MEDICAL POLICY

POLICY TITLE	DRUG INFUSION SITE OF SERVICE
POLICY NUMBER	MP 3.016

Effective Date:	1/1/2024

I. POLICY

Note: An injectable medication must meet applicable medical necessity criteria for coverage. When coverage criteria are met for the injectable medication, this policy is used to determine the medical necessity of the requested site of care.

This policy applies to the following infusions administered by health care professionals:

- Abatacept; **and**
- Agalsidase beta; **and**
- Alemtuzumab; and
- Alglucosidase alfa; **and**
- Avalglucosidase alfa-ngpt; and
- Benralizumab; **and**
- C1 esterase inhibitor; **and**
- Certolizumab pegol; **and**
- Crizanlizumab-tmca; **and**
- Denosumab; **and**
- Eculizumab; **and**
- Efgartigimod alfa-fcab; **and**
- Elosulfase alfa; **and**
- Evinacumab-dgnb; **and**
- Galsulfase; **and**
- Givosiran; **and**
- Golimumab; **and**
- Idursulfase; **and**
- Imiglucerase; **and**
- Immune globulin intravenous (IVIG) (see coding section for applicable codes); **and**
- Immune globulin intravenous (Human)-slra; **and**
- Immune globulin subcutaneous (Human)-hipp; **and**
- Inebilizumab-cdon; **and**
- Infliximab; **and**
- Infliximab-dyyb; **and**
- Infliximab-abda; **and**
- Infliximab-axxq; **and**
- Laronidase; **and**
- Lumasiran; **and**
- Luspatercept-aamt; **and**

- Mepolizumab; **and**
- Natalizumab; **and**
- Ocrelizumab; **and**
- Olipudase alfa-rpcp; and
- Omalizumab; **and**
- Patisiran; **and**
- Plasminogen; Human-tmvh; **and**
- Ravulizumab-cwvz; **and**
- Romosozumab-aqqg; **and**
- Sebelipase alfa; **and**
- Sutimlimab-jome; **and**
- Taliglucerase alfa; **and**
- Teprotumumab-trbw; **and**
- Tildrakizumab; **and**
- Tocilizumab; **and**
- Ustekinumab; **and**
- Vedolizumab
- Velaglucerase alfa; **and**
- Vestronidase alfa-vjbk; **and**
- Vutrisiran;**and**
- Vygart

Infusion of a medication initiated in the hospital outpatient setting is subject to a one-time 30-day approval period to facilitate transition to a medically necessary alternative less intensive site of care. Alternative less intensive site of care facilities include:

- Non-hospital affiliated outpatient infusion (e.g., ambulatory infusion center or physician office); **or**
- Home infusion

Infusion of one of the listed medications administered in an alternative less intensive site of care facility (see definition above) when criteria for coverage of the medication are met is considered **medically necessary** unless both of the following criteria are met:

- There is not a non-hospital affiliated, outpatient infusion center within an acceptable distance to the patients' home. Refer to link below:
  - PA Code 9.679 Access requirements in service areas; **or**
- There is not a non-hospital affiliated, outpatient infusion center within **20 miles** of the patient's home **and** the patient does not live in the state of Pennsylvania; **and**
- The member's home is not eligible for home infusion services (such as home is not within the service area or is deemed unsuitable for care by the home infusion provider).

Or ONE of the following;
Infusion of one of the listed medications in a hospital outpatient setting or at a hospital-affiliated infusion suite is considered **medically necessary** for an individual when there is clinical documentation of **ANY** one of the following:

- The patient is under the age of 18; **or**

- The prescribed medication has a site of care restriction for administration per the Food and Drug Administration (FDA) approved label; **or**
- Clinical documentation of a severe or potentially life-threatening adverse event during or following infusion of the prescribed drug, and the adverse event cannot be managed through pre-medication in the home or office setting; **or**
- There is clinical documentation 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; **or**
- Clinical documentation of unstable vascular access; **or**
- Clinical documentation of physical or cognitive impairments such that home infusion would present an unnecessary health risk; **or**
- Patients current condition requires monitoring that cannot be provided in a less intensive site of care; **or**
- Patient is concurrently being treated with another medication that must be administered in a hospital setting; **or**
- Initiating a new therapy; **or**
- Reinitiating therapy after being off therapy for at least six months.

