

Corporate Medical Policy

Place of Service for Medical Infusions

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Description of Procedure or Service

Inpatient hospital and outpatient facilities are uniquely equipped to handle and support emergency medical situations. It is appropriate for patients, who are medically unstable and in danger of needing medical services only available in a hospital outpatient setting, to have access to medical infusions in these facilities.

However, for those patients who are considered medically stable, drug infusions may be administered in settings that would be considered less intensive, yet safe and effective alternatives. Acceptable alternative sites of care include non-hospital outpatient centers, physician/professional offices, infusion suites/ambulatory infusion centers, and infusions administered at home.

Alternative places of services may be more convenient for the patient, less expensive and lessen the risk of exposure to hospital acquired infections.

**Please note, this policy specifically applies to the infusion drugs that are addressed separately in individual medical policies as referenced below.

Related Policies:

- Abatacept (Orencia®)
- Alemtuzumab(Lemtrada™)
- Alpha 1-Antitrypsin Inhibitor Therapy
- Eculizumab (Soliris®)
- Edaravone (Radicava™)
- Enzyme Replacement Therapy for Lysosomal Storage Disorders
- Golimumab (Simponi Aria)
- Immune Globulin Therapy
- Infliximab, Infliximab-dyyb
- Infusion Therapy in the Home
- Interleukin-5 Antagonists
- Natalizumab (Tysabri)
- Ocrelizumab (Ocrevus™)
- Private Duty Nursing Services
- Tocilizumab (Actemra)
- Treatment of Hereditary Angioedema
- Vedolizumab (Entyvio)
- Xolair® (Omalizumab)

Place of Service for Medical Infusions

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Medical Infusions in an outpatient facility when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Medical Infusion is covered

Medical infusion therapy in a hospital outpatient setting is considered medically necessary if the following criteria are met:

1. History of mild adverse events that have not been successfully managed through mild pre-medication (diphenhydramine, acetaminophen, steroids, fluids, etc.), OR
2. History of severe adverse event following that infusion (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure), OR
3. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access), OR
4. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity, OR
5. One of the following:
 - a. The patient is new to therapy, defined as initial infusion OR less than 3 months since initial infusion, OR
 - b. The patient is receiving the first infusion after six months of no infusions for drugs with an approved dosing interval less than 6 months duration, OR
 - c. The patient is receiving the first infusion after at least a one-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration, OR

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 professional.

When Medical Infusion is not covered

Inpatient and hospital outpatient infusion, in the absence of the clinical indications above, is considered not medically necessary.

An inpatient admission for the sole purpose of IV infusion is not medically necessary.

Policy Guidelines

Numerous guidelines and agencies support first infusions of most drugs in well-controlled, hospital based settings. This is to ensure emergency access to care to address serious infusion-associated adverse reactions, such as anaphylaxis or severe hypotension.

Place of Service for Medical Infusions

Research has shown the safety and efficacy of administering subsequent infusions in a less intensive environment, including the home setting.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 86711, 90283, 90284, 99506, 99601, 99602, C9014, C9399, C9478, J0129, J0180, J0202, J0220, J0221, J0256, J0257, J0596, J0597, J0598, J1290, J1300, J1322, J1458, J1459, J1555, J1556, J1557, J1559, J1561, J1562, J1566, J1568, J1569, J1572, J1575, J1599, J1602, J1743, J1744, J1745, J1786, J1931, J2182, J2323, J2350, J2357, J2786, J2840, J3060, J3262, J3380, J3385, J3397, J3490, J3590, S0353, S0354, S5035, S5036, S5497, S5498, S5501, S5502, S5517, S5518, S5520, S5521, S5522, S5523, S9123, S9124, S9208, S9325, S9326, S9327, S9328, S9329, S9330, S9331, S9336, S9338, S9345, S9346, S9347, S9348, S9349, S9351, S9353, S9355, S9357, S9359, S9361, S9363, S9364, S9365, S9366, S9367, S9368, S9370, S9372, S9373, S9374, S9375, S9376, S9377, S9379, S9490, S9494, S9497, S9500, S9501, S9502, S9503, S9504, S9537, S9538, S9542, S9558, S9559, S9810, E0691-E0694, Q5103, Q5104, Q5109

Charges for routinely included supplies such as gauze, infusion sets, needles, cassettes, tape, cleansing solutions (betadine, alcohol), heparin and saline flushes, diluents for mixing drugs, and splints are included in the infusion reimbursement.

