Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH030.0826	**MISCELLANEOUS PRODUCTS INFUSION THERAPY SITE OF CARE**
Effective Date: 10/1/2026	**Review/Revised Date**: 11/19, 02/20, 05/20, 09/20, 08/21, 03/22, 08/22, 09/22, 07/23, 07/24, 12/24, 03/25, 07/25, 09/25, 11/25, 07/26 (JWL)
Original Effective Date: 01/20	**P&T Committee Meeting Date**: 10/19, 12/19, 04/20, 06/20, 08/20, 10/21, 04/22 (cv), 06/22, 08/22, 10/22, 08/23, 08/24. 02/25, 04/25, 08/25, 10/25, 12/25, 07/26 (cv), 08/26
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial

Definitions:
1. **Site of Care** – the physical location where the infusion therapy is administered (such as an inpatient hospital, outpatient hospital-based infusion center, stand-alone infusion center, healthcare provider's office, or home infusion)
2. **Alternative Site of Care** – any outpatient infusion site of care outside of an outpatient hospital-based infusion center (such as provider's office or home infusion service providers
3. **Approved Site of Care** - alternative sites of care or approved hospital-based infusion centers
4. **Unapproved Site of Care** – any site of care that has been deemed as medically unnecessary, including unapproved hospital-based infusion centers that increase the cost of care compared to approved sites of care

POLICY CRITERIA:

COVERED USES:
The Company requires the infusion of certain medications (see Table 1) to be administered at an approved site of care, when an unapproved hospital-based infusion setting is determined to be no longer medically necessary.

REQUIRED MEDICAL INFORMATION:
1. Prior authorization for the medication must be obtained, if necessary. Refer to individual drug specific policies for clinical criteria.
    a. For medications that require prior authorization for clinical criteria, the approval or denial of administration in an unapproved hospital outpatient setting is not indicative of approval or denial of the prior authorization for the medication based on clinical criteria.

2. The unapproved hospital-based outpatient infusion center may be considered medically necessary if one of the following criteria is met:
    a. The patient has concomitant conditions or clinical history that may increase the risk of infusion reactions or drug specific adverse events, defined as one of the following:
        i. Recent documented history of severe adverse drug reactions or anaphylaxis to prior treatments of the same or similar therapy.
        ii. Concomitant complex medical conditions that may increase the risk of infusion reactions or complications to therapy. For example, the presence of antibodies that may increase the risk of infusion reactions, severely compromised cardiac and respiratory function.
        iii. Use of multiple concurrent therapies of which one or more require infusion services at a higher level of care (such as cytotoxic chemotherapy, CAR-T given over same treatment period as requested medication)
        iv. Chronic vascular access complications that require hospital-based interventions or equipment not available to home infusion providers
        v. Mental health or cognitive changes that require increased level of care for the safe administration of infusions
    b. The unapproved hospital-based infusion center is deemed a more appropriate option, as defined by the following criteria:
        i. Home infusion services are not an option because the member's home is ineligible for infusion services. The eligibility of a member's home for home infusion can be affected by such factors as:
            1) The location of the member's home being outside of the infusion provider's service area, or
            2) Upon inspection, the home infusion provider considers the member's home to be unfit or unsafe for home infusion services.
3. Site of Care criteria shall be waived for the administration of the first dose for all drugs, to allow enough time to arrange for an approved site of care setting for the drug infusion. Select drugs such as enzyme replacements and oncology immunotherapies will be permitted to stay at a non-approved site of care location for additional doses to assess tolerability in a higher level of care setting. This period will also allow time to facilitate the coordination of transfer to an approved site of care if continued use of the unapproved site has been deemed not medically necessary. The number of additional doses has been established based on the drug's safety profile and the manufacturer's recommendation for clinical monitoring. Refer to the drug tables below for specific number of doses allowed at a non-approved SOC prior to the transition mandate to an approved Site of Care provider/facility.

REAUTHORIZATION:

Occurs every six months and will require documentation that the member continues to meet the clinical criteria for approval, based on clinical and administration notes from the past six months of treatment at the unapproved site of care. Reauthorization will also include consideration of any newly available approved sites of care, such as hospital-based infusion centers or ambulatory infusion suites, for transfer.

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
This policy applies to those members who are 13 years of age and older.