When the criteria above are not met, infusion of one of the listed medications in a hospital outpatient setting or hospital-affiliated infusion suite is considered **not medically necessary**.

Note: A hospital outpatient setting or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (Advanced Cardiac Life support (ACLS) protocol), emergency services, and inpatient admission or intensive care, if necessary.

Cross-reference:

- For medical necessity criteria, refer to the specific medical injectable policy
- MP 2.176 - Self Administered Medications
- MP 3.015 - Office Based Procedures Performed in a Facility

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND TOP

This policy outlines the site of care for medication infusions. It provides the criteria used to determine the medical necessity of the site of care for delivery of infused medications.

IV. RATIONALE TOP

NA

POLICY TITLE	DRUG INFUSION SITE OF SERVICE
POLICY NUMBER	MP 3.016

V. DEFINITIONS

TOP

NA

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes
90281, 90283, 90284, J0129, J0180, J0202, J0221, J0222, J0223, J0224, J0225, J0517, J0596, J0597, J0598, J0717, J0791, J0897, J1300, J1302, J1303, J1305, J1322, J1458, J1459, J1555, J1556, J1557, J1558, J1559, J1561, J1566, J1568, J1569, J1572, J1575, J1599, J1602, J1743, J1745, J1786, J1823, J1931, J2182, J2323, J2350, J2357, J2840, J3060, J3111, J3241, J3245, J3262, J3358, J3380, J3385, J3397, J9332, Q5103, Q5104, Q5121, J0218, J0219, J0896, J1551, J1554, J2998, J9334

ICD-10-CM Diagnosis Code*	Description
See above	Please reference the medical policy specific to the drug to determine coverage and appropriate diagnosis codes.

IX. REFERENCES

TOP

1. *Aeschlimann FA, Hofer KD, Schneider EC, Schroeder S, Saurenmann RK, et al. Infliximab in pediatric rheumatology patients: a retrospective analysis of infusion reactions and severe adverse events during 2246 infusions over 12 years. J Rheumatol. 2014; 41(7):1409-1415.*
2. *American Academy of Allergy Asthma and Immunology. Guidelines for the site of care for administration of IGIV therapy. 2011 Dec. Polinski JM, Kowal MK, Gagnon M, et al. Home infusion: safe clinically effective, patient preferred, and cost saving. Healthcare. 2016.*
3. *ASHP Guidelines on Home Infusion Pharmacy Services. Approved 2013 Accessed September 28, 2022.*
4. *Berthelot JM, Benoist-Gerard S, le Goff B, Muller-Chevalet F, Maugars Y. Outcome and safety of TNF alpha antagonist therapy in 475 consecutive outpatients (with rheumatoid arthritis or spondyloarthropathies) treated by a single physician according to their eligibility for clinical trials. Joint Bone Spine. 2010; 77(6):564-569.*
5. *Buisson A, Seigne AL, D'Huart M C, Bigard MA, Peyrin-Biroulet L. The extra burden of infliximab infusions in inflammatory bowel disease. Inflamm Bowel Dis. 2013; 19(11):2464-2467.*
6. *Chavis-Parker, P. Safe Chemotherapy in the Home Environment. Home Healthcare Now May 2015, Volume 33 Number 5, p 246 - 251 Accessed September 28, 2022.*
7. *Choquette D, Faraawi R, Chow A, Rodrigues J, Nantel F, et al. Incidence and management of infusion reactions to infliximab in a prospective real-world community registry. J Rheumatol. 2015; 42(7):1105-1111.*
8. *Colombel JF, Loftus EV, Tremaine WJ, Egan LJ, Sandborn WJ, et al. The safety profile of infliximab in patients with Crohn's disease: The Mayo Clinic experience in 500 patients. Gastroenterology. 2004; 126(1):19-31.*
9. *Condino, A., et al. A Home Infliximab Infusion Program. Journal of Pediatric Gastoenterology and Nutrition: January 2005. Volume 40, Issue 1, pp 67-69.*
10. *Crohn's & Colitis Foundation. Accessed September 28, 2022.*
11. *de Eusebio E, Armario-Hita JC, de Miquel VA. Treatment of psoriasis: focus on clinic-based management with infliximab. Am J Clin Derm. 2014; 15 Suppl 1(Feb): S5-16.*
12. *Ducharme J, Pelletier C, Zacharias R. The safety of infliximab infusions in the community setting. Can J Gastroenterol. 2010 May; 24(5):307-11. PMID: 20485705*
13. *Einodshofer, M. T., & Duren, L. N. (2012). Cost Management through Care Management, Part 2: The Importance of Managing Specialty Drug Utilization in the Medical Benefit. American health & drug benefits, 5(6), 359–364.*
14. *Fabrazyme® [package insert]. Cambridge, MA: Genzyme Corp. Revised 12/2018.*

