

Health Plan of Washington

UTILIZATION MANAGEMENT GUIDELINE – 11.01.523 Site of Service: Infusion Drugs and Biologic Agents

Effective Date:	Aug. 1, 2024*	RELATED	MEDICAL POLICIES:
Last Revised:	July 9, 2024	5.01.536	Nulojix (belatacept) for Adults
Replaces:	N/A	5.01.550	Pharmacotherapy of Arthropathies
		5.01.556	Rituximab: Non-oncologic and Miscellaneous Uses
		5.01.559	IL-5 Inhibitors
*This policy has b	been revised.	5.01.563	Pharmacotherapy of Inflammatory Bowel Disorder
		5.01.564	Pharmacotherapy of Miscellaneous Autoimmune Diseases
Click here to viev	v the upcoming	5.01.565	Pharmacotherapy of Multiple Sclerosis
changes effective Nov. 1, 2024.		5.01.570	Pharmacologic Treatment of Duchenne Muscular Dystrophy
		5.01.571	C5 Complement Inhibitors
Click here to view the upcoming		5.01.576	Drugs for Rare Diseases
changes effective	e Dec. 5, 2024.	5.01.587	Hereditary Angioedema
		5.01.591	Immune Checkpoint Inhibitors
		8.01.503	Immune Globulin Therapy

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Introduction

Infusion of a drug is the delivery of a drug directly into the bloodstream of a individual through a vein, usually located in the arm or hand. This is also called infusion therapy or intravenous (IV) therapy. IV therapy is used to treat and manage certain diseases and may be recommended by a doctor as part of a treatment approach for many neurological and similar disorders.

IV therapy can be given in many different places. One is a location within a hospital for people who are not staying in the hospital under a doctor's order. This is called a hospital-based outpatient infusion center. IV therapy can also be provided in an infusion center or infusion suite, which is not located within a hospital and is designed specifically to provide IV therapy services. Individuals can also be given IV therapy in their doctor's office or in their home through companies that specialize in these services and hire licensed nurses to deliver IV therapy.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs providers about when a service may be covered.

Policy Coverage Criteria

We will review specific intravenous (IV) and injectable drugs for medical necessity for all ages.

For those age 13 and older, we also will review the site of service for medical necessity. Site of service is defined as the location where the drug is administered, such as a hospital-based outpatient setting, an infusion center, a physician's office, or at home.

Site of Service	Medical Necessity
Administration	
Medically necessary sites	IV infusion therapy of various medical or biologic agents will
of service	be covered in the most appropriate, safe and cost effective
Physician's office	site:
Infusion center	• These are the preferred medically necessary sites of service for
Home infusion	specified drugs.
Hospital-based outpatient	IV infusion therapy of various medical or biologic agents will
setting	be covered in the most appropriate, safe and cost-effective
Outpatient hospital IV	site.
infusion department	
Hospital-based outpatient	This site is considered medically necessary for the first 90 days
clinical level of care	for the following:
	• The initial course of infusion of a pharmacologic or biologic
	agent
	OR
	• Re-initiation of an agent after 6 months or longer following
	discontinuation of therapy*
	Note: *This does not include when standard dosing between infusions is 6 months or longer



Site of Service	Medical Necessity
Administration	
	This site is considered medically necessary when there is no outpatient infusion center within 50 miles of the individual's home and there is no contracted home infusion agency that will travel to their home, or a hospital is the only place that offers infusions of this drug.
	This site is considered medically necessary only when the individual has a clinical condition which puts him or her at increased risk of complications for infusions, including any
	 ONE of the following: Known cardiac condition (e.g., symptomatic cardiac arrhythmia) or pulmonary condition (e.g., significant respiratory disease, serious obstructive airway disease, %FVC ≤ 40%) that may increase the risk of an adverse reaction Unstable renal function which decreases the ability to respond to fluids
	 Difficult or unstable vascular access Acute mental status changes or cognitive conditions that impact the safety of infusion therapy A known history of severe adverse drug reactions and/or anaphylaxis to prior treatment with a related or similar drug
Hospital-based outpatient setting • Outpatient hospital IV	These sites are considered not medically necessary for infusion and injectable therapy services of various medical and biologic
 Outpatient nospital IV infusion department Hospital-based outpatient clinical level of care 	agents when the site-of-service criteria in this policy are not met.

