



Medication Policy Manual

Policy No: dru408

Topic: Site of Care Review

Date of Origin: July 10, 2015

Committee Approval Date: December 7, 2023

Next Review Date: 2024

Effective Date: January 15, 2024

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

Description

This policy is to review the requested site of care (SOC) for provider-administered medications. Many medications historically infused in hospital-based infusion centers have been evaluated and determined to be safe for infusion outside of hospital-based settings. Use of non-hospital-based infusion centers and home infusion services is an accepted standard medical practice and sometimes referred to as an “alternate site of care.” These settings offer high-quality services for patients and reduce the overall cost of care, as compared to costly hospital-based infusion centers.

This policy applies to fully-insured commercial and exchange plans, and the Washington State Health Care Authority (with the exception of Uniform Medical Plan Plus), based in Washington, Oregon, Idaho, and Utah. This policy may apply to other self-insured groups [a.k.a. administrative services only (ASO), depending on the group-specific benefit]. This policy does **not** apply to Medicare plans.

Policy/Criteria

I. Under most contracts, medications included in the infusion drug site of care program (see *Appendix 1*) may be considered medically necessary when individual medication policy criteria are met **AND** one of the following criterion A or B below are met:

A. The medication is administered in an approved site of care. (No formal “Site of Care” review is required)

OR

B. The medication is administered in an unapproved site of care (see *Appendix 2*), such as an unapproved hospital-based infusion center, when at least one of the criterion below (1, 2, or 3) are met:

NOTE: Site of care review criteria will be waived for payment of the initial dose(s) of a medication given during the first 30 days (starting from the date of the first dose) after the medication has been approved for pre-authorization, to allow for adequate transition time to an approved site of care for subsequent doses.

1. An approved site of care is not accessible to the member, as documented by criteria a **AND** b, being met:

a. The provider is not aware of an approved site of care that can administer the drug. Approved sites of care include, but are not limited to provider’s offices or ambulatory infusion sites.

AND

b. The member’s home is not eligible for home infusion services for reasons including, but not limited to: the home is not within the service area of the home infusion provider or is deemed unsuitable for care by the home infusion provider, unless the medication is not eligible for home infusion services (see *Appendix 1*).

OR

2. Clinical documentation of at least one long-term medical reason (specifically, medical conditions that will not change) why an approved site of care is not an option, including, but not limited to:

a. Significant behavioral issues and/or cognitive impairment including, but not limited to, those associated with developmental delay, down syndrome, dementia, or excessive anxiety such as severe needle phobia.

b. Prior severe infusion reactions, despite standard pre-medications.

c. Presence of circulating antibodies which may increase risk of infusion reactions.

d. Documented difficult IV access.

e. Treatment of Kawasaki disease.

OR

3. Clinical documentation of at least one short-term medical reason (specifically, medical conditions/rationale that will change with time) why an approved site of care is not an option, including, but not limited to:

- a. The member less than 14 years of age.
- b. Treatment within 100 days after hematopoietic stem cell transplantation (HSCT, a.k.a. bone marrow transplant).
- c. Concurrent treatment with medications that require a higher level of monitoring (such as CAR T-cell therapy, intravenous cytotoxic chemotherapy, or blood products).
- d. Treatment of antibody-mediated rejection (a.k.a. vascular rejection, acute humoral rejection) following a solid organ transplant.
- e. Acute treatment of vision changes (or high-risk of, based on disease stated).

II. Limitations and Authorization Period.

- A. For exceptions approved under criterion I.B.1. above (**no known approved sites of care and no home infusion option**), authorization **shall** be reviewed at least annually to confirm that current medical necessity criteria are met, including that an approved site of care is still not a treatment option.
- B. For exceptions approved under criteria I.B.2. above (**long-term medical reason**), authorization **may** be reviewed at least annually to confirm that current medical necessity criteria are met, including that an approved site of care is still not a treatment option.
- C. For exceptions approved under criteria I.B.3. above (**short-term medical reason**), authorization will be as follows:

Medical reason	Authorization Period	Reauthorization of the SOC exception
Member is less than 14 years of age	Until date member turns 14 years of age	None. Any request after the 14 th birthday will be subject to a new, full Site of Care Exception review.
Treatment within 100 days after HSCT	100 days, based on the date of HSCT	None. Any extension will be subject to a new, full Site of Care Exception review, based on the criteria listed in I.B.2.
Concurrent treatment with medications that require a higher level of monitoring	6 months	Authorization shall be reviewed at least every 6 months to confirm that current medical necessity criteria are met, including that an approved site of care is still not a treatment option.
Treatment of antibody-mediated rejection	6 months	None. Any additional treatment course will be subject to a new, full Site of Care Exception review.
Acute treatment of vision changes	3 months	None. Any additional treatment course will be subject to a new, full Site of Care Exception review.
Other short-term medical reason	3 months	Authorization shall be reviewed at least every 3 months to confirm that current medical necessity criteria are met, including that an approved site of care is still not a treatment option.

- III.** The medications in the infusion drug site of care program are considered not medically necessary if administered in an unapproved site of care, such as an unapproved hospital-based infusion center, when an approved site of care (e.g., physical sites or home infusion) is a treatment option.

Position Statement

- New pharmaceuticals requiring infusion therapy, may be administered safely, effectively, and much less costly outside of hospital-based infusion centers (a.k.a. hospital outpatient settings). Sites of care such as doctor's offices, infusion centers, home infusion, and approved hospital-based infusion centers are well-established, accepted by physicians, and provide the best value to patients to reduce the overall cost of care.
- A site of care exception for an infusion at an unapproved site of care location must be requested by the provider and reviewed by the health plan prior to administration of the infused medication, per the terms of the member contract with the health plan.

Site of Care Review:

- Use of non-hospital-based infusion centers and home infusion services is an accepted standard medical practice. These sites offer high-quality services for patients and reduce the overall cost of care, as compared to costly hospital-based infusion centers. [1-8]
- All medications infused outside of a hospital setting have undergone an evaluation for safe infusion and development of infusion standards, including adverse drug reaction management and reporting algorithms.
- At all sites of care, every patient undergoes an assessment during the intake process by the infusion provider, which includes evaluation of individual clinical assessment parameters. These parameters may include, but are not limited to, previous tolerance of products (such as IVIG), assessment of kidney function, risk factors for developing thromboembolic events, and venous access. [9-10]
- For use of home infusion services, an assessment is conducted to determine if the home is a safe, appropriate site of care, with adequate support for infusion in the home.
- Because providers need time to arrange for assessment and coordination of care, the first dose of provider-administered medications may be covered in a hospital-based infusion center, if needed, to allow adequate time for a seamless transition of care. This may include arranging for delivery of medications, appointment scheduling, and/or patient education, such as for self-administration of medications such as subcutaneous immune globulin (SCIG).
- Claims submitted for infusion services performed at an unapproved site of care, such as an unapproved hospital-based infusion center (such as on-campus or off-campus hospital outpatient settings, denoted by place of service codes 22 or 19; see *Appendix 3*), are considered not medically necessary when an approved site of care is a treatment option or when preauthorization for the unapproved site of care had not been requested for review. This is waived for claims given during the first 30 days (starting from the date of the first dose) after the medication has been approved for pre-authorization, to allow for adequate transition time to an approved site of care for subsequent doses.

- Pediatric patients often differ from adult patients in physiology, development, and cognitive and emotional function. They may also require doses, infusion rates, and equipment that vary and differ compared to adult patients. Special infusion training and expertise is needed. Therefore, this policy allows for patients under 14 years to obtain infusion services in approved sites of care or unapproved sites of care, such as unapproved hospital-based infusion centers.
- Clinical criteria considered for site of care exception review, aside from young age, include long-term and short-term medical reasons. Long-term medical reasons are not expected to change with time, such as behavioral issues or infusion reactions to the specific drug. Short-term medical reasons for a site of care exception would change over time; therefore, short-term medical reason requests would be re-reviewed as outlined by the authorization periods defined above in Section II.C.