Catheter care may be reported separately when used as a stand-alone therapy, or during days not covered under per diem by another therapy. PICC line care will only be allowed as a separate charge if there is no other therapy in the last 30 days in the home.

Home infusion therapy includes all of the components related to such therapy, such as, but not limited to, nursing services, durable medical equipment, supplies, Prescription and non-Prescription Legend Drugs and solutions, pharmacy compounding and dispensing, specimen collection, patient and family education, delivery of drugs and supplies, and management of emergencies arising from said therapy.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

National Home Infusion Association. About Infusion Therapy and Medicare Home Infusion Site of Care Act Report.

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>

Specialty Matched Consultant Advisory Panel review 2/2020

Medical Director review 3/2020

Policy Implementation/Update Information

Place of Service for Medical Infusions

- 4/28/17 New policy developed. Medical infusion therapy in a hospital outpatient setting is considered medically necessary if the following criteria are met: 1. History of mild adverse events that have not been successfully managed through mild pre-medication (diphenhydramine, acetaminophen, steroids, fluids, etc.), OR 2. History of severe adverse event following that infusion (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure), OR 3. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access), OR 4. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity, OR 5. First infusion, OR 6. Less than 3 months since first infusion, OR 7. First infusion after six months of no infusions. Medical Director review 4/2017. **Policy noticed 4/28/17 for effective date 6/30/17.**
- 1/12/18 Added list of related policies to Description section. The following codes added to the Billing/Coding section: 86711, 90283, 90284, C9014, C9399, J0129, J0202, J0221, J0256, J0257, J0596, J0597, J0897, J1290, J1300, J1459, J1555, J1556, J1557, J1559, J1561, J1562, J1566, J1568, J1569, J1572, J1575, J1599, J1602, J1726, J1744, J1745, J2182, J2323, J2350, J2357, J2786, J2840, J3262, J3380, J3490, S0353, S0354, S9123, S9124, S9208, S9537, S9538, S9542, S9558, S9559, E0691 – E0694, Q5102. **Policy noticed 1/12/18 for effective date 4/1/18.** (an)
- 3/9/18 Denosumab (Prolia™, XGEVA™) and Progesterone Therapy in High Risk Pregnancies removed from the list of Related Policies in the Description section. Codes J0897 and J1726 removed from the Billing/Coding section. Policy remains on notice for effective date **4/1/18**. Specialty Matched Consultant Advisory Panel review 2/28/18. (an)
- 12/31/18 Corrected typo in Billing/Coding section. Correct code is 90284. (an)
- 3/12/19 Specialty Matched Consultant Advisory Panel review 2/20/2019. No change to policy statement. (an)
- 7/30/19 Added HCPCS codes J0598, J3397 and Q5109 to Billing/Coding section and replaced code Q5102 with codes Q5103 and Q5104. (krc)
- 3/10/20 Specialty Matched Consultant Advisory Panel review 2/19/2020. No change to policy statement. (eel)
- 3/24/20 Updated “Description” section with the following clarification: “Please note, this policy specifically applies to the infusion drugs that are addressed separately in individual medical policies as referenced below”. Medical Director review 3/2020. (krc)
- 8/11/20 Updated criteria in “When Covered” section from “first infusion OR less than 3 months since first infusion” to “the patient is new to therapy, defined as initial infusion OR less than 3 months since initial infusion” for clarity. Added the following to “When Covered” section: “first infusion after at least a one-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration,” and added the following clarification to “first infusion after six months of no infusions”: “for drugs with an approved dosing interval less than 6 months duration”. **Notification given 8/11/2020 for effective date 10/13/2020.** (krc)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.