

# Medical Policy Specialty Medication Administration – Site of Care

Policy Number: 052

	Commercial and Connector/Qualified Health Plans
Authorization required for specialty infusion medications site of care	x

This Specialty Medication Administration – Site of Care policy is not available for MassHealth and Medicare Advantage plans.

#### Overview

The purpose of this document is to describe guidelines to determine medical appropriateness for site of care delivery in a hospital outpatient facility versus a less intensive site of care, such as in the home. Mass General Brigham Health Plan collaborates with Optum Fusion for most specialty infusion medications. This policy does not pertain to the authorization of the actual medication.

When hospital outpatient administration is requested for a medication on Table A the request for site of care will be reviewed and authorized by Optum Fusion. Authorization for hospital outpatient administration may be granted for a term not to exceed 6 months at a time, after which criteria for authorization will be re-evaluated.

This policy applies only to those who are 14 years of age and older.

#### **Coverage Guidelines**

Mass General Brigham Health Plan will utilize grace periods specific to the infused medication to determine when a member can be safely transitioned from a hospital outpatient facility to a less intensive site of care such as in the home. After such time, Optum Fusion may continue to authorize infusion medication in the hospital outpatient facility setting when the criteria below are met.

# Criteria for Infusion in the Hospital Outpatient Facility Setting

Mass General Brigham Health Plan covers infusion in a hospital outpatient facility setting for medications included in this policy when there is clinical documentation that indicates the member meets one or more of the following:

- 1. The member is medically unstable for infusions at alternative levels of care as noted by any of the following:
  - a. History of severe adverse event following infusion (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that require a more intense level of care and have not been successfully managed through pre-medications (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); or
  - b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); or
  - c. Complex patient status that requires enhanced monitoring beyond the capabilities of the office or home infusion settings; or
  - d. To start new therapy or re-initiate products for a short duration (note: approval will be for 4 weeks); or
  - e. Outpatient treatment in the office setting or home setting present a health risk due to a clinically significant physical or cognitive impairment; or



f. Homecare or infusion provider has deemed that the individual, caregiver, or home environment is not suitable for infusion therapy.

# Exclusions

- 1. When relevant criteria listed above are not met.
- 2. When the specialty infusion medication has been denied.

# Criteria for Home Infusion Therapy

Mass General Brigham Health Plan considers the home setting to be the appropriate setting for delivery of care when:

- 1. The member's home environment has been assessed as:
  - a. Being accessible to 911 services and urgent care;
  - b. Having adequate refrigeration;
  - c. Meeting general cleanliness standards determined by an onsite home nursing assessment.
- 2. The member is medically stable and able to participate in their care; and
- 3. The member has reliable venous access.

# Definitions

<u>Home Infusion Therapy</u>: The administration of prescription medications through a needle or catheter into a patient's vein in the patient's home setting. It is furnished by a qualified home infusion therapy provider to an individual who is under the care of physician. The therapy is provided in an integrated manner under a plan established and periodically reviewed by a physician.

<u>Home Setting:</u> Any place where the member has established his/her place of residence for the time period when home care services are being provided. This may include his/her own dwelling, an apartment, the home of a friend or family member, a group home, a homeless shelter or other temporary place of residency or a community setting. It does not include hospitals, skilled nursing facilities, intermediate care facility for the developmentally disabled, or any other institutional facility providing medical, nursing, rehabilitative, or related care. A day care setting, adult day care, or adult medical care does not meet the definition of a home setting.

# Medically Necessary or Medical Necessity:

# **Division of Insurance Definition**

Medically Necessary health care services are those that are consistent with generally accepted principles of professional medical practice as determined by whether:

- a) The service is the most appropriate available supply or level of service for the insured in question considering potential benefits and harms to the individual;
- b) Is known to be effective, based on scientific evidence, professional standards, and expert opinion, in improving health outcomes; or
- c) For services and interventions not in widespread use, is based on scientific evidence.

<u>Site of Care</u>: Choice for physical location of infusion administration. Sites of care include hospital inpatient, hospital outpatient, community office, ambulatory infusion suite, or home-based setting.

# Effective

January 2024: Off-cycle review. Criteria changed to reflect new pharmacy vendor Optum Fusion. Overview section revised. Criteria for infusion section edited.

August 2023: Off-cycle review. Infusion Drugs Reviewed, Site of Care list updated. Table A added.

November 2022: Annual Review. References updated.

September 2021: Annual Review.

October 2020: Off-cycle review. Overview section revised for clarity with language added "versus a less intensive site of care, such as in home." Language added regarding age requirement. Guidelines section updated to



remove statement regarding "two dosage authorization in hospital" with language regarding grace period allowance. Criteria section changed to reflect new adverse event requirements found in sections 1a, 1b, and 1c. Removed sentence

"The member's home has been determined to be inappropriate for home infusion by a social worker, case manager, or previous home nurse assessment." Subheading edited to "Criteria for Home Infusion Therapy". October 2019: Annual update. Language edited in Overview section. MassHealth definition removed from Definitions section.

