Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH030.0225	**MISCELLANEOUS PRODUCTS INFUSION THERAPY SITE OF CARE**
Effective Date: 3/1/2025	**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 (AA)
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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 BOTH of the following criteria:
        i. An approved site of care would require an additional 15 miles of travel from the member's home as compared to unapproved hospital-based infusion center in the vicinity.

        AND

        ii. 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. The first 60 days after the drug authorization will be covered at an unapproved site of care, to accommodate for initial doses to be administered without delay to therapy. The purpose of the initial 60-day period is to allow for the determination of infusion tolerability at a higher level of care. This period will also allow for the timely submission and review of a prior authorization for the unapproved site of care, and the coordination of transition to an approved site, when the unapproved site of care has been determined to be not medically necessary.
4. An exception to the 60 days at an unapproved site will be granted for patients starting a **new** enzyme replacement medication. These drugs will be noted by an asterisk on table 1. Due to the prolonged concern with anaphylaxis reactions, an

enzyme replacement drug that is **new** to the patient will be authorized for six months at an unapproved site of care.

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 Companies will approve the use of the most affordable alternative.

Table 1. 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
J3262	Actemra	tocilizumab
J0791	Adakveo	crizanlizumab
J1931*	Aldurazyme*	laronidase*
J1426	Amondys 45	casimersen
J0225	Amvuttra	vutrisiran
J0256	Aralast NP, Prolastin-C, Zemaira	alpha-1 proteinase inhibitor
J0881	Aranesp	darbepoetin alfa
J1554	Asceniv	immune globulin

HCPCS	Trade Name	Drug Name
J9023	Bavencio	avelumab
J0490	Benlysta	belimumab
J1556	Bivigam	immune globulin
J9039	Blincyto	blinatumomab
J2329	Briumvi	ublituximab-xiiy
J0741	Cabenuva	cabotegravir/rilpivirine
J1952	Camcevi	leuprolide
J1786*	Cerezyme*	imiglucerase*
J1932	Cipla	lanreotide
J3247	Cosentyx IV	secukinumab (IV)
J0584	Crysvita	burosumab-twza
J1551	Cutaquig	immune globulin
J1555	Cuvitru	immune globulin
J9145	Darzalex	daratumumab
J9144	Darzalex Faspro	daratumumab-hyaluronidase
J1743*	Elaprase*	idursulfase*
J3060*	Elelyso*	taliglucerase alfa*
J9217	Eligard; Lupron Depot	leuprolide acetate depot, per 7.5 mg
J3380	Entyvio	vedolizumab
J3111	Evenity	romosozumab-aqqg
J1305	Evkeeza	evinacumab
J1428	Exondys 51	eteplirsen
J0180*	Fabrazyme*	agalsidase beta*
J9395	Faslodex	fulvestrant
J1951	Fensolvi	leuprolide acetate
J9155	Firmagon	degarelix
J1569	Gammagard	immune globulin
J1561	Gammaked, Gamunex-C	immune globulin
J1557	Gammaplex	immune globulin
J0223	Givlaari	givosiran
J0257	Glassia	alpha-1 proteinase inhibitor
J9356	Herceptin Hylecta	trastuzumab and hyaluronidase
J1559	Hizentra	immune globulin
J1575	Hyqvia	immune globulin
J0638	Ilaris	canakinumab
J3245	Ilumya	tildrakizumab
J9173	Imfinzi	durvalumab

HCPCS	Trade Name	Drug Name
Q5103	Inflectra	infliximab-dyyb
J1576	IVIG non-lyophilized, NOS Panzyga	immune globulin
J9272	Jemperli	dostarlimab-gxly
J2840*	Kanuma*	sebelipase alfa*
J9271	Keytruda	pembrolizumab
J2507	Krystexxa	pegloticase
J0174	Leqembi	lecanemab-irmb
J1306	Leqvio	inclisiran
J1954	Leuprolide Acetate Depot	leuprolide acetate depot, per 7.5 mg
J0221*	Lumizyme*	alglucosidase alfa*
J1950	Lupron Depot	leuprolide acetate, per 3.75 mg
J3397*	Mepsevii*	vestronidase alfa-vjbk*
Q5107	Mvasi	bevacizumab-awwb
J1458*	Naglazyme*	galsulfase*
J0219	Nexviazyme*	avalglucosidase alfa-ngpt
J2796	Nplate	romiplostim
J0485	Nulojix	belatacept
J2350	Ocrevus	ocrelizumab
J1568	Octagam	immune globulin
J0222	Onpattro	patisiran
J9299	Opdivo	nivolumab
J9298	Opdualag	nivolumab & relatlimab-rmbw
J0129	Orencia	abatacept
J1459	Privigen	immune globulin
J0897	Prolia, Xgeva	denosumab
J1301	Radicava	edaravone
J0896	Reblozyl	luspatercept-aamt
J1745	Remicade	infliximab
Q5104	Renflexis	infliximab-abda
J3590, C9399	Revcovi	elapegademase-lvlr
J9311	Rituxan Hycela	rituximab and hyaluronidase
Q5119	Ruxience	rituximab-pvvr
J9333	Rystiggo	rozanolixizumab
J2353	Sandostatin LAR Depot	octreotide
J0491	Saphnelo	anifrolumab-fnia
J1602	Simponi Aria	golimumab

HCPCS	Trade Name	Drug Name
J1300	Soliris	eculizumab
J1930	Somatuline Depot	lanreotide
J9022	Tecentriq	atezolizumab
J3241	Tepezza	teprotumumab-trbw
Q5133	Tofidence	tocilizumab-bavi
Q5115	Truxima	rituximab-abbs
Q5135	Tyenne	Tocilizumab-aazg
J1303	Ultomiris	ravulizumab-cwvz
J1823	Uplizna	inebilizumab-cdon
J9303	Vectibix	panitumumab
J1427	Viltepso	viltolarsen
J1322*	Vimizim*	elosulfase alfa*
J3385*	VPRIV*	velaglucerase alfa*
J3032	Vyepti	eptinezumab-jjmr
J1429	Vyondys 53	golodirsen
J9332	Vyvgart	efgartigimod
J9334	Vyvgart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc
J1558	Xembify	immune globulin
J9228	Yervoy	ipilimumab
Q5118	Zirabev	bevacizumab-bvzr
J9202	Zoladex	goserelin acetate

*Enzyme replacement medication may be allowed 6 months at non-approved Site of Care if the drug is NEW to the patient.

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)