15. *Halcomb K, Harris J. Commercial Specialty Medication Research: 2016 Benchmark Projections. Milliman Research Report. Accessed September 28, 2022*
16. *Huynh TK, Ostergaard A, Egsmose C, Madsen OR. Preferences of patients and health professionals for route and frequency of administration of biologic agents in the treatment of rheumatoid arthritis. Patient Prefer Adherence. 2014; 8:93-99.*
17. *Inflectra (infliximab-dyyb) [package insert]. LakeForest, IL. Jansen Pfizer Company: 7/2018.*
18. *Kalb RE, Gurske J. Infliximab for the treatment of psoriasis: clinical experience at the State University of New York at Buffalo. J Am Acad Dermatol. 2005; 53(4):616-622.*
19. *Katzberg H, Rasutis V, Bril V Home iVIG for CIDP: A Focus on Patient Centred Care Can JNeurol Sci. 2013; 40: 384-388.*
20. *Kuin S, Stolte SB, Van Den Brink GR, et al. Remicade infusions at home: an alternative setting of infliximab therapy for patients with Crohn's disease. Eur J Gastroenterol Hepat. 2016;28(2):222-225.s*
21. *Kuin S, Stolte SB, van den Brink GR, Ponsioen CY, Fockens P, D'Haens GR, Löwenberg M.Remicade infusions at home: an alternative setting of infliximab therapy for patients with Crohn's disease. Eur J Gastroenterol Hepatol. 2016 Feb; 28(2):222-5. doi: 10.1097/MEG.0000000000000530:*
22. *Lequerre T, Vittecoq O, Klemmer N, Goeb V, Loet X, et al. Management of infusion reactions to infliximab in patients with rheumatoid arthritis or spondyloarthritis: Experience from an immunotherapy unit of rheumatology. J Rheumatol. 2006;33(7):1307-1314.*
23. *Micromedex®Solutions Compendia. 2017. Alglucosidase alfa.*
24. *Micromedex®Solutions Compendia. 2020. Benralizumab.*
25. *Micromedex®Solutions Compendia. 2020. C1 esterase inhibitor.*
26. *Micromedex®Solutions Compendia. 2020. Certolizumab pegol.*
27. *Micromedex®Solutions Compendia. 2020. Denosumab.*
28. *Micromedex®Solutions Compendia. 2018. Eculizumab.*
29. *Micromedex®Solutions Compendia. 2020. Elosulfase alfa.*
30. *Micromedex®Solutions Compendia. 2020. Infliximab-abda.*
31. *Micromedex®Solutions Compendia. 2020. Infliximab-axxq.*
32. *Micromedex®Solutions Compendia. 2020. Infliximab-dyyb.*
33. *Micromedex®Solutions Compendia. 2020. Galsulfase.*
34. *Micromedex®Solutions Compendia. 2020. Golimumab.*
35. *Micromedex®Solutions Compendia. 2020. Idursulfase.*
36. *Micromedex®Solutions Compendia. 2020. Imiglucerase.*
37. *Micromedex®Solutions Compendia. 2020. Laronidase.*
38. *Micromedex®Solutions Compendia. 2020. Omalizumab.*
39. *Micromedex®Solutions Compendia. 2020. Patisiran.*
40. *Micromedex®Solutions Compendia. 2020. Ravulizumab-cwvz.*
41. *Micromedex®Solutions Compendia. 2020. Romosozumab-aqqg.*
42. *Micromedex®Solutions Compendia. 2020. Sebelipase alfa.*
43. *Micromedex®Solutions Compendia. 2020. Taliglucerase alfa.*
44. *Micromedex®Solutions Compendia. 2020. Tildrakizumab.*
45. *Micromedex®Solutions Compendia. 2020. Tocilizumab.*

