Provider Administered Drugs – Site of Care

Policy Number: 2026D0121X
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➲ Instructions for Use

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Community Plan Policy

- Provider Administered Drugs – Site of Care

Related List

- Provider Administered Drugs – Site of Care: Applicable Medications

Coverage Rationale

➲ See Benefit Considerations

A medication will be subject to this Provider Administered Drugs – Site of Care policy when the medication is listed on the Provider Administered Drugs – Site of Care: Applicable Medications.

This policy addresses the criteria for consideration of allowing hospital outpatient facility infusion services for specialty medications and intravenous Immune Globulin (IVIG) and subcutaneous Immune Globulin (SCIG) therapy. 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 suites, 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.

Submission of medical records documenting that outpatient hospital facility-based administration is medically necessary for individuals who meet at least one of the following criteria:

- The patient is medically unstable and is at risk of requiring medical services and equipment available only in an outpatient hospital setting (e.g., endotracheal tube, chest tube insertion equipment, cricothyroidotomy set, mechanical ventilator) during administration of the requested drug based on **one** of the following:
  - History of cardiopulmonary conditions that cause an increased risk of severe adverse reactions during or immediately following infusion; **or**
  - An inability to tolerate fluid volume load (for intravenous infusions only) despite using the minimum amount of fluid required for infusion (e.g., unstable renal function); **or**
  - Risk of becoming medically unstable due to concomitant use of medications or other drug-drug or drug-disease interaction(s)

  or
- Treatment at an alternative Site of Care presents a health risk due to a clinically significant physical or cognitive impairment; **or**
- Severe patent vascular access issues (for intravenous infusions only) that require specialized equipment only available in an outpatient hospital setting (e.g., ultrasound guidance); **or**
- Previous episode(s) of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure), not including the first or second infusion, that have occurred

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while receiving requested therapy that was unresponsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual while administering at alternative Sites of Care; **or**

- Initial infusion or re-initiation of previous therapy after more than 6 months (excludes drugs dosed at an interval of 6 months or greater) for a short duration of time (e.g., 4 weeks); **or**
- **All** of the following:
  - Homecare or home infusion provider has deemed that the individual or home environment is not suitable for home infusion therapy; **and**
  - The prescriber is unable to administer in the office setting; **and**
  - There are no ambulatory infusion suite options available for this member

  or
- **For IVIG or SCIG only**: Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; **or**
- **For Oncology Drugs only:**
  - The patient is receiving concurrent chemotherapy or other infusion therapy that would require member to be treated at an outpatient hospital facility; **or**
  - The patient is less than 19 years of age; **or**
  - The patient is pregnant; **or**
  - The patient has immunoglobulin A (IgA) deficiency with anti-IgA antibodies

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.

Note: If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed.

Definitions

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Immune Globulin: Immune Globulins are components of the immune system. There are several types of Immune Globulin produced by the body (e.g., IgA, IgD, IgE, IgG, IgM). This medical policy addresses therapeutic use of Immune Globulin G (IgG), an antibody normally produced by B lymphocytes. References to Immune Globulin within this medical policy refer to IgG. IgG products have been referred to in multiple ways, some of which are: Immune Globulin (IG), immunoglobulin, gamma globulin, and by its route of administration - intravenous Immune Globulin (IVIG), Immune Globulin intravenous (IGIV), subcutaneous Immune Globulin (SCIG), Immune Globulin subcutaneous (IGSC).

Oncology Drugs: Oncology Drugs are medications used to prevent, treat, or manage cancer.

Site of Care: Choice for physical location of infusion administration. Sites of Care include hospital inpatient, hospital outpatient, physician office, ambulatory infusion suite, or home-based setting.

Applicable Codes

Refer to the Provider Administered Drugs – Site of Care: Applicable Medications for the list of applicable codes and corresponding medications.

Description of Services

According to the American Academy of Allergy Asthma and Immunology (AAAAI), Immunoglobulin G (IgG) is a type of antibody in blood plasma. Individuals who suffer from immunodeficiency diseases involving low IgG levels and/or function may, under certain circumstances, benefit from immunoglobulin replacement therapy, also known as IVIg or SCIg. The IgG can be administered each month intravenously or under the skin (subcutaneous, SCIg) once a week or bi-weekly. Both methods are effective at replacing IgG with levels essential to fight infections. Each technique has pros and cons that should be discussed with an allergist/immunologist. IgG replacement therapy is commonly well tolerated, though side effects such as allergic reactions and headaches can occur (AAAAI, 2022).

