Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH030.0823	**MISCELLANEOUS PRODUCTS INFUSION THERAPY SITE OF CARE**
Effective Date: 10/1/2023 **Robert Gluckman, M.D.** **Chief Medical Officer**	Review/Revised Date: 11/19, 02/20, 05/20, 09/20, 08/21, 03/22, 08/22, 09/22, 07/23 (AA) 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 Original Effective Date: 01/20 Approved by: Oregon Region Pharmacy and Therapeutics Committee Page 1 of 7

SCOPE:
Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions 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
J0129	Orencia	abatacept
J0180*	Fabrazyme*	agalsidase beta*
J0221*	Lumizyme*	alglucosidase alfa*

HCPCS	Trade Name	Drug Name
J0256	Aralast NP, Prolastin-C, Zemaira	alpha-1 proteinase inhibitor
J0257	Glassia	alpha-1 proteinase inhibitor
J0219	Nexviazyme*	avalglucosidase alfa-ngpt
J0485	Nulojix	belatacept
J0490	Benlysta	belimumab
J0584	Crysvita	burosumab-twza
J0741	Cabenuva	cabotegravir/rilpivirine
J0638	Ilaris	canakinumab
J0791	Adakveo	crizanlizumab
J0881	Aranesp	darbepoetin alfa
J0897	Prolia, Xgeva	denosumab
J1300	Soliris	eculizumab
J1301	Radicava	edaravone
J9332	Vyvgart	efgartigimod
C9399, J3590	Vyvgart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc
C9399, J3590	Revcovi	elapegademase-lvlr
J1322*	Vimizim*	elosulfase alfa*
J3032	Vyepti	eptinezumab-jjmr
J1458*	Naglazyme*	galsulfase*
J0223	Givlaari	givosiran
J1602	Simponi Aria	golimumab
J1743*	Elaprase*	idursulfase*
J1786*	Cerezyme*	imiglucerase*
J1554	Asceniv	immune globulin
J1556	Bivigam	immune globulin
J1566	Carimune NF, Gammagard S/D	immune globulin
J1551	Cutaquig	immune globulin
J1555	Cuvitru	immune globulin
J1572	Flebogamma, Flebogamma DIF	immune globulin
J1569	Gammagard	immune globulin
J1561	Gammaked, Gamunex-C	immune globulin
J1557	Gammaplex	immune globulin
J1559	Hizentra	immune globulin
J1575	Hyqvia	immune globulin
J1599	IVIG non-lyophilized, NOS	immune globulin

HCPCS	Trade Name	Drug Name
	Panzyga	
J1568	Octagam	immune globulin
J1459	Privigen	immune globulin
J1558	Xembify	immune globulin
J1306	Leqvio	inclisiran
J1745	Remicade	infliximab
Q5104	Renflexis	infliximab-abda
Q5121	Avsola	infliximab-axxq
Q5103	Inflectra	infliximab-dyyb
Q5109	Ixifi	Infliximab-qbtx
J1930	Somatuline Depot	lanreotide
J1931*	Aldurazyme*	laronidase*
J0174	Leqembi	lecanemab-irmb
J1961	Sunlenca	lenacapavir sodium
J1952	Camcevi	leuprolide
J1951	Fensolvi	leuprolide acetate
J9217	Eligard; Lupron Depot	leuprolide acetate depot, per 7.5 mg
J1954	Leuprolide Acetate Depot	leuprolide acetate depot, per 7.5 mg
J1950	Lupron Depot	leuprolide acetate, per 3.75 mg
J2350	Ocrevus	ocrelizumab
J2353	Sandostatin LAR Depot	octreotide
J0222	Onpattro	patisiran
J1303	Ultomiris	ravulizumab-cwvz
J2796	Nplate	romiplostim
J3111	Evenity	romosozumab-aqqg
J2840*	Kanuma*	sebelipase alfa*
J3060*	Elelyso*	taliglucerase alfa*
J3241	Tepezza	teprotumumab-trbw
J3245	Ilumya	tildrakizumab
J3262	Actemra	tocilizumab
J2329	Briumvi	ublituximab-xiiy
J3380	Entyvio	vedolizumab
J3385*	VPRIV*	velaglucerase alfa*
J3397*	Mepsevii*	vestronidase alfa-vjbk*
J0225	Amvuttra	vutrisiran

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

POSITION STATEMENT:
In 2010, the National Home Infusion Association (NHIA) published a survey of home infusion providers that showed 829,000 patients were receiving therapy via home infusion. Of these patients, 1.24 million therapies were being administered via home infusion in 2008. Due to an aging population and an increase in chronic conditions requiring higher levels of treatment and monitoring, the U.S. home infusion market has continued to expand and provide clinical and safety data to support its use as a trusted site of care.

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. National Infusion Center Association. https://infusioncenter.org (Accessed 2019 Sept 2)
2. 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)
3. National Home Infusion Association releases first-ever study of alternate-site infusion industry. www.nhia.org/press_release/pr101811.html (Accessed 2019 Sept 2)
4. 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.
5. 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)
6. Remicade package insert. Horsham, PA: Janssen Biotech, Inc.; 2018 June.
7. 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.