Note: This policy does not address intravenous (IV) and injectable therapy services for individual's receiving inpatient services.

This guideline applies to any of the following selected drugs in the injected and/or infused form:

Pharmacologic /	Medical Policy (see Related Policies above)
Biologic Agent	
C1-Esterase Inhibitor:	5.01.587 Hereditary Angioedema
Cinryze	
Immune globulins:	8.01.503 Immune Globulin Therapy
• Alyglo	
• Asceniv	
• Bivigam	
Cutaquig	
Cuvitru	
Flebogamma DIF	
Gammagard	
Gammaked	
Gammaplex	
Gamunex-C	
• Hizentra	
• Hyqvia	
• Octagam	
• Panzyga	
• Privigen	
• Xembify	
IL-5 Inhibitor:	5.01.559 IL-5 Inhibitors
• Cinqair	
Immunosuppressive:	5.01.536 Nulojix (belatacept) for Adults
• Nulojix	
Miscellaneous monoclonal	5.01.550 Pharmacotherapy of Arthropathies
antibodies and others:	5.01.556 Rituximab: Non-oncologic and Miscellaneous Uses
• Actemra	5.01.563 Pharmacotherapy of Inflammatory Bowel Disorders
• Avsola	5.01.564 Pharmacotherapy of Miscellaneous Autoimmune
• Benlysta	Diseases
Cosentyx IV	5.01.629 Pharmacologic Treatment of Psoriasis
• Entyvio	gg
• Inflectra	
• Infliximab (Janssen –	
unbranded)	
Orencia	
Remicade	
Renflexis	



Pharmacologic /	Medical Policy (see Related Policies above)
Biologic Agent	
Rituxan (non-oncologic)	
Ruxience (non-oncologic)	
• Simponi Aria	
• Skyrizi IV	
Spevigo IV	
• Stelara IV	
Tofidence IV	
Truxima (non-oncologic)	
• Tyruko	
• Tysabri	
• Uplizna	
C5 complement inhibitors	5.01.571 C5 Complement Inhibitors
Soliris	
Ultomiris	
Antisense Oligonucleotides	5.01.570 Pharmacologic Treatment of Duchenne Muscular
Amondys 45	Dystrophy
Exondys 51	
Vyondys 53	
Multiple sclerosis	5.01.565 Pharmacotherapy of Multiple Sclerosis
• Briumvi	
Ocrevus	
• Tyruko	
• Tysabri	
Drugs for rare diseases:	5.01.576 Drugs for Rare Diseases
Aldurazyme	
Cerezyme	
Crysvita	
• Elaprase	
• Elelyso	
• Fabrazyme	
• Kanuma	
Lumizyme	
Mepsevii	
Naglazyme	
Nexviazyme	
Vimizim	
• Vpriv	

Pharmacologic /	Medical Policy (see Related Policies above)
Biologic Agent	
Immune Checkpoint	5.01.591 Immune Checkpoint Inhibitors
Inhibitors	
• Keytruda	Note: Keytruda and Opdivo are subject to review for site of service
Opdivo	administration except when it is used concurrently with other IV
-	medications for cancer treatment.
Alpha-1 Proteinase	5.01.624 Alpha-1 Proteinase Inhibitors
Inhibitors	
Aralast NP	
• Glassia	
Prolastin-C	
• Zemaira	
Sickle cell disease	5.01.640 Pharmacologic Treatment of Sickle Cell Disease
Adakveo	

Coding

Code	Description
СРТ	
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each
HCPCS	
J0129	Injection, abatacept (Orencia)
J0180	Injection, agalsidase beta (Fabrazyme), 1 mg
J0219	Injection, avalglucosidase alfa-ngpt (Nexviazyme), 4 mg
J0221	Injection, alglucosidase alfa, (Lumizyme), 10 mg
J0256	Injection, alpha 1-proteinase inhibitor (human), not otherwise specified,(Aralast NP, Prolastin-C and Zemaira) 10 mg
J0257	Injection, alpha 1 proteinase inhibitor (human), (GLASSIA), 10 mg
J0485	Injection, belatacept (Nulojix), 1 mg
J0490	Injection, belimumab (Benlysta), 10 mg
J0584	Injection, burosumab-twza (Crysvita) 1 mg