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As hospital settings can relate to a risk of introducing individuals with infectious conditions, the benefits of outpatient and home therapy should serve as an incentive to reexamine an individual and their appropriateness for a specific Site of Care (AAAAI, 2011).

Benefit Considerations

This policy applies to members who have medical necessity language in their Certificate of Coverage (COC) or Summary Plan Document with benefits available for health care services if medically necessary and have been approved for the requested medication clinical use.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined above are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

Clinical Evidence

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.

In a trial evaluating patients with paroxysmal nocturnal hemoglobinuria, after initial 2-5 doses of eculizumab (Soliris), 79 patients received continued infusion with every 14 days in the home setting for the duration of the study – 1-98 months, mean duration of 39 months. The survival of patients treated with eculizumab was not different from age- and sex-matched normal controls ($p = 0.46$) but was significantly better than 30 similar patients managed before eculizumab ($p = 0.030$). Three patients on eculizumab, all over 50 years old, died of causes unrelated to PNH. Twenty-one patients (27%) had a thrombosis before starting eculizumab (5.6 events per 100 patient-years) compared with 2 thromboses on eculizumab (0.8 events per 100 patient-years; $p < 0.001$). Twenty-one patients with no previous thrombosis discontinued warfarin on eculizumab with no thrombotic sequelae. Forty of 61 (66%) patients on eculizumab for more than 12 months achieved transfusion independence. The 12-month mean tra requirement reduced from 19.3 units before eculizumab to 5.0 units in the most recent 12 months on eculizumab ($p < 0.001$). Eculizumab dramatically alters the natural course of PNH, reducing symptoms and disease complications as well as improving survival to a similar level to that of the general population.

Infliximab has been shown to be safely infused in the community setting. 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. Infliximab infusions are safe in the community setting. Severe ADRs were rare. A total of 524 (2.5% of all infusions) acute ADRs in 353 patients (11.2%) were recorded. Most reactions (i.e., ADRs) were mild [n = 263 (50.2%, 1.3% of all infusions)] or moderate [n = 233 (44.5%, 1.1% of all infusions)]. Twenty-eight reactions (5.3%, 0.1% of all infusions) were severe. Emergency medical services were called to transport patients to hospital for seven of the severe reactions, of which none required admission. As per pre-established medical directives adrenaline was administered three times. 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. The children received 59 home infusions with a dose range of 7.5 to 10 mg/kg/dose. Home infusions ranged from 2 to 5 hours. 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. One infusion was stopped because of arm pain above the IV site. This patient had his next infusion in the hospital before returning to the home infusion program. 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. Alpha-1-antitrypsin therapy is generally considered safe and effective, exhibiting few and usually well tolerated side effects.

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In a retrospective data analysis of over one thousand patients (n = 1,076) with primary immunodeficiency diseases (PIDD), Wasserman et al. (2017), examined the infection rates for patients who received IVIG at home or in a hospital outpatient infusion center (HOIC). Patients were eligible for analysis if they had at least 1 inpatient or emergency room claim or at least 2 outpatient claims with a PIDD diagnosis from January 2002 and March 2013, 12 months of continuous health plan enrollment prior to index date (i.e., first IVIG infusion date), and 6 months of continuous IVIG at the same site of care after the index date. Incidences of pneumonia (bacterial or viral) and bronchitis (all types) within 7 days of IVIG infusion were retrospectively determined and compared between sites of care. Of the patients included in the analysis, 51% received IVIG in the home whereas 49% received it at an HOIC. The event/patient year of pneumonia was significantly lower in patients receiving IVIG at home compared to an outpatient hospital (0.102 vs. 0.216, p = 0.0071). The event/patient year of bronchitis was also significantly lower among patients infusing at home compared to an outpatient hospital (0.150 vs. 0.288, p < 0.0001). The authors concluded that patients with PIDD receiving IVIG in the home experienced significantly lower rates of pneumonia and bronchitis than those who received outpatient hospital based IVIG treatment. The lower infection rates in the home setting suggest that infection risk may be an important factor in site of care selection. The study is further limited by its observational nature.