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Initial authorization and reauthorization will be approved for up to one year.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
In the outpatient setting, infusion therapy was originally administered at outpatient hospital facilities, but improved technology now allows for safe and effective administration at alternative sites of care, such as medical clinics, stand-alone infusion providers, or home infusion. The practice of providing infusions outside of the hospital setting is well-established and accepted in clinical practice.

Alternative sites of care offer high-quality infusion services for patients and reduce the overall cost of care when compared to unapproved hospital outpatient infusion centers. When more than one medically appropriate site of care is available, the PHP will approve the use of the most affordable alternative.

Table 1. Site of Care criteria shall be waived for the administration of the first dose for all drugs, to allow enough time to arrange for an approved site of care setting for the infusion. Additional dose exceptions only apply for new start patients or patients reinitiating following a discontinuation of therapy. The administration of the following medications requires prior authorization for the use of an unapproved hospital-based infusion center when an approved site of care is an available treatment option.

HCPCS	Trade Name	Drug Name	New Start Dose Exceptions
J0791	Adakveo	crizanlizumab	1

HCPCS	Trade Name	Drug Name	New Start Dose Exceptions
J1931	Aldurazyme	laronidase	6 doses within 90 days
J1552	Alyglo	immune globulin	1
J1426	Amondys 45	casimersen	1
J0225	Amvuttra	vutrisiran	1
J0256	Aralast NP, Prolastin-C, Zemaira	alpha-1 proteinase inhibitor	1
J0881	Aranesp	darbepoetin alfa	1
J1554	Asceniv	immune globulin	1
Q5121	Avsola	Infliximab-axxq	1
J9023	Bavencio	avelumab	4 doses within 60 days
J1556	Bivigam	immune globulin	1
Q5152	Bkemv	eculizumab-aeeb	1
J2329	Briumvi	ublituximab-xiiy	1
J1786	Cerezyme	imiglucerase	6 doses within 90 days
J1932	Cipla	lanreotide	1
J0584	Crysvita	burosumab-twza	1
J1551	Cutaquig	immune globulin	1
J1555	Cuvitru	immune globulin	1
J9145	Darzalex	daratumumab	4 doses within 60 days
J9144	Darzalex Faspro	daratumumab-hyaluronidase	4 doses within 60 days
J1743	Elaprase	idursulfase	6 doses within 90 days
J3060	Elelyso	taliglucerase alfa	6 doses within 90 days
J3380	Entyvio	Vedolizumab	1
Q5151	Epysqli	eculizumab-aagh	1
J9055	Erbitux	Cetuximab	4 doses within 60 days
J3111	Evenity	romosozumab-aqqg	1
J1305	Evkeeza	Evinacumab	1
J1428	Exondys 51	Eteplirsen	1
J0180	Fabrazyme	agalsidase beta	6 doses within 90 days
J9395	Faslodex	fulvestrant	4 doses within 60 days
J9394	Fresenius Kabi 505(b)(2)	fulvestrant	4 doses within 60 days
J1569	Gammagard, Gammagard ERC	immune globulin	1
J1561	Gammaked, Gamunex-C	immune globulin	1
J1557	Gammaplex	immune globulin	1

HCPCS	Trade Name	Drug Name	New Start Dose Exceptions
J0223	Givlaari	givosiran	1
J0257	Glassia	alpha-1 proteinase inhibitor	1
J9356	Herceptin Hylecta	trastuzumab and hyaluronidase	2 doses within 60 days
J1559	Hizentra	immune globulin	1
J1575	Hyqvia	immune globulin	1
J0638	Ilaris	canakinumab	1
J3245	Ilumya	tildrakizumab	1
J9173	Imfinzi	durvalumab	2 doses within 60 days
Q5103	Inflectra	infliximab-dyyb	1
J1576	IVIG non-lyophilized, NOS Panzyga	immune globulin	1
J9272	Jemperli	dostarlimab-gxly	2 doses within 60 days
J9354	Kadcyla	ado-trastuzumab emtansine	2 doses within 60 days
J2840	Kanuma	sebelipase alfa	6 doses within 90 days
J9271	Keytruda	pembrolizumab	1
J2507	Krystexxa	pegloticase	1
J1306	Leqvio	inclisiran	1
J3263	Loqtorzi	toripalimab-tpzi	4 doses within 60 days
J0221	Lumizyme	alglucosidase alfa	6 doses within 90 days
J3397	Mepsevii	vestronidase alfa-vjbk	6 doses within 90 days
Q5107	Mvasi	bevacizumab-awwb	2 doses within 60 days
J1458	Naglazyme	galsulfase	6 doses within 90 days
J0219	Nexviazyme	avalglucosidase alfa-ngpt	6 doses within 90 days
J2802	Nplate	romiplostim	1
J0485	Nulojix	belatacept	1
J2350	Ocrevus	ocrelizumab	1
J2351	Ocrevus Zunovo™	ocrelizumab and hyaluronidase-oscq	1
J1568	Octagam	immune globulin	1
Q5114	Ogivri	trastuzumab-dkst	2 doses within 60 days
J0222	Onpattro	patisiran	1
Q5112	Ontruzant	trastuzumab-dttb	2 doses within 60 days
J9299	Opdivo	nivolumab	2 doses within 60 days
J9289	Opdivo Qvantig	nivolumab & hyaluronidase-nvhy	2 doses within 60 days