Code	Description
J0598	Injection, C-1 esterase inhibitor (human), Cinryze, 10 units
J0791	Injection, crizanlizumab-tmca (Adakveo), 5 mg
J1300	Injection, eculizumab (Soliris), 10 mg
J1303	Injection, ravulizumab-cwvz, (Ultomiris) 10 mg
J1322	Injection, elosulfase alfa (Vimizim), 1 mg
J1426	Injection, casimersen, (Amondys 45), 10 mg
J1428	Injection, eteplirsen (Exondys 51), 10 mg
J1429	Injection, golodirsen (Vyondys 53), 10 mg
J1458	Injection, galsulfase (Naglazyme) 1 mg
J1459	Injection, immune globulin, intravenous, nonlyophilized (Privigen) (e.g., liquid), 500 mg
J1551	Injection, immune globulin (Cutaquig), 100 mg
J1554	Injection, immune globulin (asceniv), 500 mg
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin (Gammaplex), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1558	Injection, immune globulin (Xembify), 100 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1561	Injection, immune globulin (Gamunex/Gamunex-C/Gammaked), nonlyophilized (e.g., liquid), 500 mg
J1566	Injection, immune globulin (Gammagard), intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin (Gammagard liquid), nonlyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin (Flebogamma/Flebogamma Dif), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase (Hyqvia), 100 mg immunoglobulin
J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg (used to report Alyglo)
J1602	Injection, golimumab (Simponi Aria), 1 mg, for intravenous use

