) intravenous (IV) infusion	J0180
	sebelipase alfa (Kanuma®) intravenous (IV) infusion	J2840
	velmanase alfa-tycv (Lamzede®) intravenous (IV) infusion	J0217
	alglucosidase alfa (Lumizyme®) intravenous (IV) infusion	J0221
	vestronidase alfa-vjbk (Mepsevii™) intravenous (IV) infusion	J3397
	galsulfase (Naglazyme®) intravenous (IV) infusion	J1458
	avalglucosidase alfa-ngpt (Nexviazyme™) intravenous (IV) infusion	J0219
	cipaglucosidase alfa-atga (Pombiliti™) intravenous (IV) infusion	C9399* J3490* J3590*

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
	elosulfase alfa (Vimizim®) intravenous (IV) infusion	J1322
	velaglucerase alfa (Vpriv®) intravenous (IV) infusion	J3385
	olipudase alfa-rpcp (Xenpozyme™) intravenous (IV) infusion	J0218
Eptinezumab-jjmr (Vyepti™)	eptinezumab-jjmr (Vyepti™) intravenous (IV) infusion	J3032
Evinacumab-dgnb (Evkeeza™)	evinacumab-dgnb (Evkeeza™) intravenous (IV) infusion	J1305
Fosdenopterin (Nulibry™)	fosdenopterin (Nulibry™) intravenous (IV) infusion	C9399* J3490* J3590*
Givosiran (Givlaari®)	givosiran (Givlaari®) subcutaneous (SC) injection	J0223
Golimumab (Simponi Aria®)	golimumab (Simponi Aria®) intravenous (IV) infusion	J1602

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
Guselkumab (Tremfya®)	guselkumab (Tremfya®) subcutaneous (SC) injection	J1628
Ibalizumab-uiyk (Trogarzo®)	ibalizumab-uiyk (Trogarzo®) intravenous (IV) infusion	J1746
Immunoglobulin Therapy	Alyglo™ intravenous (IV) immune globulin	C9399* J3490* J3590*
	Asceniv™ intravenous (IV) immune globulin	J1554 90283
	Bivigam® intravenous (IV) immune globulin	J1556 90283
	Cutaquig® subcutaneous (SC) immune globulin	J1551 90284
	Cuvitru™ subcutaneous (SC) immune globulin	J1555 90284
	Flebogamma® intravenous (IV) immune globulin	J1572 90283

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
	Gammagard S/D® intravenous (IV) immune globulin	J1566 90283
	Gammagard™ Liquid intravenous (IV) or subcutaneous (SC) immune globulin	J1569 90283 90284
	Gammaked™ intravenous (IV) or subcutaneous (SC) immune globulin	J1561 90283 90284
	Gammaplex® intravenous (IV) immune globulin	J1557 90283
	Gamunex-C® intravenous (IV) or subcutaneous (SC) immune globulin	J1561 90283 90284
	Hizentra® subcutaneous (SC) immune globulin	J1559 90284
	HyQvia™ subcutaneous (SC) immune globulin	J1575 90284
	Octagam® intravenous (IV) immune globulin	J1568 90283

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
	Panzyga® intravenous (IV) immune globulin	J1576 J1599 90283
	Privigen® intravenous (IV) immune globulin	J1459 90283
	Xembify™ subcutaneous (SC) immune globulin	J1558 90284
Inclisiran (Leqvio®)	inclisiran (Leqvio®) subcutaneous (SC) injection	J1306
Inebilizumab-cdon (Uplizna™)	inebilizumab-cdon (Uplizna™) intravenous (IV) infusion	J1823
Infliximab (Remicade®) and Infliximab Biosimilars	infliximab (Remicade®) or Infliximab intravenous (IV) infusion	J1745
	infliximab-axxq (Avsola™) intravenous (IV) infusion	Q5121
	infliximab-dyyb (Inflectra®) intravenous (IV) infusion	Q5103

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
	infliximab-abda (Renflexis®) intravenous (IV) infusion	Q5104
Interleukin-5 Antagonists	reslizumab (Cinqair®) intravenous (IV) infusion	J2786
	benralizumab (Fasenra®) subcutaneous (SC) injection	J0517
	mepolizumab (Nucala®) subcutaneous (SC) injection	J2182
Letermovir (Prevymis™)	letermovir (Prevymis™) intravenous (IV) infusion	C9399* J3490* J3590*
Lumasiran (Oxlumo™)	lumasiran (Oxlumo™) subcutaneous (SC) injection	J0224
Luspatercept-aamt (Reblozyl®)	luspatercept-aamt (Reblozyl®) subcutaneous (SC) injection	J0896
Natalizumab (Tysabri®) and Natalizumab Biosimilars	natalizumab (Tysabri®) intravenous (IV) infusion	J2323