Appendix 1: Medications Included in the Infusion Drug Site of Care Program

Medication	Effective Date	Policy Number	Home infusion eligible ^b	HCPCS Code
Actemra, tocilizumab ^a	3/1/2015	dru444, dru900 (UMP)	Yes	J3262
Adakveo, crizanlizumab-tmca	5/15/2020	dru628	Yes	J0791
Aldurazyme, laronidase	4/1/2016	dru426	Yes	J1931
Asceniv, immune globulin	10/1/2019	dru020	Yes	J1554
Avsola, infliximab-axxq	1/1/2021	dru620	Yes	Q5121
Bivigam, immune globulin	3/1/2015	dru020	Yes	J1556
Briumvi-xiiy, ublituximab-xiiy	4/15/2023	dru753, dru907 (UMP)	Yes	J2329
Carimune NF, immune globulin	3/1/2015	dru020	Yes	J1566
Cerezyme, imiglucerase	4/1/2017	dru649	Yes	J1786
Cimzia, certolizumab pegol ^a	1/1/2017	dru444, dru900 (UMP)	Yes	J0717
Cinqair, reslizumab	1/1/2022	dru538	Yes	J2786
Cutaquig, immune globulin	10/1/2019	dru020	Yes	J1551
Cuvitru, immune globulin	9/15/2016	dru020	Yes	J1555
Elaprase, idursulfase	4/1/2016	dru426	Yes	J1743
Elfabrio, pegunigalsidase alfa-iwxj	1/1/2024	dru575	Yes	No code
Entyvio, vedolizumab	7/10/2015	dru444, dru900 (UMP)	Yes	J3380
Evenity, romosozumab-aqqg	10/1/2019	dru612	Yes	J3111
Fabrazyme, agalsidase beta	7/1/2015	dru575	Yes	J0180
Fasenra, benralizumab ^a	1/1/2022	dru538	Yes	J0517
Flebogamma, immune globulin	3/1/2015	dru020	Yes	J1572
Gammagard, immune globulin	3/1/2015	dru020	Yes	J1569
Gammagard S/D, immune globulin	3/1/2015	dru020	Yes	J1566
Gammaked, immune globulin	3/1/2015	dru020	Yes	J1561
Gammaplex, immune globulin	3/1/2015	dru020	Yes	J1557

Medication	Effective Date	Policy Number	Home infusion eligible ^b	HCPCS Code
Gamunex/Gamunex-C, immune globulin	3/1/2015	dru020	Yes	J1561
Hizentra, immune globulin	3/1/2015	dru020	Yes	J1559
Hyqvia, immune globulin	3/1/2015	dru020	Yes	J1575
Immune globulin (IVIG, SCIG)	3/1/2015	dru020	Yes	J1459, J1555, J1556, J1557, J1559, J1561, J1566, J1568, J1569, J1572, J1575, J1599
Inflectra, infliximab-dyyb	1/1/2017	dru620	Yes	Q5103
Ixifi, infliximab-qbtx	10/1/2018	dru620	Yes	Q5109
Kanuma, sebelipase alfa	6/10/2016	dru426	Yes	J2840
Leqvio, inclisiran	6/1/2022	dru697	Yes	J1306
Lumizyme, alglucosidase alfa	7/1/2015	dru426	Yes	J0221
Nexviazyme, avalglucosidase alfa-ngpt	1/1/22	dru426	Yes	J0219
Nucala, mepolizumab ^a	1/1/2022	dru538	Yes	J2182
Ocrevus, ocrelizumab	9/1/2018	dru753, dru902 (UMP)	Yes	J2350
Octagam, immune globulin	3/1/2015	dru020	Yes	J1568
Orencia, abatacept ^a	3/1/2015	dru444, dru900 (UMP)	Yes	J0129
Panzyga, immune globulin	9/1/2018	dru020	Yes	J1599, J1576
Privigen, immune globulin	3/1/2015	dru020	Yes	J1459
Radicava IV, edaravone ^a	8/11/2017	dru510	Yes	J1301
Reblozyl, luspatercept	5/15/2020	dru631	Yes	J0896
Remicade, infliximab	3/1/2015	dru620	Yes	J1745
Renflexis, infliximab-abda	8/11/2017	dru620	Yes	Q5104
Rystiggo (rozanolixizumab),	1/15/2024	dru696	Yes	No code
Saphnelo, anifrolumab-fnia	1/1/2022	dru688	Yes	J0491
Simponi Aria, golimumab ^a	3/1/2015	dru444, dru900 (UMP)	Yes	J1602
Soliris, eculizumab	5/1/2015	dru385	Yes	J1300
Tepezza, teprotumumab-trbw	5/15/2020	dru632	Yes	J3241
Ultomiris, ravulizumab-cwvz	7/1/2019	dru385	Yes	J1303
Uplizna, inebilizumab- cdon	1/1/2021	dru657	Yes	J1823
VPRIV, velaglucerase alfa	4/1/2017	dru649	Yes	J3385
Vyepti, eptinezumab	1/1/2022	dru540	Yes	J3032
Vyvgart, efgartigimod	7/15/2022	dru696	Yes	J9332
Vyvgart Hytrulo, efgartigimod alfa and hyaluronidase-qvfc	1/1/2024	dru696	Yes	No code
Vyjuvek, beremagene geperpavec-svdt	1/1/2024	dru759	Yes	No code
Xembify, immune globulin	5/15/2020	dru020	Yes	J1558
Xolair, omalizumab ^a	1/1/2022	dru538	Yes	J2357