J1743Injection, idursulfase (Elaprase), 1 mgJ1745Injection infliximab. excludes biosimilar (Remicade or Janssen unbranded), 10 mgJ1747Injection, spesolimab-sbzo (Spevigo), 1 mgJ1786Injection, iniglucerase (Cerezyme), 10 unitsJ1823Injection, inebilizumab-cdon, (Uplizna) 1 mgJ1931Injection, laronidase (Aldurazyme), 0.1 mgJ3060Injection, ratalizumab (Tysabri), 1mgJ2323Injection, ratalizumab (Tysabri), 1mgJ2324Injection, ratalizumab-riza, intravenous (Skyrizi), 1 mgJ2325Injection, reslizumab (Cerevus), 1 mgJ2326Injection, cerelizumab (Cerevus), 1 mgJ2350Injection, cerelizumab (Cerevus), 1 mgJ2361Injection, sebelipase alfa (Kanuma), 1 mgJ3862Injection, secukinumab, IV (Costentyx), 1 mgJ3862Injection, veolizumab (Cerevus), 1 mgJ3874Injection, veolizumab (Cerevus), 1 mgJ3885Ustekinumab, for intravenous injection, (Stelara), 1 mgJ3895Injection, veolizumab (Keytruda), 1 mgJ3806Injection, veolizumab (Keytruda), 1 mgJ3817Injection, relizumab (Opdivo), 1 mgJ3818Injection, inviolumab (Opdivo), 1 mgJ3819Injection, inviolumab (Opdivo), 1 mgJ3829Injection, inviolumab (Opdivo), 1 mgJ3930Injection, inviolumab (Opdivo), 1 mgJ3931Injection, infikimab-abd, biosimilar, (Inflectra), 10 mgJ3932Injection, infikimab-abd, biosimilar, (Inflectra), 10 mgJ3933Injection, infikimab-abd, biosimilar, (Ratenlesis), 10 mg <t< th=""><th>Code</th><th>Description</th></t<>	Code	Description
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J2350Injection, ocrelizumab (Ocrevus), 1 mgJ2786Injection, reslizumab (Cinqair), 1 mgJ2840Injection, sebelipase alfa (Kanuma), 1 mgJ3247Injection, secukinumab, IV (Costentyx), 1 mgJ3262Injection, tocilizumab (Actemra), 1 mgJ3358Ustekinumab, for intravenous injection, (Stelara),1 mgJ3380Injection, vedolizumab (Entyvio), 1 mgJ3385Injection, vedolizumab (Keytruda), 1 mgJ3312Injection, rituximab, (Rituxan)10 mgJ9299Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5103Injection, infliximab-abda, biosimilar, (Renflexis), 10 mgQ5115Injection, rituximab-abda, biosimilar, (Ruxience), 10 mgQ5121Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, rituximab-abavi (Tofidence), biosimilar, 1 mg	J2327	Injection, risankizumab-rzaa, intravenous (Skyrizi), 1 mg
J2786Injection, reslizumab (Cinqair), 1 mgJ2840Injection, sebelipase alfa (Kanuma), 1 mgJ3247Injection, secukinumab, IV (Costentyx), 1 mgJ3262Injection, tocilizumab (Actemra), 1 mgJ3358Ustekinumab, for intravenous injection, (Stelara),1 mgJ3380Injection, vedolizumab (Entyvio), 1 mgJ3385Injection, vedolizumab (Keytruda), 1 mgJ3385Injection, vedolizumab (Keytruda), 1 mgJ9312Injection, rituximab, (Rituxan)10 mgJ9299Injection, nirolumab (Opdivo), 1 mgQ5103Injection, infliximab-abda, biosimilar, (Inflectra), 10 mgQ5115Injection, rituximab-abda, biosimilar, (Renflexis), 10 mgQ5121Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5123Injection, rituximab-arxx, biosimilar, (Rabni), 10 mgQ5133Injection, rituximab-arxx, biosimilar, (Riabni), 10 mgQ5133Injection, rituximab-arxx, biosimilar, (Riabni), 10 mg	J2329	Injection, ublituximab-xiiy (Briumvi), 1mg
J2840Injection, sebelipase alfa (Kanuma), 1 mgJ3247Injection, secukinumab, IV (Costentyx), 1 mgJ3262Injection, tocilizumab (Actemra), 1 mgJ3358Ustekinumab, for intravenous injection, (Stelara),1 mgJ3380Injection, vedolizumab (Entyvio), 1 mgJ3385Injection, velaglucerase alfa (Vpriv), 100 unitsJ9271Injection, pembrolizumab (Keytruda), 1 mgJ9312Injection, rituximab, (Rituxan)10 mgJ9299Injection, nivolumab (Opdivo), 1 mgQ5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5115Injection, rituximab-, abbs, biosimilar, (Renflexis), 10 mgQ5119Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5121Injection, rituximab-abra, biosimilar, (Ruxience), 10 mgQ5123Injection, rituximab-arx, biosimilar, (Riabni), 10 mgQ5133Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg	J2350	Injection, ocrelizumab (Ocrevus), 1 mg
J3247Injection, secukinumab, IV (Costentyx), 1 mgJ3262Injection, tocilizumab (Actemra), 1 mgJ3358Ustekinumab, for intravenous injection, (Stelara), 1 mgJ3380Injection, vedolizumab (Entyvio), 1 mgJ3385Injection, vedolizumab (Entyvio), 100 unitsJ9271Injection, pembrolizumab (Keytruda), 1 mgJ9312Injection, rituximab, (Rituxan)10 mgJ9299Injection, nivolumab (Opdivo), 1 mgQ5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5115Injection, rituximab-abda, biosimilar, (Renflexis), 10 mgQ5119Injection, rituximab-abda, biosimilar, (Ruxience), 10 mgQ5121Injection, nivolumab-pvvr, biosimilar, (Ruxience), 10 mgQ5123Injection, nituximab-arrx, biosimilar, (Rabni), 10 mgQ5133Injection, rituximab-arrx, biosimilar, (Rabni), 10 mg	J2786	Injection, reslizumab (Cinqair), 1 mg
J3262Injection, tocilizumab (Actemra), 1 mgJ3358Ustekinumab, for intravenous injection, (Stelara), 1 mgJ3380Injection, vedolizumab (Entyvio), 1 mgJ3385Injection, vedolizumab (Entyvio), 1 mgJ3385Injection, vedolizumab (Keytruda), 1 mgJ9271Injection, pembrolizumab (Keytruda), 1 mgJ9312Injection, rituximab, (Rituxan)10 mgJ9299Injection, nivolumab (Opdivo), 1 mgQ5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5115Injection, infliximab-abda, biosimilar, (Renflexis), 10 mgQ5119Injection, rituximab-abbs, biosimilar, (Ruxience), 10 mgQ5121Injection, infliximab-apyt, biosimilar, (Axsola), 10 mgQ5123Injection, infliximab-arxx, biosimilar, (Riabini), 10 mgQ5133Injection, rituximab-arxx, biosimilar, (Riabini), 10 mg	J2840	Injection, sebelipase alfa (Kanuma), 1 mg