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
	natalizumab-sztn (Tyruko®) intravenous (IV) infusion	C9399* J3490* J3590*
Nedosiran (Rivfloza™)	nedosiran (Rivfloza) subcutaneous (SC) injection	C9399* J3490* J3590*
Ocrelizumab (Ocrevus®)	ocrelizumab (Ocrevus®) intravenous (IV) infusion	J2350
Omalizumab (Xolair®)	omalizumab (Xolair®) subcutaneous (SC) injection	J2357
Patisiran (Onpattro®)	patisiran (Onpattro®) intravenous (IV) infusion	J0222
Pegcetacoplan (Empaveli™)	pegcetacoplan (Empaveli™) subcutaneous (SC) infusion	C9399* J3490* J3590*
Plasminogen, human-tvmh (Ryplazim®)	plasminogen, human-tvmh (Ryplazim®) intravenous (IV) infusion	J2998
Pozelimab-bbfg (Veopoz™)	pozelimab-bbfg (Veopoz™) intravenous (IV) infusion or subcutaneous (SC) injection	C9399* J3490* J3590*

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
Ravulizumab-cwvz (Ultomiris®)	ravulizumab-cwvz (Ultomiris®) intravenous (IV) infusion	J1303
Romiplostim (NPlate®)	romiplostim (NPlate®) subcutaneous (SC) injection	J2796
Romosozumab-aqqg (Evenity™)	romosozumab-aqqg (Evenity™) subcutaneous (SC) injection	J3111
Secukinumab (Cosentyx®)	secukinumab (Cosentyx®) intravenous (IV) infusion	C9399* J3490* J3590*
Somatostatin Analogs	octreotide (Sandostatin®) intravenous (IV) infusion or subcutaneous (SC) injection	J2354
	octreotide (Sandostatin® LAR Depot) gluteal intramuscular (IM) injection	J2353
	pasireotide (Signifor® LAR) intramuscular (IM) injection	J2502
	lanreotide (Somatuline® Depot) subcutaneous (SC) injection	J1930 J1932

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
Sutimlimab (Enjaymo™)	sutimlimab (Enjaymo™) intravenous (IV) infusion	J1302
Teprotumumab-trbw (Tepezza™)	teprotumumab-trbw (Tepezza™) intravenous (IV) infusion	J3241
Tezepelumab-ekko (Tezspire™)	tezepelumab-ekko (Tezspire™) subcutaneous (SC) injection	J2356
Tildrakizumab-asmn (Ilumya®)	tildrakizumab-asmn (Ilumya®) subcutaneous (SC) injection	J3245
Tocilizumab (Actemra®)	tocilizumab (Actemra®) intravenous (IV) infusion or subcutaneous (SC) injection	J3262
Treatment of Hereditary Angioedema	C1 esterase inhibitor (Berinert®) intravenous (IV) injection	J0597
	C1 esterase inhibitor (Cinryze®) intravenous (IV) injection	J0598
	icatibant (Firazyr®) subcutaneous (SC) injection	J1744

Restricted Product(s) Applicable to Policy		
Related Corporate Medical Policy	**Medication**	**HCPCS**
	ecallantide (Kalbitor®) subcutaneous (SC) injection	J1290
	C1 esterase inhibitor (Ruconest®) intravenous (IV) injection	J0596
Ublituximab-xiiy (Briumvi™)	ublituximab-xiiy (Briumvi™) intravenous (IV) infusion	J2329
Ustekinumab (Stelara®)	ustekinumab (Stelara®) intravenous (IV) infusion or subcutaneous (SC) injection	J3357 J3358
Vedolizumab (Entyvio®)	vedolizumab (Entyvio®) intravenous (IV) infusion	J3380
Vutrisiran (Amvuttra™)	vutrisiran (Amvuttra™) subcutaneous (SC) injection	J0225

***Non-specific assigned HCPCS codes, please refer to product NDC**

Other service codes that may be applicable: 86711, 99506, 99601, 99602, S0353, S0354, S5035, S5036, S5497, S5498, S5501, S5502, S5517, S5518, S5520, S5521, S5522, S5523, S9123, S9124, S9208, S9325, S9326, S9327, S9328, S9329, S9330, S9331, S9336, S9338, S9345, S9346, S9347, S9348, S9349, S9351, S9353, S9355, S9357, S9359, S9361, S9363, S9364, S9365, S9366, S9367, S9368, S9370, S9372, S9373, S9374, S9375, S9376, S9377, S9379, S9490, S9494, S9497, S9500, S9501, S9502, S9503, S9504, S9537, S9538, S9542, S9558, S9559, S9810, E0691-E0694

NOTE:

- Charges for routinely included supplies such as gauze, infusion sets, needles, cassettes, tape, cleansing solutions (e.g., betadine, alcohol), heparin and saline flushes, diluents for mixing drugs, and splints are included in the infusion reimbursement.
- Catheter care may be reported separately when used as a stand-along therapy, or during days not covered under per diem by another therapy. PICC line care will only be allowed as a separate charge if there is no other therapy in the last 30 days in the home.
- Home infusion therapy includes all of the components related to such therapy, such as, but not limited to, nursing services, durable medical equipment, supplies, Prescription and non-Prescription Legend Drugs and solutions, pharmacy compounding and dispensing, specimen collection, patient and family education, delivery of drugs and supplies, and management of emergencies arising from said therapy.

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q4 annually.

