LifeWise
Health Plan of Washington

UTILIZATION MANAGEMENT GUIDELINE – 11.01.523

Site of Service: Drugs and Biologic Agents

Effective Date:	**Nov. 6, 2026***
Last Revised:	Jul. 14, 2026
Replaces:	N/A

*Click here to view the current version.

RELATED MEDICAL POLICIES:

5.01.513	Omalizumab Products
5.01.536	Nulojix (belatacept) for Adults
5.01.550	Pharmacotherapy of Arthropathies
5.01.556	Rituximab: Non-oncologic and Miscellaneous Uses
5.01.558	Pharmacologic Treatment of High Cholesterol
5.01.559	IL-5 Inhibitors
5.01.563	Pharmacotherapy of Inflammatory Bowel Disorder
5.01.564	Pharmacotherapy of Miscellaneous Autoimmune Diseases
5.01.570	Pharmacologic Treatment of Duchenne Muscular Dystrophy
5.01.571	C5 Complement Inhibitors
5.01.576	Drugs for Rare Diseases
5.01.584	CGRP Inhibitors for Migraine Prophylaxis
5.01.587	Hereditary Angioedema
5.01.591	Immune Checkpoint Inhibitors
5.01.593	Pharmacologic Treatment of Transthyretin-Mediated Amyloidosis
5.01.596	Pharmacologic Treatment of Osteoporosis
5.01.616	Pharmacologic Treatment of Gout
5.01.624	Alpha-1 Proteinase Inhibitors
5.01.627	Thymic Stromal Lymphopoietin (TSLP) Inhibitors
5.01.629	Pharmacologic Treatment of Psoriasis
5.01.640	Pharmacologic Treatment of Sickle Cell Disease
5.01.644	Medical Pharmacologic Treatment of Multiple Sclerosis
8.01.503	Immune Globulin Therapy

The Site of Service Medical Necessity criteria within this policy DO NOT apply to Alaska fully-insured members; refer to the infusion and injection drug Medical Necessity criteria only.

Site of Service *and* the infusion and injection drug Medical Necessity criteria apply to all other plan members.

Please contact Customer Service for more information.

Select a hyperlink below to be directed to that section.

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EVIDENCE REVIEW | REFERENCES | HISTORY

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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. Drugs can also be given subcutaneously into the fatty tissue layer under the skin of an individual through an injection. This is called the subcutaneous, SC, SubQ, or SubC route. IV and SC injection therapy are used to treat and manage certain diseases and may be recommended by a doctor as part of a treatment approach for many disorders.

IV and SC injection 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 and SC injection 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 and SC injection therapy services. Individuals can also be given IV and SC injection therapy in their doctor's office or in their home through companies that specialize in these services and hire licensed nurses to deliver IV and SC injection 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

Site of Service (SOS) Medical Necessity criteria applies ONLY to medical benefit reviews. SOS Medical Necessity criteria does NOT apply to Alaska fully-insured members; refer to the infusion and injection drug Medical Necessity criteria only. Please contact Customer Service for more information.

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 Administration	Medical Necessity
Medically necessary sites of service • **Physician's office** • **Infusion center** • **Home infusion**	**IV infusion and injection therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost effective site:** • These are the preferred **medically necessary** sites of service for specified drugs.
Hospital-based outpatient setting • **Outpatient hospital IV infusion department** • **Hospital-based outpatient clinical level of care**	**IV infusion and injection therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost-effective site.** **This site is considered medically necessary for the first 90 days for the following:** • The initial course of infusion or injection of a pharmacologic or biologic agent **OR** • Re-initiation of an agent after 6 months or longer following discontinuation of therapy* * This does not include when standard dosing between infusions or injections is 6 months or longer **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 or injections 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 or injections, including any 1 of the following:** • Known cardiac condition (e.g., symptomatic cardiac arrhythmia) or pulmonary condition (e.g., significant respiratory disease, serious obstructive airway disease, %FVC less than or equal to 40%) that may increase the risk of an adverse reaction

Site of Service Administration	Medical Necessity

	• 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 or injection therapy
	• A known history of severe adverse drug reactions and/or anaphylaxis to prior treatment with a related or similar drug
	