J3358Ustekinumab, for intravenous injection, (Stelara),1 mgJ3380Injection, vedolizumab (Entyvio), 1 mgJ3385Injection, velaglucerase alfa (Vpriv), 100 unitsJ9271Injection, pembrolizumab (Keytruda), 1 mgJ9312Injection, rituximab, (Rituxan)10 mgJ9299Injection, nivolumab (Opdivo), 1 mgQ5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5104Injection, rituximab-abda, biosimilar, (Renflexis), 10 mgQ5115Injection, Rituximab-abbs, biosimilar, (Ruxience), 10 mgQ5121Injection, infliximab-axaq, biosimilar, (Avsola), 10 mgQ5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg	J3247	Injection, secukinumab, IV (Costentyx), 1 mg
JaaaInjection, vedolizumab (Entyvio), 1 mgJ3380Injection, vedolizumab (Entyvio), 1 mgJ3385Injection, vedaglucerase alfa (Vpriv), 100 unitsJ9271Injection, pembrolizumab (Keytruda), 1 mgJ9312Injection, rituximab, (Rituxan)10 mgJ9299Injection, nivolumab (Opdivo), 1 mgQ5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5104Injection, infliximab-abda, biosimilar, (Renflexis), 10 mgQ5115Injection, rituximab-abbs, biosimilar, (Truxima), 10 mgQ5121Injection, nirfliximab-abbs, biosimilar, (Ruxience), 10 mgQ5123Injection, infliximab-arxq, biosimilar, (Avsola), 10 mgQ5133Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg	J3262	Injection, tocilizumab (Actemra), 1 mg
J3385Injection, velaglucerase alfa (Vpriv), 100 unitsJ9271Injection, pembrolizumab (Keytruda), 1 mgJ9312Injection, rituximab, (Rituxan)10 mgJ9299Injection, nivolumab (Opdivo), 1 mgQ5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5104Injection, infliximab-abda, biosimilar, (Renflexis), 10 mgQ5115Injection, rituximab-abbs, biosimilar, (Ruxience), 10 mgQ5121Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5123Injection, infliximab-axxq, biosimilar, (Avsola), 10 mgQ5133Injection, rituximab-arx, biosimilar, (Riabni), 10 mg	J3358	Ustekinumab, for intravenous injection, (Stelara),1 mg
J9271Injection, pembrolizumab (Keytruda), 1 mgJ9312Injection, rituximab, (Rituxan)10 mgJ9299Injection, nivolumab (Opdivo), 1 mgQ5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5104Injection, infliximab-abda, biosimilar, (Renflexis), 10 mgQ5115Injection, rituximab-abbs, biosimilar, (Truxima), 10 mgQ5119Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5121Injection, infliximab-axxq, biosimilar, (Rusience), 10 mgQ5123Injection, rituximab-arxx, biosimilar, (Riabni), 10 mgQ5133Injection, rituximab-arxx, biosimilar, (Riabni), 10 mg	J3380	Injection, vedolizumab (Entyvio), 1 mg
J9312Injection, rituximab, (Rituxan)10 mgJ9299Injection, nivolumab (Opdivo), 1 mgQ5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5104Injection, infliximab-abda, biosimilar, (Renflexis), 10 mgQ5115Injection, rituximab-abds, biosimilar, (Truxima), 10 mgQ5121Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5123Injection, infliximab-axxq, biosimilar, (Avsola), 10 mgQ5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg	J3385	Injection, velaglucerase alfa (Vpriv), 100 units
J9299Injection, nivolumab (Opdivo), 1 mgQ5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5104Injection, infliximab-abda, biosimilar, (Renflexis), 10 mgQ5115Injection, rituximab-abbs, biosimilar, (Truxima), 10 mgQ5119Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5121Injection, infliximab-axxq, biosimilar, (Avsola), 10 mgQ5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, rituximab-arry, biosimilar, (Riabni), 10 mg	J9271	Injection, pembrolizumab (Keytruda), 1 mg
Q5103Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mgQ5104Injection, infliximab-abda, biosimilar, (Renflexis), 10 mgQ5115Injection, rituximab-abbs, biosimilar, (Truxima), 10 mgQ5119Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5121Injection, infliximab-axxq, biosimilar, (Avsola), 10 mgQ5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, rituximab-arry, biosimilar, (Riabni), 10 mg	J9312	Injection, rituximab, (Rituxan)10 mg
Q5104Injection, infliximab-abda, biosimilar, (Renflexis), 10 mgQ5115Injection, rituximab-abbs, biosimilar, (Truxima), 10 mgQ5119Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5121Injection, infliximab-axxq, biosimilar, (Avsola), 10 mgQ5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg	J9299	Injection, nivolumab (Opdivo), 1 mg
Q5115Injection, rituximab-abbs, biosimilar, (Truxima), 10 mgQ5119Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5121Injection, infliximab-axxq, biosimilar, (Avsola), 10 mgQ5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg	Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5119Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mgQ5121Injection, infliximab-axxq, biosimilar, (Avsola), 10 mgQ5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg	Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121Injection, infliximab-axxq, biosimilar, (Avsola), 10 mgQ5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg	Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5123Injection, rituximab-arrx, biosimilar, (Riabni), 10 mgQ5133Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg	Q5119	Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mg
Q5133 Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg	Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg
	Q5123	Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg
Q5134 Injection, natalizumab-sztn (Tyruko), biosimilar, 1 mg	Q5133	Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg
	Q5134	Injection, natalizumab-sztn (Tyruko), biosimilar, 1 mg