^a This policy only applies to the formulations of these medications covered under the medical benefit.

Formulations for self-administration may be available through the pharmacy benefit for most members.

^b As of the date of the policy publication.

Appendix 2: Glossary

Term	Description
Approved site of care	<p>Location where medications are safely and effectively administered by a health care professional.</p> <p>Approved sites of care include:</p> <ul style="list-style-type: none"> • Doctor’s offices • Standalone ambulatory infusion centers • Home infusion • Approved hospital-based infusion centers
Unapproved site of care	<p>Location where medications are administered by a professional and the facility is reimbursed for the medication and services at a much higher rate than approved sites of care.</p> <p>Unapproved sites of care include:</p> <ul style="list-style-type: none"> • Unapproved hospital-based infusion centers (denoted by place of service codes 22 or 19; see <i>Appendix 3</i>)

Appendix 3: Place of Service Codes and Descriptions ^[11]

Place of Service Code	Place of Service Name	Description
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
12	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence.
19	Off Campus-Outpatient Hospital	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
22	On Campus-Outpatient Hospital	A portion of a hospital’s main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

References

1. Home Infusion Therapy, CMT: CMT-0009(SR). MCG Care Guidelines, 20th edition, 2016.
2. ASHP Guidelines on Home Infusion Pharmacy Services, 2013.
<http://www.ashp.org/doclibrary/bestpractices/settingsgdlhomeinfusion.aspx>.
3. Polinski JM, Kowal MK, Gagnon M, et al. Home infusion: safe clinically effective, patient preferred, and cost saving. *Healthcare*. 2016.
4. Condino AA, Fidanza S, Hoffenberg EJ. A home infliximab infusion program. *J Pediatr Gastroenterol Nutr*. 2005 Jan;40(1):67-9. PMID: 15625429
5. Ducharme J, Pelletier C, Zacharias R. The safety of infliximab infusions in the community setting. *Can J Gastroenterol*. 2010 May;24(5):307-11. PMID: 20485705
6. Foley JF, Dunne AM. Successful management of a neurology infusion practice. *Int J MS Care*. 2011 Summer;13(2):95-104. PMID: 24453711
7. Ratko TA, Marbella A, Godfrey S, Aronson N. Enzyme-Replacement Therapies for Lysosomal Storage Diseases. Agency for Healthcare Research and Quality Comparative Effectiveness Technical Briefs. 2013 Jan. Report No. 12(13)-EHC154-EF. PMID: 23390670
8. Scarpa M, Alamássy Z, Beck M, et al. Mucopolysaccharidosis type II: European recommendations for the diagnosis and multidisciplinary management of a rare disease. *Orphanet J Rare Dis*. 2011 Nov 7;6:72. PMID: 22059643
9. American Academy of Allergy Asthma and Immunology. Guidelines for the site of care for administration of IGIV therapy. 2011 Dec.
10. Souayah N, Hasan A, Khan HM, et al. The safety profile of home infusion of intravenous immunoglobulin in patients with neuroimmunologic disorders. *J Clin Neuromuscul Dis*. 2011 Jun;12 Suppl 4:S1-10. PMID: 22361589
11. Centers for Medicare & Medicaid Services Place of Service Code Set.
https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html.

