COMMUNITY HEALTH CHOICE

Clinician Administered Drugs – Site of Care

Effective Date: 10/01/2023
Medical Care Management Committee Approval: 09/21/2023

Contents

Coverage Policy 1
Hospital-based Outpatient Infusion Criteria 2
Applicable Codes 2
References 4
Policy Revision History 5

Related Medical Review Guideline

- Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®)

Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to medication infusion services provided by hospital outpatient facilities to patients who are ≥ 18 years of age with the following Place of Service codes:

- 19 - Off Campus-Outpatient Hospital; and
- 22 - On Campus-Outpatient Hospital

Infusion services provided to patients < 18 years of age are not subject to this policy.

The following alternative non-hospital sites of care are preferred, and should be used for medication infusion therapy if clinically appropriate in non-emergency situations for patients who are considered medically stable:

- Non-hospital outpatient infusion centers
- Physician office
- Ambulatory infusion centers

- Home infusion services

Community will provide coverage for medication infusion services in hospital-based outpatient infusion facilities for patients who meet the requirements for Hospital-based Outpatient Infusion criteria. This policy applies only to the site of care where the patient receives the infusion. Additional prior authorization approval may be required for the requested medication.

Hospital-based Outpatient Infusion Criteria

Medication infusion in a hospital outpatient setting is medically necessary for patients who meet at least one of the following requirements:

- Documentation showing severe or potentially life-threatening adverse events from previous infusions that were not successfully managed through pre-medications (e.g., acetaminophen, diphenhydramine, steroids, etc.)
- Patient has complex medical status or therapy that requires monitoring or potential intervention beyond the capabilities of the alternative non-hospital sites of care
- Patient has condition(s) that increase(s) risk for severe adverse event (e.g., cardiopulmonary disorder, fluid overload status, unstable renal function, unstable vascular access)
- Patient is unable to adhere to treatment at an alternative non-hospital site of care due to physical or cognitive impairment
- First infusion, or to re-initiate therapy after at least 6 months of no infusion
- If the provider cannot infuse in the office setting, attestation from the prescriber that the patient's home environment is not suitable for home infusion therapy

Approval for medication infusion in a hospital outpatient setting will be limited to 6 months to allow for reassessment of the patient's ability to receive treatment at an alternative non-hospital site of care.

Applicable Codes

This policy applies to the following clinician administered drugs:

HCPCS Code	Description
C9399	Unclassified drugs or biologicals
J0129	Injection, abatacept, 10 mg
J0180	Injection, agalsidase beta, 1 mg
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
J0221	Injection, alglucosidase alfa, (Lumizyme), 10 mg
J0222	Injection, patisiran, 0.1 mg
J0223	Injection, givosiran, 0.5 mg
J0224	Injection, lumasiran, 0.5 mg
J0225	Injection, vutrisiran, 1 mg

J0256	Injection, alpha 1-proteinase inhibitor (human), not otherwise specified, 10 mg
J0257	Injection, alpha 1 proteinase inhibitor (human), (Glassia), 10 mg
J0490	Injection, belimumab, 10 mg
J0491	Injection, anifrolumab-fnia, 1 mg
J0517	Injection, benralizumab, 1 mg
J0584	Injection, burosumab-twza, 1 mg
J0638	Injection, canakinumab, 1 mg
J0717	Injection, certolizumab pegol, 1 mg
J0739	Injection, cabotegravir, 1 mg
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg
J0791	Injection, crizanlizumab-tmca, 5 mg
J1300	Injection, eculizumab, 10 mg
J1301	Injection, edaravone, 1 mg
J1302	Injection, sutimlimab-jome, 10 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
J1305	Injection, evinacumab-dgnb, 5 mg
J1322	Injection, elosulfase alfa, 1 mg
J1426	Injection, casimersen, 10 mg
J1427	Injection, viltolarsen, 10 mg
J1428	Injection, eteplirsen, 10 mg
J1429	Injection, golodirsen, 10 mg
J1459	Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1551	Injection, immune globulin (Cutaquig), 100 mg
J1554	Injection, immune globulin (Asceniv), 500 mg
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1458	Injection, galsulfase, 1 mg
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1558	Injection, immune globulin (Xembify), 100 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1561	Injection, immune globulin, (Gamunex/ Gamunex-C/Gammaked), nonlyophilized (e.g., liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), nonlyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, 100 mg immuneglobulin
J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1602	Injection, golimumab, 1 mg, for intravenous use

