Prominence Health Plan		Effective Date:	10/1/2019
Policy Title:	Provider Administered Infusions – Site of Care	Last Review Date:	10/27/2020
Policy Category:	Utilization Management	Last Revision Date:	10/27/2020
Policy Number:	UM-100	Next Review Date:	10/1/2021
Department:	Utilization Management		
Applies to:	☒ Commercial ☐ Medicare ☐ TPA/ASO ☐ All		

Scope:	This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes: • 19 Off Campus-Outpatient Hospital; and • 22 On Campus-Outpatient Hospital Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well-accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.
Purpose:	This policy provides assistance in interpreting Prominence Health Plan medical necessity for certain sites of care for infusions. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. Prominence Health Plan reserves the right to modify its Policies and Guidelines as necessary. This Utilization Review Guideline is provided for informational purposes. It does not constitute medical advice. Prominence Health Plan may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist in administering health benefits. Prominence Health Plan's Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.
Definition(s):	**CMS:** Centers for Medicare and Medicaid Services **NCQA**: National Committee for Quality Assurance **Site of Care:** Choice for physical location of infusion administration. Sites of Care include hospital inpatient, hospital outpatient, community office, ambulatory infusion suite, or home-based setting.

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Procedure:	**Outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least ONE of the following criteria (submission of medical records is required):** 1. Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by any of the following: a. History of mild adverse events that have not been successfully managed through mild premedication (diphenhydramine, acetaminophen, steroids, fluids, etc.), b. History of severe adverse event following that infusion (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure), thereby increasing risk to the individual when administration is in the home or office setting c. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access) d. Inability to physically and cognitively adhere to the treatment schedule and regimen e. complexity f. Initial infusion or re-initiation of therapy after more than 6 months g. Less than 3 months since first infusion 2. Homecare or infusion provider has deemed that the individual, home caregiver or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting) 3. The selected oncology agents may be administered in an outpatient hospital facility if any of the following criteria are met: a. The prescribed medication has a site of care restriction for administration per the Food and Drug Administration (FDA) approved label b. The patient has a documented history of an adverse event warranting a more intense level of care during or following infusion of the prescribed medication unless the adverse event can be appropriately managed by the use of pre-medication(s) or other preventative actions c. The patient has a documented history of a significant comorbidity (e.g. cardiopulmonary disorder) or concerns regarding fluid overload status that precludes treatment at an alternative, less intensive site of care. d. The patient is receiving combination therapy or chemotherapy e. The patient is new to therapy, defined as within the first 6 months of treatment Members who do not meet the criteria above are appropriate for infusion therapy in a home-based infusion or physician office setting with or without supervision by a certified healthcare

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professional.

Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative site of care.

This policy applies to these specialty medications that require healthcare provider administration:

Brand name	Generic name	HCPCS Code
Aralast NP, Zemaira, Glassia, Prolastin C	A1-Proteinase Inhibitors	J0256, J0257
Orencia	Abatacept	J0129
Fabrazyme	Agalsidase beta	J0180
Lemtrada	Alemtuzumab	J0202, J9010, Q9979
Lumizyme	Alglucosidase alfa	J0221, J0220
Tecentriq	Atezolizumab	J9022, C9483
Benlysta	Belimumab	J0490
Crysvita	Burosumab	J0584
Ilaris	Canakinumab	J0638
Adakveo	Crizanlizumab-tmca	J0791, C9053
Darzalex	Daratumumab	J9145
Soliris	Eculizumab	J1300
Radicava	Edaravone	J1301
Revcovi	Elapegademase-lvlr	J3590
Vimizim	Elosulfase alfa	J1322
Vyepti	Eptinezumab-jjmr	C9063
Exondys 51	Eteplirsen	J1428
Naglazyme	Galsulfase	J1458
Simponi Aria	Golimumab	J1602
Trogarzo	Ibalizumab	J1746
Elaprase	Idursulfase	J1743
Cerezyme	Imiglucerase	J1786
Remicade	Infliximab	J1745
Renflexis	Infliximab-abda	Q5104
Inflectra	Infliximab-dyyb	Q5103
Gamunex, Gammagard, Flebogamma, etc.	Intravenous Immunoglobulin	J1567, J1561, J1569, J1572
Uplizna	Inebilizumab-codn	J3590
Yervoy	Ipilimumab	J9228
Aldurazyme	Laronidase	J1931
Tysabri	Natalizumab	J2323
Opdivo	Nivolumab	J9299, C9453
Ocrevus	Ocrelizumab	J2350

