



Oregon and Utah



Idaho and select counties of Washington

Independent licensees of the Blue Cross and Blue Shield Association

**Medication Policy Manual**

**Policy No:** dru408

**Topic:** Site of Care Review

**Date of Origin:** July 10, 2015

**Committee Approval Date:** July 24, 2019

**Next Review Date:** July 2020

**Effective Date:** October 1, 2019

**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 plans, exchange plans, and select self-insured groups [a.k.a. administrative-services only (ASO)] based in Washington, Oregon, Idaho, and Utah. This policy does **not** apply to Medicare plans.

**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**

The purpose of medication policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

## 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 criteria (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 criteria below (1. or 2.) are met:

**NOTE:** Site of care review criteria will be waived for payment of the first dose of a medication, to allow for adequate transition time to an approved site of care for subsequent infusions.

1. There is no nearby approved site of care **AND** home infusion is not an option, as documented by criteria a. **AND** b. being met:
  - a. All approved sites of care are greater than 10 miles further from the member’s home than from the unapproved site of care, such as an unapproved hospital-based infusion center (example: the member’s house is 41 miles from an approved site of care, but 30 miles to the unapproved site of care).

**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 medical reason why an approved site of care is not an option, including, but not limited to:
  - i. The member is 13 years of age or younger.
  - ii. 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.
  - iii. Prior severe infusion reactions, despite standard pre-medications.
  - iv. Presence of circulating antibodies which may increase risk of infusion reactions.
  - v. Treatment within 100 days after hematopoietic stem cell transplantation (HSCT, a.k.a. bone marrow transplant).

- vi. Concurrent treatment with medications that require a higher level of monitoring (such as CAR T-cell therapy, intravenous cytotoxic chemotherapy, or blood products).
- vii. Treatment of antibody-mediated rejection (a.k.a. vascular rejection, acute humoral rejection) following a solid organ transplant.
- viii. Treatment of Kawasaki disease.

**II.** Limitations and Authorization Period – 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.

**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 is a treatment option.

### **Position Statement**

- New technologies and pharmaceuticals allow therapeutic services, such as infusion therapy, to 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.

### **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 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.
- 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 aged 13 years and younger to obtain infusion services in approved sites of care or unapproved sites of care, such as unapproved hospital-based infusion centers.

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

Medication <sup>a</sup>	Effective Date	Policy Number	Home infusion eligible <sup>b</sup>	HCPCS Code
Actemra, tocilizumab <sup>a</sup>	3/1/2015	dru444	Yes	J3262
Adagen, pegademase bovine	4/1/2016	dru426	Yes	J2504
Aldurazyme, laronidase	4/1/2016	dru426	Yes	J1931
Benlysta, belimumab	9/1/2015	dru248	Yes	J0490
Cerezyme, imiglucerase	4/1/2017	dru002	Yes	J1786
Cimzia, certolizumab pegol <sup>a</sup>	3/1/2018	dru444	Yes	J0717
Crysvita, burosomab	11/1/2019	dru547	Yes	J0584
Elaprase, idursulfase	4/1/2017	dru426	Yes	J1743
Elelyso, taliglucerase alfa	9/1/2018	dru002	Yes	J3060
Entyvio, vedolizumab	3/1/2015	dru444	Yes	J3380
Evenity, romosozumab	10/1/2019	dru594	Yes	J3590
Fabrazyme, agalsidase beta	7/1/2015	dru575	Yes	J0180
Inflectra, infliximab-dyyb	1/1/2017	dru444	Yes	Q5103
Immune globulin	3/1/2015	dru020	Yes	J1459, J1555, J1556, J1557, J1559, J1561, J1566, J1568, J1569, J1572, J1575, J1599
Ixifi, infliximab-qbtx	10/1/2018	dru444	Yes	Q5109
Kanuma, sebelipase alfa	6/10/2016	dru426	Yes	J2840
Lumizyme, alglucosidase alfa	7/1/2015	dru426	Yes	J0221
Myozyme, alglucosidase alfa	7/1/2015	dru426	Yes	J0220
Naglazyme, galsulfase	4/1/2016	dru426	Yes	J1458
Ocrevus, ocrelizumab	9/1/2018	dru479	Yes	J2350
Onpattro, patisiran	4/1/2019	dru577	Yes	C9036
Orencia, abatacept <sup>a</sup>	3/1/2015	dru444	Yes	J0129
Prolia, denosumab	7/1/2015	dru223	Yes	J0897
Radicava, edaravone	8/11/2017	dru510	Yes	J1301
Remicade, infliximab	3/1/2015	dru444	Yes	J1745
Renflexis, infliximab-abda	8/11/2017	dru444	Yes	Q5104
Revcovi, elapeademase	4/1/2019	dru426	Yes	J3590
Simponi Aria, golimumab <sup>a</sup>	3/1/2015	dru444	Yes	J1602
Soliris, eculizumab	5/1/2015	dru385	Yes	J1300
Trogarzo, ibalizumab-uiyk	6/1/2018	dru542	Yes	J1746

