

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

- Abatacept (Orencia[®])
- Alpha 1-Antitrypsin Inhibitor Therapy
- Belimumab (Benlysta[®])
- 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 (Vyepi[™])
- Evinacumab-dgnb (Evkeeza[™])
- Fosdenopterin (Nulibry[™])
- Givosiran (Givlaari[®])
- Golimumab (Simponi Aria[®])
- Guselkumab (Tremfya[®])
- Ibalizumab-uiyk (Trogarzo[®])
- Immunoglobulin Therapy
- Inebilizumab-cdon (Uplizna[™])
- Infliximab (Remicade[®]) and Infliximab Biosimilars
- Interleukin-5 Antagonists
- Letermovir (Prevymis[™])
- Lumasiran (Oxlumo[™])
- Luspatercept-aamt (Reblozyl[®])
- Natalizumab (Tysabri[®])
- Ocrelizumab (Ocrevus[®])
- Omalizumab (Xolair[®])

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- Patisiran (Onpattro[®])
- Pegcetacoplan (Empaveli[™])
- Plasminogen, human-tvmh (Ryplazim[®])
- Ravulizumab-cwvz (Ultomiris[®])
- Romiplostim (NPlate[®])
- Romosozumab-aqqg (Evenity[™])
- Somatostatin Analogs
- Teprotumumab-trbw (Tepezza[™])
- Tocilizumab (Actemra[®])
- Tildrakizumab-asmn (Ilumya[®])
- Treatment of Hereditary Angioedema
- Ustekinumab (Stelara[®])
- Vedolizumab (Entyvio[®])

****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.

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- 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
Alpha 1-Antitrypsin Inhibitor Therapy	alpha1-proteinase inhibitor (human) (Aralast NP™) intravenous (IV) infusion	J0256
	alpha1-proteinase inhibitor (human) (Glassia®) intravenous (IV) infusion	J0257
	alpha1-proteinase inhibitor (human) (Prolastin®-C) intravenous (IV) infusion	J0256
	alpha1-proteinase inhibitor (human) (Zemaira®) intravenous (IV) infusion	J0256
Belimumab (Benlysta®)	belimumab (Benlysta®) intravenous (IV) infusion or subcutaneous (SC) injection	J0490
Burosumab-twza (Crysvita®)	burosumab-twza (Crysvita®) subcutaneous (SC) injection	J0584
Canakinumab (Ilaris®)	canakinumab (Ilaris®) subcutaneous (SC) injection	J0638

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Certolizumab pegol (Cimzia®)	certolizumab pegol (Cimzia®) subcutaneous (SC) injection	J0717
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

	agalsidase beta (Fabrazyme®) intravenous (IV) infusion	J0180
	sebelipase alfa (Kanuma®) intravenous (IV) infusion	J2840
	alglucosidase alfa (Lumizyme®) intravenous (IV) infusion	J0221
	vestronidase alfa-vjvk (Mepsevii™) intravenous (IV) infusion	J3397
	galsulfase (Naglazyme®) intravenous (IV) infusion	J1458
	elosulfase alfa (Vimizim®) intravenous (IV) infusion	J1322
	velaglucerase Alfa (Vpriv®) intravenous (IV) infusion	J3385
Eptinezumab-jjmr (Vyepti™)	eptinezumab-jjmr (Vyepti™) intravenous (IV) infusion	J3032

Evinacumab-dgnb (Evkeeza™)	evinacumab-dgnb (Evkeeza™) intravenous (IV) infusion	C9079 J3490* J3590*
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
Guselkumab (Tremfya®)	guselkumab (Tremfya®) subcutaneous (SC) injection	J1628
Ibalizumab-uiyk (Trogarzo®)	ibalizumab-uiyk (Trogarzo®) intravenous (IV) infusion	J1746
Immunoglobulin Therapy	Asceniv™ intravenous (IV) immune globulin	J1554 J1599 90283
	Bivigam® intravenous (IV) immune globulin	J1556 J1599 90283

	Carimune [®] NF intravenous (IV) immune globulin	J1566 J1599 90283
	Cutaquig [®] subcutaneous (SC) immune globulin	C9399* J3490* J3590* 90284
	Cuvitru [™] subcutaneous (SC) immune globulin	J1555 90284
	Flebogamma [®] intravenous (IV) immune globulin	J1572 J1599 90283
	Gammagard S/D [®] intravenous (IV) immune globulin	J1569 J1566 J1599 90283
	Gammagard [™] Liquid intravenous (IV) or subcutaneous (SC) immune globulin	J1569 J1599 90283 90284
	Gammaked [™] intravenous (IV) or subcutaneous (SC) immune globulin	J1561 J1599 90283 90284
	Gammaplex [®] intravenous (IV) immune globulin	J1557 J1599 90283

	Gamunex-C [®] intravenous (IV) or subcutaneous (SC) immune globulin	J1561 J1599 90283 90284
	Hizentra [®] subcutaneous (SC) immune globulin	J1559 90284
	HyQvia [™] subcutaneous (SC) immune globulin	J1575 90284
	Octagam [®] intravenous (IV) immune globulin	J1568 J1599 90283
	Panzyga [®] intravenous (IV) immune globulin	J1599 90283
	Privigen [®] intravenous (IV) immune globulin	J1459 J1599 90283
	Xembify [™] subcutaneous (SC) immune globulin	J1558 90284
Inebilizumab-cdon (Uplizna [™])	inebilizumab-cdon (Uplizna [™]) intravenous (IV) infusion	J1823

Infliximab (Remicade®) and Infliximab Biosimilars	infliximab (Remicade®) intravenous (IV) infusion	J1745
	infliximab-axxq (Avsola™) intravenous (IV) infusion	Q5121
	infliximab-dyyb (Inflectra®) intravenous (IV) infusion	Q5103
	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
Letemovir (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®)	natalizumab (Tysabri®) intravenous (IV) infusion	J2323
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	C9399* J3490* J3590*

Ravulizumab-cwvz (Ultomiris [®])	ravulizumab-cwvz (Ultomiris [®]) intravenous (IV) infusion	J1303
Romiplostim (NPlate [®])	romiplostim (NPlate [®]) subcutaneous (SC) injection	J2796
Romozosumab-aqqg (Evenity [™])	romozosumab-aqqg (Evenity [™]) subcutaneous (SC) injection	J3111
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
Teprotumumab-trbw (Tepezza [™])	teprotumumab-trbw (Tepezza [™]) intravenous (IV) infusion	J3241

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
	ecallantide (Kalbitor®) subcutaneous (SC) injection	J1290
	C1 esterase inhibitor (Ruconest®) intravenous (IV) injection	J0596
Ustekinumab (Stelara®)	ustekinumab (Stelara®) intravenous (IV) infusion or subcutaneous (SC) injection	J3357 J3358

Vedolizumab (Entyvio®)	vedolizumab (Entyvio®) intravenous (IV) infusion	J3380
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***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-alone 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

October 2021: Criteria change: Expanded policy to include the following restricted products: Benlysta, Crysvisa, Ilaris, Cimzia, Adakveo, Vyepti, Evkeeza, Nulibry, Givlaari, Tremfya, Trogarzo, Uplizna, Prevymis, Oxlummo, 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.**

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*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.

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