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Definition of Terms

Admitted: A individual who is receiving inpatient services with a doctor's order.

Hospital-based outpatient/outpatient services: These services include emergency department services, intravenous drug infusion or injection, observation services, outpatient surgery, lab tests, or X-rays, or any other hospital services, and the doctor hasn't written an order to admit the individual to a hospital as an inpatient. The individual's status is considered outpatient even if the individual spends the night in the hospital.

Infusion services: A service that provides infusion of a drug that is delivered directly into the bloodstream of a individual through a vein, usually located in the arm or hand.

Infusion center (aka, infusion suite): A location where infusion services are provided and is independent of a hospital.

Inpatient services: Services provided when an individual is formally admitted to the hospital with a doctor's order.

Evidence Review

Consideration of Age

The age described in this policy for medical necessity of select intravenous and injectable therapy services is 13 years of age or older. The age criterion is based on the following: Pediatric individuals are not small adults. Pediatric individuals differ physiologically, developmentally, cognitively, and emotionally from adult individuals, and vary by age groups from infancy to teen. Children often require smaller doses than adults, lower infusion rates, appropriately sized equipment, the right venipuncture site determined by therapy and age, and behavioral management during administration of care. Specialty infusion training is therefore necessary for pediatric IV insertions and therapy. Due to pediatrics unique physiology and psychology, this policy is limited to individuals above the age of 13.



N/A

History

Date	Comments
03/10/16	New policy, add to Utilization Management section. Policy outlines medical necessity criteria for hospital-based infusion administration of drugs as specified; considered medically necessary ONLY when criteria are met. Policy effective July 1, 2016, pursuant to provider notification.
04/14/16	Coding update, HCPCS codes J0180, J0202, J0220, J0221, J0256, J0257, J0638, J1300, J1324, J1599, J1786, J2323, J2796 and J3060 removed from the policy; the drugs associated with the codes are not subject to review for site of service. Age criteria added: site of service review only applies to patients aged 13 years or older.
07/01/16	Interim Review, approved June 14, 2016. Coverage Guidelines updated and Definition of Terms clarified.
11/01/16	Interim Review, approved October 11, 2016. Clarified age criteria language indicating that site of service review is applicable to only those age 13 and older; drug criteria review applies to all ages. Added HCPCS code Q5102 to coding section.
03/01/17	Annual Review, approved February 14, 2017. Added "Aria" to Simponi to designate IV formulation.
06/20/17	Minor edit. Policy section and coding updated with Soliris.
09/01/17	Interim Review, approved August 15, 2017. Added Renflexis to coverage criteria and to the coding section.
11/01/17	Interim Review, approved October 3, 2017. Clarified site of service exception criterion related to access: There is no outpatient infusion center within 50 miles of the patient's home and there is no contracted home infusion agency that will travel to their home, or a hospital is the only place that offers infusions of this drug. Removed related policy 5.01.566; it does not have site of service review application.
11/21/17	Coding update, Removed HCPCS code J1560.
01/01/18	Coding update, Added HCPCS code J1555 (new code effective 1/1/18).