	This site is considered medically necessary when the individual has cytokine release syndrome (CRS) and all the following are met:
	• CRS is grade 3 or 4 as evidenced by ALL the following:
	  ○ Temperature at least 38 °C
	  ○ Hypotension that requires 1 or more vasopressors
	  ○ Hypoxia that requires oxygen through a high-flow nasal cannula, face mask, non-rebreather mask, or Venturi mask OR positive pressure (continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, or mechanical ventilation)
	AND
	• The individual will be admitted into an inpatient setting as soon as possible

Hospital-based outpatient setting • **Outpatient hospital IV infusion department** • **Hospital-based outpatient clinical level of care**	**These sites are considered not medically necessary for infusion and injectable therapy services of various medical and biologic 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 / Biologic Agent	Medical Policy (see Related Policies above)
Anti-IgE Antibody • Omlyclo • Xolair	5.01.513 Omalizumab Products
Immunosuppressive • Nulojix	5.01.536 Nulojix (belatacept) for Adults
Miscellaneous Monoclonal Antibodies and Others • Actemra IV • Avsola • Avtozma IV • Benlysta IV • Cosentyx IV • Entyvio IV • Inflectra • Infliximab (Janssen – unbranded) • Orencia • Remicade • Renflexis • Riabni (non-oncologic) • Rituxan (non-oncologic) • Ruxience (non-oncologic) • Rystiggo • Saphnelo • Simponi Aria • Spevigo IV • Tofidence IV • Truxima (non-oncologic) • Tyenne IV • Tyruko • Tysabri • Uplizna • Vyvgart • Vyvgart Hytrulo • Zymfentra	5.01.550 Pharmacotherapy of Arthropathies 5.01.556 Rituximab: Non-oncologic and Miscellaneous Uses 5.01.563 Pharmacotherapy of Inflammatory Bowel Disorders 5.01.564 Pharmacotherapy of Miscellaneous Autoimmune Diseases 5.01.629 Pharmacologic Treatment of Psoriasis 5.01.645 Pharmacologic Treatment of Psoriatic Arthritis 5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies 5.01.652 Miscellaneous Pharmacologic Treatments of Psoriasis
Antilipemic Small Interfering Ribonucleic Acid (siRNA) Agent	5.01.558 Pharmacologic Treatment of High Cholesterol

Pharmacologic / Biologic Agent	Medical Policy (see Related Policies above)
• Leqvio	
IL-5 Inhibitors • Cinqair • Fasenra • Nucala	5.01.559 IL-5 Inhibitors
Interleukin-1β Blocker • Ilaris	5.01.564 Pharmacotherapy of Miscellaneous Autoimmune Diseases 5.01.616 Pharmacologic Treatment of Gout
Antisense Oligonucleotides • Amondys 45 • Exondys 51 • Vyondys 53	5.01.570 Pharmacologic Treatment of Duchenne Muscular Dystrophy
C5 Complement Inhibitors • Bkemv • Epysqli • Soliris • Ultomiris	5.01.571 C5 Complement Inhibitors
Drugs for Rare Diseases • Aldurazyme • Cerezyme • Crysvita • Elaprase • Elelyso • Fabrazyme • Givlaari • Kanuma • Lumizyme • Mepsevii • Naglazyme • Nexviazyme • Tepezza • Vimizim • Vpriv	5.01.576 Drugs for Rare Diseases
CGRP Inhibitors • Vyepti	5.01.584 CGRP Inhibitors for Migraine Prophylaxis
C1-Esterase Inhibitor • Cinryze	5.01.587 Hereditary Angioedema

Pharmacologic / Biologic Agent	Medical Policy (see Related Policies above)
Immune Checkpoint Inhibitors • **Keytruda** • **Keytruda Qlex** • **Imfinzi** • **Jemperli** • **Opdivo** • **Opdivo Qvantig** • **Tecentriq** • **Tecentriq Hybreza**	**5.01.591 Immune Checkpoint Inhibitors** **Note:** These drugs are subject to review for site of service administration except when it is used concurrently with other infusion or injection medications for cancer treatment.
Anti-Transthyretin Small Interfering Ribonucleic Acid (siRNA) Agent • **Amvuttra** • **Onpattro**	**5.01.593 Pharmacologic Treatment of Transthyretin-Mediated Amyloidosis**
Osteoporosis Drugs • **Evenity**	**5.01.596 Pharmacologic Treatment of Osteoporosis**
Alpha-1 Proteinase Inhibitors • **Aralast NP** • **Glassia** • **Prolastin-C** • **Zemaira**	**5.01.624 Alpha-1 Proteinase Inhibitors**
TSLP Inhibitor • **Tezspire**	**5.01.627 Thymic Stromal Lymphopoietin (TSLP) Inhibitors**
Sickle Cell Disease • **Adakveo**	**5.01.640 Pharmacologic Treatment of Sickle Cell Disease**
Multiple Sclerosis • **Briumvi** • **Ocrevus** • **Ocrevus Zunovo** • **Tyruko** • **Tysabri**	**5.01.644 Medical Pharmacologic Treatment of Multiple Sclerosis**
Immune Globulins • **Alyglo** • **Asceniv** • **Bivigam** • **Cutaquig**	**8.01.503 Immune Globulin Therapy**