HCPCS	Trade Name	Drug Name	New Start Dose Exceptions
J9298	Opdualag	nivolumab & relatlimab-rmbw	2 doses within 60 days
J9316	Phesgo	pertuzumab, trastuzumab, & hyaluronidase-zzxf	2 doses within 60 days
J1459	Privigen	immune globulin	1
J1301	Radicava	edaravone	1
J0896	Reblozyl	luspatercept-aamt	1
J1745	Remicade	infliximab	1
Q5104	Renflexis	infliximab-abda	1
Q5123	Riabni	rituximab-arrx	2 doses within 60 days
J9312	Rituxan	rituximab	2 doses within 60 days
J9311	Rituxan Hycela	rituximab and hyaluronidase	2 doses within 60 days
Q5119	Ruxience	rituximab-pvvr	2 doses within 60 days
J9333	Rystiggo	rozanolixizumab	2 doses within 60 days
J2353	Sandostatin LAR Depot	octreotide	1
J0491	Saphnelo	anifrolumab-fnia	2 doses within 60 days
J1602	Simponi Aria	golimumab	1
J1299	Soliris	eculizumab	1
J1930	Somatuline Depot	lanreotide	1
J9022	Tecentriq	atezolizumab	2 doses within 60 days
J9024	Tecentriq Hybreza	atezolizumab and hyaluronidase-tqjs	2 doses within 60 days
J3241	Tepezza	teprotumumab-trbw	1
Q5116	Trazimera	trastuzumab-qyyp	2 doses within 60 days
J9317	Trodelvy	sacituzumab govitecan-hziy	4 doses within 60 days
Q5115	Truxima	rituximab-abbs	2 doses within 60 days
Q5134	Tyruko	Natalizumab-sztn	1
J2323	Tysabri	Natalizumab	1
J1303	Ultomiris	ravulizumab-cwvz	1
J1823	Uplizna	inebilizumab-cdon	1
J9303	Vectibix	panitumumab	4 doses within 60 days
J1427	Viltepso	viltolarsen	1
J1322	Vimizim	elosulfase alfa	6 doses within 90 days
J3385	VPRIV*	velaglucerase alfa	6 doses within 90 days
J3032	Vyepti	eptinezumab-jjmr	1

HCPCS	Trade Name	Drug Name	New Start Dose Exceptions
J1429	Vyondys 53	golodirsen	1
J9332	Vyvgart	efgartigimod	1
J1558	Xembify	immune globulin	1
J9228	Yervoy	ipilimumab	2 doses within 60 days
Q5118	Zirabev	bevacizumab-bvzr	2 doses within 60 days

POSITION STATEMENT:
Driven by heightened emphasis on cost-effectiveness and cost-containment, and the desire of patients to resume normal lifestyles and work activities while recovering from illness, the alternate-site infusion therapy sector continues to expand. In 2020, NHIA estimated that home and specialty infusion is a $19 billion industry made up of over 900 providers serving 3.2 million patients annually. Patient and physician awareness of home infusion grew substantially during the COVID-19 pandemic when non-acute care was diverted from facilities. A robust pipeline of specialty and biologic drugs suitable for alternate site administration continues to drive interest and growth in the industry.