<b>Medication <sup>a</sup></b>	<b>Effective Date</b>	<b>Policy Number</b>	<b>Home infusion eligible <sup>b</sup></b>	<b>HCPCS Code</b>
Tysabri, natalizumab	5/1/2015	dru111	No	J2323
Ultomiris, ravulizumab	7/1/2019	dru385	Yes	J3590
Vimizim, elosulfase alfa	4/1/2016	dru426	Yes	J1322
VPRIV, velaglucerase alfa	4/1/2017	dru002	Yes	J3385

<sup>a</sup> 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.

<sup>b</sup> As of the date of the policy publication

<b>Appendix 2: Glossary</b>	
<b>Term</b>	<b>Description</b>
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"> <li>• Doctor's offices</li> <li>• Standalone ambulatory infusion centers</li> <li>• Home infusion</li> <li>• Approved hospital-based infusion centers</li> </ul>
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"> <li>• Unapproved hospital-based infusion centers</li> </ul>

**Appendix 3: Place of Service Codes and Descriptions <sup>[11]</sup>**

<b>Place of Service Code</b>	<b>Place of Service Name</b>	<b>Description</b>
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**

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*Revision History*

Revision Date	Revision Summary
7/24/2019	<ul style="list-style-type: none"> <li>Added Crysvita (burosumab) and Evenity (romosozumab) to the policy.</li> </ul>
4/25/2019	<ul style="list-style-type: none"> <li>Added Revcovi (elapegademase) and Ultomiris (ravulizumab) to the policy.</li> </ul>
1/31/2019	<ul style="list-style-type: none"> <li>Added Onpattro (patisiran) to the policy, effective 4/1/2019.</li> <li>Updated Appendix 1 HCPCS codes.</li> </ul>
8/17/2018	<ul style="list-style-type: none"> <li>No criteria changes on this annual review.</li> </ul>
6/15/2018	<ul style="list-style-type: none"> <li>Clarify home infusion criteria I.B.1.b only applies to medications eligible for home infusion.</li> <li>Updated Appendix 1, to include home infusion eligibility.</li> </ul>
5/18/2018	<ul style="list-style-type: none"> <li>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.</li> <li>Added the following medications to the policy:               <ul style="list-style-type: none"> <li>Effective 6/1/2018: Trogarzo (ibalizumab-uiyk)</li> <li>Effective 9/1/2018: Elelyso (taliglucerase alfa), Ocrevus (ocrelizumab)</li> <li>Effective 10/1/2018: Ixifi (infliximab-qbtx)</li> </ul> </li> <li>Clarified medical exception criteria for concurrent cancer immunotherapy, including CAR T-cell therapy, and age less than 13 years old.</li> </ul>
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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