Pharmacologic / Biologic Agent	Medical Policy (see Related Policies above)
• **Cuvitru** • **Flebogamma DIF** • **Gammagard** • **Gammaked** • **Gammaplex** • **Gamunex-C** • **Hizentra** • **Hyqvia** • **Octagam** • **Panzyga** • **Privigen** • **Qivigy** • **Xembify** • **Yimmugo**	

Coding

Code	Description
CPT	
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
J0222	Injection, patisiran (Onpattro), 0.1 mg
J0223	Injection, givosiran (Givlaari), 0.5 mg
J0225	Injection, vutrisiran (Amvuttra), 1 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

Code	Description
J0485	Injection, belatacept (Nulojix), 1 mg
J0490	Injection, belimumab (Benlysta), 10 mg
J0491	Injection, anifrolumab-fnia (Saphnelo), 1 mg
J0517	Injection, benralizumab (Fasenra), 1 mg
J0584	Injection, burosumab-twza (Crysvita) 1 mg
J0598	Injection, C-1 esterase inhibitor (human), Cinryze, 10 units
J0638	Injection, canakinumab (Ilaris), 1 mg
J0791	Injection, crizanlizumab-tmca (Adakveo), 5 mg
J1299	Injection, eculizumab (Soliris), 10 mg
J1303	Injection, ravulizumab-cwvz, (Ultomiris) 10 mg
J1306	Injection, inclisiran, (Leqvio) 1 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
J1552	Injection, immune globulin (alyglo), 500 mg
J1553	Injection, immune globulin (Yimmugo), 100 mg (new code effective 04/01/2026)
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

Code	Description
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 (code termed 01/01/26)
J1575	Injection, immune globulin/hyaluronidase (Hyqvia), 100 mg immunoglobulin
J1577	Injection, immune globulin (Qivigy), 100 mg
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
J1743	Injection idursulfase (Elaprase), 1 mg
J1745	Injection infliximab, excludes biosimilar (Remicade or Janssen unbranded), 10 mg
J1748	Injection, infliximab-dyyb (Zymfentra), 10 mg
J1786	Injection, imiglucerase (Cerezyme), 10 units
J1823	Injection, inebilizumab-cdon, (Uplizna) 1 mg
J1931	Injection, laronidase (Aldurazyme), 0.1 mg
J2182	Injection, mepolizumab (Nucala), 1 mg
J2323	Injection, natalizumab (Tysabri), 1 mg
J2329	Injection, ublituximab-xiiy (Briumvi), 1mg
J2350	Injection, ocrelizumab (Ocrevus), 1 mg
J2351	Injection, ocrelizumab (Ocrevus Zunovo), 1 mg and hyaluronidase-ocsq
J2356	Injection, tezepelumab-ekko (Tezspire), 1 mg
J2357	Injection, omalizumab (Xolair), 5 mg
J2786	Injection, reslizumab (Cinqair), 1 mg
J2840	Injection, sebelipase alfa (Kanuma), 1 mg
J3032	Injection, eptinezumab-jjmr (Vyepti), 1 mg
J3060	Injection, taliglucerase alfa (Elelyso), 10 units
J3111	Injection, romosozumab-aqqg (Evenity), 1 mg
J3241	Injection, teprotumumab-trbw (Tepezza), 10 mg