December 2018: Annual update. August 2017: Effective date.

### References

American Society of Health-System Pharmacists. ASHP Guidelines on Home Infusion Pharmacy Services. *Am J Health-Syst Pharm*. 2014; 71:325–41.

Basch E, Hesketh PJ, Kris MG, et al. Antiemetics: American Society of Clinical Oncology clinical practice guideline update. *J Clin Onc* 2011;29(31):4189-4198.

Chataway J, Porter B, Riazi A, et al. Home versus outpatient administration of intravenous steroids for multiple-sclerosis relapses: a randomized controlled trial. *Lancet Neurol* 2006; 5(7):565-571.

Counce J. Home Infusion's Expanding Role in Optimizing Site of Care. INFUSION. 2019; 37-44.

Ducharme J, Pelletier C, Zacharias R. The safety of infliximab infusions in the community setting. Can J Gastroenterol. 2010 May;24(5):307-11. doi: 10.1155/2010/138456. PMID: 20485705; PMCID: PMC2886572.

Gorski LA. A Look at 2021 Infusion Therapy Standards of Practice. Home Healthc Now. 2021 Mar-Apr 01;39(2):62-71. doi: 10.1097/NHH.000000000000972. PMID: 33662964.

Kochar B, Jiang Y, Chen W, et al. Home Infusions for Inflammatory Bowel Disease Are Safe: US Experience and Patient Perspectives. Crohns Colitis 360. 2021 Sep 1;3(3):otab063. doi: 10.1093/crocol/otab063. PMID: 34805985; PMCID: PMC8600957.

Loriaux A, Desmond M, Li PC. A Primer on Home Infusion Administration Methods. Open Forum Infect Dis. 2022 Oct 7;9(12):ofac525. doi: 10.1093/ofid/ofac525. PMID: 36540384; PMCID: PMC9757688.

MCG<sup>™</sup> Care Guidelines, 20<sup>th</sup> edition, 2016, Home Infusion Therapy, CMT: CMT-0009(SR).

National Home Infusion Association. About infusion therapy. Available at: <u>http://www.nhia.org/about-home-infusion.cfm</u>. Accessed on September 9, 2022.

Phase I: 2010 NHIA Provider Survey Comprehensive Aggregate Analysis Report. National Home Infusion Associate. 2011

Polinski JM, Kowal MK, Gagnon M, Brennan TA, Shrank WH. Home infusion: Safe, clinically effective, patient preferred, and cost saving. Healthc (Amst). 2017 Mar;5(1-2):68-80. doi: 10.1016/j.hjdsi.2016.04.004. Epub 2016 Apr 29. PMID: 28668202.

Riazi A, Porter B, Chataway J, et al. A tool to measure the attributes of receiving IV therapy in a home versus hospital setting: The Multiple Sclerosis Relapse Management Scale (MSRMS). *Health Qual Life Outcomes* 2011; 9:80.



Schmidt B, Kennedy PDS. Home infusion therapy: Safety, efficacy, and cost-savings. *Patient Safety & Quality Healthcare* Available at: <u>http://www.psqh.com/analysis/home-infusion-therapy-safety-efficacy-and-cost-savings/</u> Accessed on January 30, 2017.

Schultz TJ, Thomas A, Georgiou P, et al. Home infusions of natalizumab for people with multiple sclerosis: a pilot randomised crossover trial. Ann Clin Transl Neurol. 2021 Aug;8(8):1610-1621. doi: 10.1002/acn3.51410. Epub 2021 Jul 21. PMID: 34288591; PMCID: PMC8351394.

Souayah N, Hasan A, Khan H, et. al. The Safety Profile of Home Infusion of Intravenous Immunoglobulin in Patients with Neuroimmunologic Disorders. *J Clin Neuromusc Dis* 2011;12:S1-S10



TABLE A.	
Site of Care (SOC) Drug List	
COMMERCIAL AND HEALTH CONNECTOR PLAN MEMBERS ONLY	

