

UTILIZATION MANAGEMENT GUIDELINE – 11.01.523

Site of Service: Infusion Drugs and Biologic Agents


Effective Date: Dec. 5, 2024
 Last Revised: Aug. 13, 2024
 Replaces: N/A

RELATED MEDICAL POLICIES:

5.01.536	Nulojix (belatacept) for Adults
5.01.550	Pharmacotherapy of Arthropathies
5.01.556	Rituximab: Non-oncologic and Miscellaneous Uses
5.01.559	IL-5 Inhibitors
5.01.563	Pharmacotherapy of Inflammatory Bowel Disorder
5.01.564	Pharmacotherapy of Miscellaneous Autoimmune Diseases
5.01.565	Pharmacotherapy of Multiple Sclerosis
5.01.570	Pharmacologic Treatment of Duchenne Muscular Dystrophy
5.01.571	C5 Complement Inhibitors
5.01.576	Drugs for Rare Diseases
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 Administration	Medical Necessity
Medically necessary sites of service <ul style="list-style-type: none"> Physician's office Infusion center Home infusion 	<p>IV infusion therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost effective site:</p> <ul style="list-style-type: none"> These are the preferred medically necessary sites of service for specified drugs.
Hospital-based outpatient setting <ul style="list-style-type: none"> Outpatient hospital IV infusion department Hospital-based outpatient clinical level of care 	<p>IV infusion therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost-effective site.</p> <p>This site is considered medically necessary for the first 90 days for the following:</p> <ul style="list-style-type: none"> The initial course of infusion of a pharmacologic or biologic agent <p>OR</p> <ul style="list-style-type: none"> Re-initiation of an agent after 6 months or longer following discontinuation of therapy* <p>Note: *This does not include when standard dosing between infusions is 6 months or longer</p>



Site of Service Administration	Medical Necessity
	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • Known cardiac condition (e.g., symptomatic cardiac arrhythmia) or pulmonary condition (e.g., significant respiratory disease, serious obstructive airway disease, %FVC \leq 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
<p>Hospital-based outpatient setting</p> <ul style="list-style-type: none"> • Outpatient hospital IV infusion department • Hospital-based outpatient clinical level of care 	<p>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.</p>

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)
C1-Esterase Inhibitor: <ul style="list-style-type: none"> Cinryze 	5.01.587 Hereditary Angioedema
Immune globulins: <ul style="list-style-type: none"> Alyglo Asceniv Bivigam Cutaquig Cuvitru Flebogamma DIF Gammagard Gammaked Gammaplex Gamunex-C Hizentra Hyqvia Octagam Panzyga Privigen Xembify 	8.01.503 Immune Globulin Therapy
IL-5 Inhibitor: <ul style="list-style-type: none"> Cinqair 	5.01.559 IL-5 Inhibitors
Immunosuppressive: <ul style="list-style-type: none"> Nulojix 	5.01.536 Nulojix (belatacept) for Adults
Miscellaneous monoclonal antibodies and others: <ul style="list-style-type: none"> Actemra Avsola Benlysta Cosentyx IV Entyvio Inflectra Infliximab (Janssen – unbranded) Orencia Remicade Renflexis 	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



Pharmacologic / Biologic Agent	Medical Policy (see Related Policies above)
<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Soliris • Ultomiris 	5.01.571 C5 Complement Inhibitors
Antisense Oligonucleotides <ul style="list-style-type: none"> • Amondys 45 • Exondys 51 • Vyondys 53 	5.01.570 Pharmacologic Treatment of Duchenne Muscular Dystrophy
Multiple sclerosis <ul style="list-style-type: none"> • Briumvi • Ocrevus • Tyruko • Tysabri 	5.01.565 Pharmacotherapy of Multiple Sclerosis
Drugs for rare diseases: <ul style="list-style-type: none"> • Aldurazyme • Cerezyme • Crysvida • Elaprase • Elelyso • Fabrazyme • Kanuma • Lumizyme • Mepsevii • Naglazyme • Nexviazyme • Vimizim • Vpriv 	5.01.576 Drugs for Rare Diseases



Pharmacologic / Biologic Agent	Medical Policy (see Related Policies above)
Immune Checkpoint Inhibitors <ul style="list-style-type: none"> • Keytruda • Opdivo 	5.01.591 Immune Checkpoint Inhibitors Note: Keytruda and Opdivo are subject to review for site of service administration except when it is used concurrently with other IV medications for cancer treatment.
Alpha-1 Proteinase Inhibitors <ul style="list-style-type: none"> • Aralast NP • Glassia • Prolastin-C • Zemaira 	5.01.624 Alpha-1 Proteinase Inhibitors
Sickle cell disease <ul style="list-style-type: none"> • Adakveo 	5.01.640 Pharmacologic Treatment of Sickle Cell Disease

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
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



Code	Description
J1743	Injection, idursulfase (Elaprase), 1 mg
J1745	Injection infliximab, excludes biosimilar (Remicade or Janssen unbranded), 10 mg
J1747	Injection, spesolimab-sbzo (Spevigo), 1 mg
J1786	Injection, imiglucerase (Cerezyme), 10 units
J1823	Injection, inebilizumab-cdon, (Uplizna) 1 mg
J1931	Injection, laronidase (Aldurazyme), 0.1 mg
J3060	Injection, taliglucerase alfa (Elelyso), 10 units
J2323	Injection, natalizumab (Tysabri), 1mg
J2327	Injection, risankizumab-rzaa, intravenous (Skyrizi), 1 mg
J2329	Injection, ublituximab-xiiy (Briumvi), 1mg
J2350	Injection, ocrelizumab (Ocrevus), 1 mg
J2786	Injection, reslizumab (Cinqair), 1 mg
J2840	Injection, sebelipase alfa (Kanuma), 1 mg
J3247	Injection, secukinumab, IV (Cosentyx), 1 mg
J3262	Injection, tocilizumab (Actemra), 1 mg
J3358	Ustekinumab, for intravenous injection, (Stelara),1 mg
J3380	Injection, vedolizumab (Entyvio), 1 mg
J3385	Injection, velaglucerase alfa (Vpriv), 100 units
J9271	Injection, pembrolizumab (Keytruda), 1 mg
J9312	Injection, rituximab, (Rituxan)10 mg
J9299	Injection, nivolumab (Opdivo), 1 mg
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-arrr, biosimilar, (Riabni), 10 mg
Q5133	Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg
Q5134	Injection, natalizumab-sztn (Tyruko), biosimilar, 1 mg

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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.

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.



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).



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 Complement 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-vjvk) 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.
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.

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). ©2024 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member 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.