Code	Description
J3247	Injection, secukinumab, IV (Costentyx), 1 mg
J3262	Injection, tocilizumab (Actemra), 1 mg
J3380	Injection, vedolizumab (Entyvio), 1 mg
J3385	Injection, velaglucerase alfa (Vpriv), 100 units
J9022	Injection, atezolizumab (Tecentriq), 10 mg
J9024	Injection, atezolizumab (Tecentriq Hybreza), 5 mg and hyaluronidase-tqjs
J9173	Injection, durvalumab (Imfinzi), 10 mg
J9271	Injection, pembrolizumab (Keytruda), 1 mg
J9272	Injection, dostarlimab-gxly (Jemperli), 10 mg
J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph (new code effective 04/01/26)
J9289	Injection, -2mg and hyaluronidase-nvhy (Opdivo Qvantig)
J9299	Injection, nivolumab (Opdivo), 1 mg
J9312	Injection, rituximab, (Rituxan)10 mg
J9332	Injection, efgartigimod alfa-fcab (Vyvgart), 2 mg
J9333	Injection, rozanolixizumab-noli (Rystiggo), 1 mg
J9334	Injection, efgartigimod alfa (Vyvgart Hytrulo), 2 mg and hyaluronidase-qvfc
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5119	Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg
Q5123	Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg
Q5133	Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg
Q5134	Injection, natalizumab-sztn (Tyruko), biosimilar, 1 mg
Q5135	Injection, tocilizumab-aazg (Tyenne), biosimilar, 1 mg
Q5151	Injection, eculizumab-aagh (Epysqli), biosimilar, 2 mg
Q5152	Injection, eculizumab-aeeb (Bkemv), biosimilar, 2 mg
Q5154	Injection, omalizumab-igec (Omlyclo), biosimilar, 5 mg (new code effective 10/01/25)
Q5156	Injection, tocilizumab-anoh (Avtozma), biosimilar, 1 mg (new code effective 10/01/25)

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Related Information

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.

Injection services: A service that provides injection of a drug that is delivered directly into the bloodstream of a individual.

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.

2025 Update

Policy updated to indicate that Site of Service Medical Necessity criteria does not apply to Alaska fully-insured members pursuant to **Alaska HB 226** (accessed January 3, 2025). Added site of service review for Tyenne (tocilizumab-aazg) IV. Added an exception to the site-of-service requirements for certain individuals receiving treatment for cytokine release syndrome (CRS). Added site of service review for Tyenne (tocilizumab-aazg) IV. Updated policy title from "Site of Service: Infusion Drugs and Biologic Agents" to "Site of Service: Drugs and Biologic Agents." Clarified that the Site of Service Medical Necessity criteria can apply to injection drugs. Added site of service review for the following drugs: Evenity (romosozumab-aqqg), Fasenra (benralizumab), Ilaris (canakinumab), Imfinzi (durvalumab), Jemperli (dostarlimab-gxly), Nucala (mepolizumab), Ocrevus Zunovo (ocrelizumab-hyaluronidase-ocsq), Opdivo Qvantig (nivolumab-hyaluronidase-nvhy), Saphnelo (aninfrolumab-fnia), Tecentriq (atezolizumab), Tecentriq Hybreza (atezolizumab-hyaluronidase-tqjs), Tepezza (teprotumumab-trbw), Tezspire (tezepelumab-ekko), Vyepti (eptinezumab-jjmr), Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa-hyaluronidase-qvfc), Xolair (omalizumab), and Zymfentra (infliximab-dyyb). Added site of service review for Bkemv (eculizumab-aeeb) and Epysqli (eculizumab-aagh). Added site of service review for Avtozma (tocilizumab-anoh).

2026 Update

Added site of service review for Amvuttra (vutrisiran), Onpattro (patisiran), Yimmugo (immune globulin), Givlaari (givosiran), Leqvio (inclisiran), and Rystiggo (rozanolixizumab-noli). Added the following to Related Medical Policies: 5.01.558 Pharmacologic Treatment of High Cholesterol, 5.01.593 Pharmacologic Treatment of Transthyretin-Mediated Amyloidosis.

References

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).
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.

Date	Comments
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 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.

Date	Comments
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) 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