HCPCS	HCPCS Description	Drug Name
J3262	Injection, tocilizumab, 1 mg	Actemra
J0791	Injection, crizanlizumab-tmca, 5 mg	Adakveo
J1931	Injection, laronidase, 0.1 mg	Aldurazyme
J0225	Injection, vutrisiran, 1 mg	Amvuttra
J0256	Injection, alpha 1-proteinase inhibitor (human), not otherwise specified, 10 mg	Aralast NP Zemaira
		Prolastin-C
C9072	Injection, immune globulin (asceniv), 500 mg	Asceniv
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	Avsola
J0490	Injection, belimumab, 10 mg	Benlysta
J1556	Injection, immune globulin (bivigam), 500 mg	Bivigam
J3590*	Injection, ublituximab-xiiy for intravenous use	Briumvi
J3490*		
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not	Carimune NF Gammagard S/D
11200	otherwise specified, 500 mg	Gammagard S/D Less IgA
J1786	Injection, imiglucerase, 10 units	Cerezyme
J0717	Injection, certolizumab pegol, 1 mg	Cimzia
J0598	Injection, c-1 esterase inhibitor (human), cinryze, 10 units	Cinryze
J2786	Injection, reslizumab, 1 mg	Cinqair
J0584	Injection, burosumab-twza 1 mg	Crysvita
J1551	Immune globulin-hipp	Cutaquig
J1555	Injection, immune globulin (cuvitru), 100 mg	Cuvitru
90291	Cytomegalovirus immune globulin (CMV-IgIV), human, for intravenous use	Cytogam
J0850	Injection, cytomegalovirus immune globulin intravenous (human), per vial	Cytogani
J1743	Injection, idursulfase, 1 mg	Elaprase
J3060	Injection, taliglucerace alfa, 10 units	Elelyso
C9094	Injection, sutimlimab-jome, 10 mg	Enjaymo
J3380	Injection, vedolizumab, 1 mg	Entyvio
J3331	Injection, romosozumab-aqqg, 1 mg	Evenity
J1305	Injection, evinacumab-dgnb, 5 mg	Evkeeza
J0180	Injection, agalsidase beta, 1 mg	Fabrazyme
C9466	Injection, benralizumab, 1 mg	Fasenra (non-pen)
J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg	Flebogamma Flebogamma DIF
J1569	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g. liquid), 500 mg	Gammagard
J1561	Injection, immune globulin, (gamunex-c/gammaked), non- lyophilized (e.g., liquid), 500 mg	Gammaked Gamunex-C
J1557	Injection, immune globulin, (gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg	Gammaplex
J0257	Injection, alpha 1 proteinase inhibitor (human), (GLASSIA), 10 mg	Glassia
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each	Hizentra



HCPCS	HCPCS Description	Drug Name
J1559	Injection, immune globulin (hizentra), 100 mg	
J1575	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immuneglobulin	Hyqvia
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg	Inflectra
J1745	Injection, infliximab, excludes biosimilar, 10 mg	Infliximab
J2840	Injection, sebelipase alfa, 1 mg	Kanuma
J2507	Injection, pegloticase, 1 mg	Krystexxa
J1306	Injection, inclisiran, 1 mg	Leqvio
J0221	Injection, alglucosidase alfa, (Lumizyme), 10 mg	Lumizyme
J2182	Injection, mepolizumab, 1mg	Nucala (non-pen)
J2350	Injection, ocrelizumab, 1 mg	Ocrevus
J1568	Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g. liquid), 500 mg	Octagam
J0222	Injection, patisiran, 0.1 mg	Onpattro
J0129	Injection, abatacept, 10 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug	Orencia
J1599⁺	(Immune globulin -human-ifas) IV solution	Panzyga
J1459	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg	Privigen
J0897	Injection, denosumab, 1 mg	Prolia
J1301	Injection, edaravone, 1 mg	Radicava
J0896	Injection, luspatercept-aamt, 0.25 mg	Reblozyl
J1745	Injection infliximab, 10 mg	Remicade
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg	Renflexis
J3490*	Injection, elapegademase-lvlr IM injection	Revcovi
J2998	Injection, plasminogen, human-tvmh, 1 mg	Ryplazim
J0491	Injection, anifrolumab-fnia, 1 mg	Saphnelo
J1602	Injection, golimumab, 1 mg, for intravenous use	Simponi Aria
J1300	Injection, eculizumab, 10 mg	Soliris
J3241	Injection, teprotumumab-trbw, 10 mg	Tepezza
J2356	Injection, tezepelumab-ekko, 1 mg	Tezspire
J2323	Injection, natalizumab, 1 mg	Tysabri
J1303	Injection, ravulizumab-cwvz, 10 mg	Ultomiris
J1322	Injection, elosulfase alfa, 1 mg	Vimizim
J3385	Injection, velaglucerase alfa, 100 units	Vpriv
J3032	Injection, eptinezumab-jjmr, 1 mg	Vyepti
J9332	Injection, efgartigimod alfa-fcab, 2 mg	Vyugart
J1558	Injection, immune globulin (xembify), 100 mg	Xembify
J0218	Injection, olipudase alfa-rpcp, 1 mg	Xenpozyme
J2357	Injection, omalizumab, 5 mg	Xolair

\* No specific code is available for Briumvi; J3490 can be used when billing.