J1743	Injection, idursulfase, 1 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J1746	Injection, ibalizumab-uiyk, 10 mg
J1786	Injection, imiglucerase, 10 units
J1823	Injection, inebilizumab-cdon, 1 mg
J1931	Injection, laronidase, 0.1 mg
J2182	Injection, mepolizumab, 1 mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J2356	Injection, tezepelumab-ekko, 1 mg
J2786	Injection, reslizumab, 1 mg
J2840	Injection, sebelipase alfa, 1 mg
J2998	Injection, plasminogen, human-tvmh, 1 mg
J3032	Injection, eptinezumab-jjmr, 1 mg
J3060	Injection, taliglucerase alfa, 10 units
J3241	Injection, teprotumumab-trbw, 10 mg
J3245	Injection, tildrakizumab, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, 1 mg
J3385	Injection, velaglucerase alfa, 100 units
J3397	Injection, vestronidase alfa-vjbk, 1 mg
J3590	Unclassified biologics
J9332	Injection, efgartigimod alfa-fcab, 2 mg
J9381	Injection, teplizumab-mzwv, 5 mcg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg

References

Agency for Healthcare Research and Quality. Enzyme-replacement therapies for lysosomal storage diseases. Agency for Healthcare Research and Quality. Effective Health Care Program Technical Brief No.12. January 2013.

American Academy of Allergy Asthma and Immunology. Immunoglobulin (IgG) replacement therapy defined. 2023. Available at: https://www.aaaai.org/tools-for-the-public/allergy,-asthma-immunology-glossary/immunoglobulin-(igg)-replacement-therapy-defined. Accessed September 18, 2023.

Centers for Medicare & Medicaid Services: Place of Service Code Set. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set . Accessed 10/09/2020.

Condino, A., et al. A Home Infliximab Infusion Program. Journal of Pediatric Gastoenterology and Nutrition: January 2005. Volume 40, Issue 1, pp 67-69.

Gardulf A, Nicolay U, et al. Children and adults with primary antibody deficiencies gain quality of life by subcutaneous IgG self-infusions at home. J Allergy Clin Immunol. 2004 Oct;114(4):936-42.

Gerth WC, Betschel SD, Zbrozek AS. Implications to payers of switch from hospital-based intravenous immunoglobulin to home-based subcutaneous immunoglobulin therapy in patients with primary and secondary immunodeficiencies in Canada. Allergy Asthma Clin Immunol. 2014 May 7;10(1)23.

Immune Deficiency Foundation (IDF). Treatment experiences and preferences among patients with primary immunodeficiency disease. National survey of patients: 2008. May 6, 2009. Available at: https://primaryimmune.org/sites/default/files/publications/Treatment-Experiences-and-Preferences-among-Patients-with-Primary-Immunodeficiency-Disease-National-Survey-of-Patients-2008_1.pdf. Accessed September 19, 2023.

Katzberg HD, Rasutis V, Bril V. Home IVIG for CIDP: a focus on patient centered care. Can J Neurol Sci. 2013 May;40(3):384-8.

National Home Infusion Association. About Infusion Therapy. https://www.nhia.org/about-infusion-therapy/. Accessed 10/09/2020.

Souayah N, Hasan A, et al. The safety profile of home infusion of intravenous immunoglobulin in patient with neuroimmunologic disorders. J Clin Neuromuscul Dis. 2011. Jun;12 Suppl 4:S1-S10

Policy Revision History

Status	Effective Date	Description
Baseline	02/01/2021	Initial version of Clinician Administered Drugs Site of Care Policy
Revision 1	10/01/2023	Update list of applicable codes