Date	Comments
	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.
09/01/24	Interim Review, approved August 13, 2024. The following policy changes are effective December 5, 2024, following 90-day provider notification. Added site of service review for Alyglo (immune globulin intravenous, human-stwk), Cosentyx IV (secukinumab), Spevigo IV (spesolimab-sbzo), Tofidence IV (tocilizumab-bavi), and Tyruko (natalizumab-sztn). Added HCPCS codes J1599, J1747, J3247, Q5133 and Q5134.
01/01/25	Coding update. Added new HCPCS code J1552.
02/01/25	Annual Review, approved January 27, 2025. Policy updated to indicate that Site of Service Medical Necessity criteria does not apply to Alaska fully-insured members; only Medical Necessity criteria for the infusion drug applies pursuant to Alaska HB 226 (link added). Removed site of service requirements from Stelara (ustekinumab) IV and Skyrizi (risankizumab-rzaa) IV. Added an exception to the site-of-service requirements for certain individuals receiving treatment for cytokine release syndrome (CRS). Removed HCPCS codes J2327 and J3358 for Skyrizi and Stelara. The following policy change is effective May 6, 2025, following 90-day provider notification. Added site of service review for Tyenne (tocilizumab-aazg) IV.
07/01/25	Interim Review, approved June 10, 2025. The following policy changes are effective October 3, 2025, following 90-day provider notification. Added site of service review for the following drugs: Evenity (romosozumab-aqqg), Fasenra (benralizumab), Ilaris (canakinumab), Imfinzi (durvalumab), Jemperli (dostarlimab-gxly), Nucala (mepolizumab), Ocrevus Zunovo (ocrelizumab-hyaluronidase-ocsq), Opdivo Qvantig (nivolumab-hyaluronidase-nvhy), Saphnelo (aninfrolumab-fnia), Tecentriq (atezolizumab), Tecentriq Hybreza (atezolizumab-hyaluronidase-tqjs), Tepezza (teprotumumab-trbw), Tezspire (tezepelumab-ekko), Vyepti (eptinezumab-jjmr), Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa-hyaluronidase-qvfc), Xolair (omalizumab), and Zymfentra (infliximab-dyyb). Updated policy title from "Site of Service: Infusion Drugs and Biologic Agents" to "Site of Service: Drugs and Biologic Agents." Clarified that the Site of Service Medical Necessity criteria can apply to injection drugs. Added the following HCPCS codes to represent the drugs added with this criteria update: J3111 (Evenity), J0517 (Fasenra), J0638 (Ilaris), J9173 (Imfinzi), J9272 (Jemperli), J2182 (Nucala), J2351 (Ocrevus Zunovo), J9622 (Opdivo Qvantig), J0491 (Saphnelo), J9022 (Tecentriq), J9024 (Tecentriq Hybreza), J3241 (Tepezza), J2356 (Tezspire), J3032 (Vyepti), J9332 (Vygart), J9334 (Vygart Hytrulo), J2357 (Xolair), and J1748 (Zymfentra).

Date	Comments
08/01/25	Interim Review, approved July 7, 2025. Added site of service review for Bkemv (eculizumab-aeeb) and Epysqli (eculizumab-aagh). Added new HCPCS codes Q5151 (Epysqli) and Q5152 (Bkemv).
10/01/25	Coding update. HCPCS code J1747 removed; this code is no longer reviewed for site of service.
11/01/25	Interim Review, approved October 13, 2025. Added site of service review for Avtozma (tocilizumab-anoh). Added new HCPCS code Q5156, effective November 1, 2025.
01/01/26	Coding update. Notated HCPCS code J1572 is termed effective January 1, 2026. Added HCPCS codes J1743 (Elaprase) and J9289 (Opdivo); these codes were effective for this policy June 1, 2018 and July 1, 2025, respectively, However, they were not listed on this policy, though they do appear on the specific policies as referenced in the criteria section.
04/01/26	Annual Review, approved March 10, 2026. The following policy changes are effective July 2, 2026, following 90-day provider notification. Added site of service review for Amvuttra (vutrisiran), Onpattro (patisiran), Yimmugo (immune globulin), Givlaari (givosiran), Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph), Leqvio (inclisiran), and Rystiggo (rozanolixizumab-noli). Added the following to Related Medical Policies: 5.01.558 Pharmacologic Treatment of High Cholesterol, 5.01.593 Pharmacologic Treatment of Transthyretin-Mediated Amyloidosis. Added HCPCS codes J0222 patisiran (Onpattro), J0223 givosiran (givlaari), J0225 vutrisiran (Amvuttra), J1306 inclisiran (Leqvio), J1553 immune globulin (Yimmugo), J9277 pembrolizumab, 1 mg and berahyaluronidase alfa-pmph, and J9333 rozanolixizumab-noli (Rystiggo).
07/14/26	Minor clarification made to history statement.
08/01/26	Interim Review, approved July 14, 2026. Added site of service review for Omlyclo (omalizumab-igec). Updated Related Medical Policy 5.01.513 Xolair (omalizumab) to 5.01.513 Omalizumab Products. The following policy changes are effective November 6, 2026, following 90-day provider notification. Added site of service review for Qivigy (immune globulin).

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

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benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.