The U.S. home infusion therapy market size is expected to grow at a compound annual growth rate of 7.7% from 2024 to 2030. The growing elderly population prone to various severe disorders is one of the major drivers of the market growth. In addition, the growing prevalence of disorders, such as cancer, diabetes, chronic pain, and gastrointestinal diseases is also expected to fuel the U.S. market growth. Home infusion therapy offers various benefits to the patient. Some of the benefits comprise cost-effectiveness, better outcomes, better convenience, and higher safety standards.

Home infusion's overall contribution of home infusion therapy to the health care system is certainly much more significant than its current market share. The system cost of infusion therapy administered in the home or alternate-site care setting is usually significantly less than the cost of inpatient treatment.

Patients receiving therapy via home infusion have been shown to have similar rates of positive clinical outcomes and adverse events as other sites of care. Patients have also reported preference rates of as high as 95% in favor of home infusion sites of care.

A retrospective chart review was done to analyze the incidence and management of infusion reactions to infliximab in an alternative care setting. A total of 796 patients with Crohn's disease or ulcerative colitis received a combined 5581 infliximab infusions with one home infusion provider between January 2014 and November

2016. Alternative care settings reviewed in the study were identified as either patient's home or the home infusion provider's infusion suite. Patients eligible for alternative care infusion were identified by their physician and referred to either the home setting or an infusion suite. Use of premedication was determined by the referring physician, and all infusions were administered by a trained nurse following standardized protocols, who also did the post infusion monitoring for a minimum of 60min following the first 3 infusions and a minimum of 30min subsequently. In total, 109 infusion reactions (2% of all infusions) were recorded in 62 patients (7.8% of all patients). Of these reactions, 87 (79.8%) were acute, the majority of which were classified as mild (57.5%) or moderate in severity (31.0%). Ten infusions were associated with a severe reaction (11.5%, 0.2% of all infusions), and of these, 8 (9.2%, 0.1% of all infusions) resulted in an emergency room visit. The most common acute reaction was headache (23.0% of all acute IRs), followed by pruritus (14.9); other common acute reactions included dyspnea (13.8%), flushing (13.8%), chest tightness/discomfort (11.5%), and nausea and/or vomiting (10.3%). In comparison, the REMICADE (infliximab) package insert reported infusion reactions in 18% of infusions, with serious infusion reactions occurring in <1% of patients.

All exceptions to the site of care medical necessity determination will be reviewed on a case-by-case basis.

The infused medication list included in this policy is subject to change.

REFERENCE/RESOURCES:

1. Managed Healthcare Executive. Top ways to manage cost of infusible specialty therapies. https://www.managedhealthcareexecutive.com/business-strategy/top-ways-manage-cost-infusible-specialty-therapies (Accessed 2019 Sept 2)
2. National Home Infusion Association releases first-ever study of alternate-site infusion industry. www.nhia.org/press_release/pr101811.html (Accessed 2019 Sept 2)
3. Polinski JM, Kowal MK, Gagnon M et al. Home Infusion: Safe, clinically effective, patient preferred, and cost saving. *J of Del Sci Innov*. 2017;5:68-80.
4. Harris Williams & Co. Home infusion industry overview 2014. https://www.harriswilliams.com/sites/default/files/industry_reports/2014.6.12_home_infusion_industry_overview.pdf (Accessed 2019 Sept 2)
5. Remicade package insert. Horsham, PA: Janssen Biotech, Inc.; 2018 June.
6. Checkley LA, Kristofek L, Kile S et. Al. Incidence and management of infusion reactions to infliximab in an alternate care setting. Dig Dis Sci. 2019; 64(3):855-862.
7. National Home Infusion Association. https://nhia.org/about-infusion-therapy/ (Accessed 2024 July 9)

8. National Home Infusion Association Drug List. Available at https://nhia.org/about-infusion-therapy/nhia-home-infusion-drug-list/. Updated August 12,2024 (Accessed December 16, 2024)
9. Grand View Research. U.S. Home Infusion Therapy Market Size, Share & Trends Analysis Report By Product (Infusion Pumps, Needleless Connectors), By Application (Anti-Infective, Endocrinology), And Segment Forecasts, 2024 – 2030; https://www.grandviewresearch.com/industry-analysis/us-home-infusion-therapy-market (Accessed 2024, July 9)