46. *Micromedex®Solutions Compendia. 2020. Ustekinumab.*
47. *Micromedex®Solutions Compendia. 2018. Vedolizumab*
48. *Micromedex®Solutions Compendia. 2020. Velaglucerase alfa.*
49. *Micromedex®Solutions Compendia. 2020. Vestronidase alfa-vjbk.*
50. *Micromedex®Solutions Compendia. Efgartigimod alfa-fcab*
51. *Micromedex®Solutions Compendia. Mepolizumab*
52. *Ocrevus (ocrelizumab) [package insert]. South San Francisco, CA. Genentech, Inc. 11/2018*
53. *Orencia® (abatacept) package insert. Bristol-Myers Squibb Company, Princeton, NJ. 06/2017*
54. *Polinski JM, Kowal MK, Gagnon M, et al. Home infusion: safe clinically effective, patient preferred, and cost saving. Healthcare. 2016.*
55. *Remicade® (Infliximab, cA2) [package insert]. Horsham, PA. Jansen BIotech: 06/2018.*
56. *Renflexis (infliximab-abda) [package insert]. Kenilworth, NJ. Merck Sharp & Dohme Corp.:11/2017.*
57. *Stuby U, Biesenbach G, Pieringer H. Administration of infliximab in general practitioners' offices is safe. Clin Rheumatol. 2007; 26(11):1863-1866.*
58. *Tursi A, Elisei W, Picchio M, et al. Effectiveness and safety of infliximab and adalimumab for ambulatory Crohn's disease patients in primary gastroenterology centres. Eur J Intern Med. 2014; 25(5):485-490.*
59. *Wasserman MJ, Weber DA, Guthrie JA, Bykerk VP, Lee P, Keystone EC. Infusion-related reactions to infliximab in patients with rheumatoid arthritis in a clinical practice setting: relationship to dose, antihistamine pretreatment, and infusion number. J Rheumatol. 2004; 31(10):1912-1917.*
60. *Amvuttra™ (vutrisiran) package insert. Alnylam Pharmaceuticals, Inc., Cambridge, MA 2/2023.*
61. *Enjaymo™ (sutimlimab-jome) package insert. Bioverativ USA Inc., Waltham, MA 02451. A SANOFI COMPANY. 1/2023.*
62. *Asceniv™(Immune Globulin Intravenous (Human)-slra) package insert. ADMA Biologics, Inc. Boca Raton, FL. 12/2022.*
63. *Cutaquig® (Immune Globulin Subcutaneous (Human)-hipp) package insert. Octapharma USA Inc. Vienna, Austria. 11/2021.*
64. *Reblozy® l (Luspatercept-aamt) package insert. Celgene Corporation, a Bristol-Myers Squibb Company. Summit, NJ. 2022.*
65. *Ryplazim® (Plasminogen, Human-tmvh) ProMetic Liminal BioSciences. Lavel, Quebec, Canada. 6/2023.*
66. *Nexviazyme® (avalglucosidase alfa-ngpt) package insert. Genzyme Corporation, A SANOFI COMPANY. Cambridge, MA 02141.*
67. *Xenpozyme™ (olipudase alfa-rpcp) package insert. Genzyme Corporation, A SANOFI COMPANY. Cambridge, MA 02141.*

X. POLICY HISTORY

TOP

MP 3.016	**12/8/20 Minor review.** IVIG and infliximab products added. References Reviewed. Coding updated.
	1/31/21 Minor review. Multiple drugs added. References updated. Coding updated.
	2/10/2022 Minor Review. Multiple drugs added. References reviewed. Coding updated. Added new code J2356. Cross reference updated. Removal of GamaSTAN from policy.
	7/7/2022 Administrative update. Removal of J2356
	9/26/2022 Minor Review. Addition of J2182 and J9332
	3/10/2023 Minor Review. Annual review. References updated. Addition of J0225 and J1302.
	8/4/2023 Minor review. Addition of J0218, J0219, J0896, J1551, J1554, J2998. References updated. Alemtuzumab added to drug list as editorial update. Code has been on policy since adopted 2021.
	12/13/2023 Administrative update. Added J9334 eff 1/1/2024.

Top