February 2024: Criteria update: Added ADAMTS13 recombinant-krhn (Adzynma), intravenous immune globulin (Alyglo), secukinumab (Cosentyx IV), cipaglucosidase alfa-atga (Pombiliti), nedosiran (Rivfloza), natalizumab-sztn (Tyruko), pozelimab-bbfg (Veopoz) to policy with HCPCS codes C9399, J3490, and J3590. For Vyjuvek, added HCPCS code J3401 to dosing reference table effective 1/1/2024; deleted C9399, J3490, and J3590 termed 12/31/2023. Added HCPCS code J0217 for Lamzede to dosing reference table effective 1/1/2024; deleted C9399, J3490, J3590 termed 12/31/2023. Added HCPCS code J2508 for Elfabrio to dosing reference table effective 1/1/2024; deleted C9399, J3490, J3590 termed 12/31/2023.
August 2023: Criteria update: Added pegunigalsidase alfa-iwxj (Elfabrio) and velmanase alfa-tycv (Lamzede) to policy with HCPCS codes C9399, J3490, and J3590. Added beremagene geperpavec-svdt (Vyjuvek) to policy with HCPCS codes C9399, J3490, and J3590. Added non-branded Infliximab for clarity with associated HCPCS code for Remicade (J1745).
August 2023: Coding change: For IVIG products: Added HCPCS code J1576 for Panzyga effective 7/1/2023; removed J1599 from Asceniv, Bivigam, Flebogamma, Gammagard Liquid, Gammaked, Gammaplex, Gamunex-C, Octagam, and Privigen for clarity according to coding definition; removed J1599 and J1569 from Gammagard S/D for clarity according to coding definition; removed Carimune NF from policy due to product discontinuation. For Briumvi, added HCPCS code J2329 to restricted product table effective 7/1/2023, deleted C9399, J3490, and J3590 termed 6/30/2023.
April 2023: Coding update: For Xenpozyme, added HCPCS code J0218 to restricted product table effective 4/1/2023, deleted C9399, J3490, and J3590 termed 3/31/2023.
April 2023: Criteria update: Added ublituximab-xiiy (Briumvi) to policy with HCPCS codes C9399, J3490, and J3590.

January 2023: Coding update: For Amvuttra, added HCPCS code J0225 to restricted product table effective 1/1/2023, deleted C9399, J3490, and J3590 termed 12/31/2022.
October 2022: Criteria update: Added enzyme replacement therapy, olipudase alfa-rpcp (Xenpozyme) to policy with HCPCS codes C9399, J3490, and J3590. Updated codes for multiple drugs: For Enjaymo, added HCPCS code J1302, deleted C9094, J3490, J3590; for lanreotide (Somatuline Depot), added HCPCS J1932.
August 2022: Criteria update: Added vutrisiran (Amvuttra) to policy with HCPCS codes C9399, J3490, and J3590. Updated codes for multiple drugs: For Saphnelo, added HCPCS code J0491 effective 4/1/22, deleted C9086, J3490, J3590; for Nexviazyme, added HCPCS code J0219 effective 4/1/2022, deleted C9085, J3490, J3590; for Cutaquig, added HCPCS code J1551 effective 7/1/2022, deleted C9399, J3490, and J3590 termed 6/30/2022; for Leqvio, added HCPCS code J1306 effective 7/1/2022, deleted C9399, J3490, and J3590 termed 6/30/2022; for Ryplazim, added HCPCS code J2998 effective 7/1/2022, deleted C9399, J3490, and J3590 termed 6/30/2022; for Enjaymo, added HCPCS code C9094 effective 7/1/2022, deleted C9399 termed 6/30/2022; for Tezspire, added HCPCS code J2356 effective 7/1/2022, deleted C9399, J3490, and J3590 termed 6/30/2022.
February 2022: Criteria update: Added the following drugs and HCPCS codes for clarity, with criteria also available in individual policies: Nexviazyme (C9085, J3490, J3590), Saphnelo (C9086, J3490, J3590), Tezspire (C9399, J3490, J3590), Enjaymo (C9399** J3490**, J3590**), and Leqvio (C9399, J3490, J3590). Updated HCPCS code for Evkeeza to J1305.
October 2021: Criteria change: Expanded policy to include the following restricted products: Benlysta, Crysvita, Ilaris, Cimzia, Adakveo, Vyepti, Evkeeza, Nulibry, Givlaari, Tremfya, Trogarzo, Uplizna, Prevymis, Oxlumo, Reblozyl, Onpattro, Ryplazim, Empaveli, NPlate, Evenity, Somatostatin Analogs, Tepezza, Ilumya, Stelara; added associated HCPCS/CPT codes: J0490, J0584, J0638, J0717, J0791, J3032, C9079, C9399, J3490, J3590, J0223, J1628, J1746, J1823, J0224, J0896, J0222, J2796, J3111, J2354, J2353, J2502, J1930, J3241, J3245, J3357, J3358. Corrected restricted products and codes for clarity to include: Asceniv, Fasenra, Radicava, and Ultomiris with associated codes J1554, J0517, J1301, and J1303; medical policy formatting change. **Policy notification given 8/2/2021 for effective date 10/1/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.