Date	Comments
02/14/18	Interim Review, approved February 13, 2018. Update hospital based outpatient coverage from 30 days to 90 days.
02/20/18	Coding update, Removed HCPCS code J1460.
04/01/18	Coding update, Added new HCPCS codes Q5103 and Q5104 (effective 4/1/18), noted that Q5102 terminated 4/1/18.
04/27/18	Coding updated, added HCPCS codes J1428, J0180, J0221, J1322, J1743, and J1786 that will be subject to review for site of service effective June 1, 2018.
06/01/18	Minor update; removed note and link to updated policy. Added Exondys 51 (eteplirsen) to list of agents. Added 5.01.570 to Related Policies.
06/21/18	Added 5.01.576 to Related Policies, added HCPCS code J3385 to policy.
11/01/18	Annual Review, approved October 19, 2018. Reorganized policy statements with minor edits for clarity only. No other changes made.
11/16/18	Minor update; clarifying edits were made to the "hospital-based outpatient setting" criteria.
01/01/19	Coding update, Added new HCPCS codes J0584, J9311, J9312, and Q5109 (new codes effective 1/1/19).
09/01/19	Annual Review, approved August 22, 2019, effective December 5, 2019. Added Cuvitru and Hyqvia to Immune Globulin Therapy policy for site of service. Added Ultomiris to C5 Compliment Inhibitors policy for site of service. Added Truxima to Rituximab: Non- oncologic and Miscellaneous Uses policy for site of service. Added HCPCS code J1303 for Ultomiris (new code effective 10/1/19) and added HCPCS code Q5115 for Truxima. Removed HCPCS Q5102 as it was terminated 4/1/18.
12/01/19	Interim Review, approved November 12, 2019, effective March 5, 2020. Added Ocrevus to Pharmacotherapy of Multiple Sclerosis policy for site of service.
12/12/19	Coding update, Added HCPCS code J3060.
01/01/20	Coding update, Removed HCPCS code J9310 as it was terminated 1/1/19.
07/01/20	Annual Review, approved June 18, 2020, effective October 2, 2020. Added Avsola and Ruxience (non-oncologic) to site of service policy under miscellaneous monoclonal antibodies and others. Changes to Avsola and Ruxience (non-oncologic) for site of service review are effective for dates of service on or after October 2, 2020, following 90-day provider notification. Added HCPCS codes Q5119 and Q5121.
10/01/20	Interim Review, approved September 8, 2020, effective January 1, 2021. Added site of service review for Tysabri (natalizumab) for dates of service on or after January 1, 2021. Added HCPCS J2323.
01/01/20	Interim Review, approved December 17, 2020. Removed Simponi from miscellaneous monoclonal antibodies and others (Simponi Aria remains) with change effective January 1, 2021. Carimune NF and GamaSTAN S/D removed from list of immune globulins with change effective January 1, 2021. Xembify added to the list of immune