Revision History

Revision Date	Revision Summary
12/7/2023	Added Rystiggo (rozanolixizumab) to policy.
9/14/2023	Added Elfabrio (pegunigalsidase alfa-iwxj), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), and Vyjuvek (beremagene geperpavec-svdt) to policy.
6/15/2023	Updated policy numbers in Appendix 1 for Briumvi (ublituximab-xiiy) and Ocrevus (ocrelizumab) for new combination policy dru753 (effective 9/1/2023).
3/16/2023	Added Briumvi-xiiy, ublituximab-xiiy to policy effective 4/15/2023.
12/9/2022	<ul style="list-style-type: none"> • Modified status of administrative services only (ASO) groups. • Updated HCPCS codes in Appendix 1. • Removed the following medications from the policy (effective 1/15/2023): Crysvida (burosumab-twza), Elelyso (taliglucerase alfa), Naglazyme (galsulfase), Onpattro (patisiran), Revcovi (elapegademase-lvlr), and Vimizim (elosulfase alfa).
6/17/2022	<ul style="list-style-type: none"> • Added Vyvgart (efgartigimod) to policy effective 7/15/2022. • Updated HCPCS and policy numbers in Appendix 1.
3/18/2022	Added Leqvio (inclisiran) to policy (effective 6/1/2022).
10/15/2021	<ul style="list-style-type: none"> • Added Xolair, Vyepeti, Cinqair, Nucala, Fasentra, and Saphnelo to policy effective 1/1/2022. • Clarified policy criteria. No changes to intent of criteria. • Updated dru policy numbers as needed. • Updated HCPCS code for Adakveo. • Added UMP policy numbers.
7/16/2021	<p>Effective 8/15/2021:</p> <ul style="list-style-type: none"> • Updated the lines of business impacted by this program. • Updated access requirements for administration at non-approved sites of care (Criteria B.1.). • Removed Adagen (pegademase bovine), Myozyme (alglucosidase alfa), Prolia (denosumab), and Tysabri (natalizumab) from program.
10/28/2020	<ul style="list-style-type: none"> • Added Avsola (infliximab-axxq) and Uplizna (inebilizumab) to policy (effective 1/1/2021). • Clarified policy criteria. No changes to intent of criteria. • Updated dru policy numbers as needed.
7/22/2020	<ul style="list-style-type: none"> • Removed Trogarzo (ibalizumab-uiyk) from policy (effective 8/15/20). • Trogarzo policy to be archived effective 8/15/2020.
6/1/2020	<ul style="list-style-type: none"> • Updated Appendix 1 with correct effective dates and HCPCS codes.
4/22/2020	<ul style="list-style-type: none"> • Added Adakveo (crizanlizumab), Reblozyl (luspatercept), and Tepezza (teprotumumab-trbw) to the policy.

Revision Date	Revision Summary
1/22/2020	<ul style="list-style-type: none"> • Clarified situations where no SOC review is needed. • Added medical exception criteria for acute treatment of vision-threatening disease. • Updated exception authorization periods.
7/24/2019	Added Crysvida (burosumab) and Evenity (romosozumab) to the policy.
4/25/2019	Added Revcovi (elapegademase) and Ultomiris (ravulizumab) to the policy.
1/31/2019	<ul style="list-style-type: none"> • Added Onpattro (patisiran) to the policy, effective 4/1/2019. • Updated Appendix 1 HCPCS codes.
8/17/2018	No criteria changes on this annual review.
6/15/2018	<ul style="list-style-type: none"> • Clarified home infusion criteria I.B.1.b only applies to medications eligible for home infusion. • Updated Appendix 1 to include home infusion eligibility.
5/18/2018	<ul style="list-style-type: none"> • No change to intent of coverage criteria. Clarification of description, policy language, and addition of applicable J-codes. Defined approved and unapproved sites of care. • Added the following medications to the policy: <ul style="list-style-type: none"> ○ Effective 6/1/2018: Trogarzo (ibalizumab-uiyk). ○ Effective 9/1/2018: Elelyso (taliglucerase alfa), Ocrevus (ocrelizumab). ○ Effective 10/1/2018: Ixifi (infliximab-qbtx). • Clarified medical exception criteria for concurrent cancer immunotherapy, including CAR T-cell therapy, and age less than 13 years old.
8/11/2017	Updated Appendix 1.
1/17/2017	Removed Lemtrada and Exondys from site of care program.
12/16/2016	Updated Appendix 1.
11/11/2016	Updated Appendix 1.
9/23/2016	Updated Appendix 1.
9/9/2016	Select Utah plans are now included in the site of care review.
7/15/2016	Updated formatting of policy, added additional medical rationale for potential waivers to policy, noted distinction between approved and unapproved hospital outpatient settings, clarified affected members, and updated references.

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