	Onpattro	Patisiran	C9036
	Krystexxa	Pegloticase	J2507
	Keytruda	Pembrolizumab	J9271, C9027
	Ultomiris	Ravulizumab-cwvz	J3590
	Cinqair	Reslizumab	J2786
	Rituxan	Rituximab (for non-oncology indications)	J9312
	Octreotide Depot	Sandostatin Depot	J2353
	Octreotide Non-Depot	Sandostatin	J2354
	Kanuma	Sebelipase alfa	J2840
	Herceptin, Kanjinti, Ontruzant, Herzuma, Ogivri, Trazimera	Trastuzumab	J9355, J9356, C9131, J9354, Q5112, Q5113, Q5114, Q5117
	Elelyso	Taliglucerase	J3060
	Ilumya	Tildrakizumab-asmn	J3245
	Actemra	Tocilizumab	J3262
	Entyvio	Vedolizumab	J3380
	Vpriv	Velaglucerase	J3385
	Mepsevii	Vestronidase alfa-vjbk	J3397

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Clinical Rationale	Home infusion as a place of service is well established and accepted by physicians. A 2010 home infusion provider survey by the National Home Infusion Association reported providing 1.24 million therapies to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications. A chart review of 3161 patients who received a combined 20,976 infusions in community clinics was conducted to evaluate safety across all types of patients. The authors concluded that infliximab infusions are safe in the community setting. Severe ADRs were rare. None required active physician intervention; nurses were able to treat all reactions by following standardized medical directives. Ten children were enrolled in the home infusion program if they were compliant with hospital-based infliximab infusions and other medications, had no adverse events during hospital-based infliximab infusions, were in remission and had access to experienced pediatric homecare nursing. Since infusions could be performed any day of the week, school absenteeism was decreased. The average patient satisfaction rating for home infusions was 9 on a scale from 1 to 10 (10 = most satisfied). Three patients experienced difficulty with IV access requiring multiple attempts, but all were able to receive their infusions. No severe adverse events (palpitations, blood pressure instability, hyperemia, respiratory symptoms) occurred during home infusions. In the carefully selected patients, infliximab infusions administered at home were safe and are cost-effective. Patients and families preferred home infusions, since time missed from school and work was reduced. Several studies have demonstrated the safety of infusing a variety of infused medications in the home setting. Infusions of enzyme replacement therapies including agalsidase, elosulfase, galsulfase, iduronidase, idursulfase, velaglucerase have been demonstrated to be infused safely in the home. In addition, a self-administered formulation of belimumab is currently available, indicating the appropriateness of home administration. References: • Phase I: 2010 NHIA Provider Survey Comprehensive Aggregate Analysis Report. National Home Infusion Association. 2011. • Ducharme J, Pelletier C, Zacharias R. The safety of infliximab infusions in the community setting. Can J Gastroenterol 2010;24(5):307-311. • Burton BK, Guffon N, Roberts J, et al. Home treatment with intravenous enzyme replacement therapy with idursulfase for mucopolysaccharidosis type II data from the Hunter Outcome Survey. Mol Genet Metab. 2010 Oct-Nov;101(2-3):123-9. For more information, below are additional scientific references that indicates appropriateness of infusions at specific places of services: • National Home Infusion Association. About Infusion Therapy and Medicare Home Infusion Site of Care Act Report.

Prominence SM Health Plan		Effective Date:	10/1/2019
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	• American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20Resources/Guidelines-for-the-site-of-care-for-administration-of-IGIV-therapy.pdf			
Regulatory Requirement:	☐ CMS Statute	☐ NCQA Standard	☐ Commercial Statute by State	☒ Other

Department Author/Review Process

Author/Reviewer	Title	Date Created/ Reviewed	Comments
David Huang, Pharm D	Director, Pharmacy	10/1/2019	Creation of Policy
Tavan Parker	Clinical Pharmacist	10/27/2020	Update of Policy

Approval Process

Approver	Title	*Approval Date	Comments
Traci Biondi, MD	Chief Medical Officer	11/11/2020	

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