Date	Comments
	globulins with change effective for dates of service on or after April 7, 2021, following provider notification. Added HCPCS code J1558. Removed HCPCS codes J9311 and Q5109.
05/01/21	Annual Review, approved April 22, 2021. Added site of service review for Vyondys 53 (golodirsen) for dates of service on or after August 6, 2021. Added HCPCS code J1429.
11/01/21	Interim Review, approved October 12, 2021. Added site of service review for Adakveo (crizanlizumab-tmca), Aldurazyme (laronidase), Amondys 45 (casimersen), Asceniv (immune globulin intravenous, human – slra), Cinqair (reslizumab), Cinryze (C1 esterase inhibitor [human]), Kanuma (sebelipase alfa), Stelara (ustekinumab) IV, Stelara (ustekinumab) SC, and Uplizna (inebilizumab-cdon) for dates of service on or after February 4, 2022. Added HCPCS codes J0598, J0791, J1426, J1554, J1823, J1931, J2786, J2840, J3357 and J3358.
04/01/22	Annual Review, approved March 8, 2022. Added site of service review for Keytruda (pembrolizumab) and for Opdivo (nivolumab) for dates of service on or after July 7, 2022. Added HCPCS codes J9271 and J9299.
05/01/22	Interim Review, approved April 25, 2022. Added site of service review for Nexviazyme (avalglucosidase alfa-ngpt) for dates of service on or after August 5, 2022. Added HCPCS code J0219.
06/01/22	Interim Review, approved May 23, 2022. Added site of service review for Infliximab (Janssen – unbranded) for dates of service on or after June 1, 2022.
08/01/22	Interim Review, approved July 12, 2022. Added site of service review for Cutaquig (immune globulin) for dates of service on or after November 4, 2022. Added HCPCS code J1551.
12/01/22	Interim Review, approved November 8, 2022. Added site of service review for Mepsevii (vestronidase alfa-vjbk) and Naglazyme (galsulfase) effective for dates of service on or after March 1, 2023. Added HCPC code J1458. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/23	Annual Review, approved June 26, 2023. No policy statement changes.
09/01/23	Coding update. Added HCPCS code Q5123. These policy updates are effective for dates of service on or after December 7, 2023, following a 90-day provider notification.
01/01/24	Interim Review, approved December 12, 2023. Added site of service review for Panzyga (immune globulin). Added HCPCS code J1576 for Panzyga. Removed HCPCS code J1562 as we no longer manage this code.
02/01/24	Annual Review, approved January 22, 2024. Updated medical policy number for Adakveo in policy.
03/01/24	Interim Review, approved February 26, 2024. Removed Stelara (ustekinumab) subcutaneous (SC) injection site of service requirement. The following policy changes are effective June 7, 2024: added site of service review for Skyrizi (risankizumab-rzaa)

Date	Comments
	intravenous (IV). Removed HCPCS code J3357 and added HCPCS code J2327. Changed name of medication for HCPCS code J1566 per pharmacy.
04/01/24	Interim Review, approved March 12, 2024. Added medical policy number to the miscellaneous monoclonal antibodies and others category. The following policy changes are effective July 4, 2024, following 90-day provider notification. Added Briumvi (ublituximab-xiiy) to Pharmacotherapy of Multiple Sclerosis policy for site of service. Added HCPCS code J2329 for Briumvi.
08/01/24	Interim Review, approved July 9, 2024. The following policy changes are effective November 1, 2024, following 90-day provider notification. Added Aralast NP, Glassia, Prolastin-C, and Zemaira to the Alpha-1 Proteinase Inhibitors policy for site of service. Added HCPCS codes J0256 and J0257.

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Language Assistance

<u>ATENCIÓN</u>: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-817-3056 (TTY: 711). 注意:如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 800-817-3056 (TTY: 711)。 <u>CHÚÝ</u>: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-817-3056 (TTY: 711). <u>주의</u>: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-817-3056 (TTY: 711) 번으로 전화해 주십시오. <u>BHИМАНИЕ</u>: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-817-3056 (телетайп: 711). <u>PAUNAWA</u>: Кипg nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Титаwag sa 800-817-3056 (TTY: 711). <u>УВАГА!</u> Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки.

Телефонуйте за номером 800-817-3056 (телетайп: 711).

<u>ملحوظة:</u> إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-817-3056 (رقم هاتف الصم والبكم: 711). <u>पिਆਨ ਦਿਉ</u>: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-817-3056 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ। <u>ACHTUNG</u>: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-817-3056 (TTY: 711). <u>ਪਿਨਕਾਹ</u>: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລຶການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມືພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-817-3056 (TTY: 711). <u>ATANSYON</u>: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-817-3056 (TTY: 711).

<u>ATTENTION</u> : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-817-3056 (ATS : 711). <u>UWAGA</u>: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-817-3056 (TTY: 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-817-3056 (TTY: 711).

<u>ATTENZIONE</u>: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-817-3056 (TTY: 711). توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با (TTY: 711) 800-817-3056 تس