The Immune Deficiency Foundation surveyed 1,030 patients on where they were treated with immune globulin. Twenty-six percent usually received infusions at a hospital outpatient department (21%) or at a hospital clinic (5%). Other sites reported included a doctor's private office (9%) or an infusion suite (16%). The most common site was in the home (42%), most administered by a nursing professional (2008).

A retrospective analysis by Hopson S et al. (2018)[25] investigated differences by site-of-care (SOC) between physician office (PO) and hospital outpatient (HO) setting in treatment patterns, quality, and cost among patients with cancer undergoing first-line infusion therapy. Differences by SOC in first-line treatment patterns and quality of care at end-of-life, defined as infusions or hospitalizations 30 days prior to death, were evaluated. The study reported differences in duration of therapy and number of infusions for some therapy regimens by SOC, in which patients in the HO had shorter duration of therapy and fewer infusions. There were no differences in quality of care at end-of-life by SOC. Total healthcare costs were 15% higher among patients in HO compared to PO. Another retrospective analysis by Fisher DM et al. (2017)[26] investigated health care use and costs among cancer patients receiving intravenous (IV) chemotherapy in physician offices (PO) and hospital outpatient settings (HOP). This study was based on medical and pharmacy claims data, included patients (age, 18 to 64 years) initiating IV chemotherapy/biologic treatment between January 1, 2006, and August 31, 2012, who were diagnosed with early or metastatic breast cancer, metastatic lung cancer, metastatic colorectal cancer, or non-Hodgkin lymphoma or chronic lymphocytic leukemia. Patients were assigned to PO or HOP groups on the basis of where they received > 95% of their IV cancer therapy (n = 18,740). The study reported higher all-cause and cancer-related healthcare costs in HOP compared to PO despite of similar resource use. Overall office visits (21.8 ±13.8 PO v 21.2 ±12.9, p < .005) and outpatient services (50.8 ±35.5 PO v 48.5 ±33.6, p < .001) were higher in the PO group than in the HOP group. Cancer-related inpatient hospitalizations (0.6 ±1.2 PO v 0.7 ±1.4 HOP, p = 0.002) were lower in the PO group than in the HOP group. Although quality-of-care metrics were similar between the HOP and PO groups, follow-up all-cause costs ($82,773 PO v $122,473 HOP) and cancer-related health care costs ($69,037 PO v $108,177 HOP) were higher in the HOP group than in the PO group.

Hernandez JM et al (2023)[27] demonstrated home-based infusion of immunotherapy can be achieved and provides a convenient option with high patient satisfaction and low incidence of infusion related reactions (IRRs).

Clinical Practice Guidelines

American Academy of Allergy Asthma and Immunology (AAAAI)

The American Academy of Allergy Asthma and Immunology has published guidelines for the suitability of patients to receive treatment in various care setting including clinical characteristics of patients needing a high level of care in the hospital outpatient facility which includes patient characteristics: previous serious infusion reaction such as anaphylaxis, seizure, myocardial infarction, or renal failure, immune globulin therapy naïve, continual experience of moderate or serious infusion related adverse reactions, physical or cognitive impairment.

AAAAI treatment guidelines provide several site of care options for administering immune globulin, with the appropriate option being based on the patient's clinical condition:

- Hospital inpatient physician/nurse supervised infusion
- Hospital outpatient physician/nurse supervised infusion
- Physician office-based physician/nurse supervised infusion
- Home based infusion with nurse supervision
- Home based infusion without nurse supervision

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The guidelines provide guidance on specific situation that may require a higher level of supervision, such as initial infusion of IVIG, changes in IVIG products, and specific clinical situations (AAAAI, 2011).
AAAAI Guidelines for IGIV site of administration:

- All initial infusions of IGIV should be administered under physician supervision in a facility equipped to manage the most severe acute medical complications
- Changes in IGIV products should be provided under physician supervision in a facility prepared to manage the most severe acute medical complications
- Certain individuals continue to need higher levels of supervision and intervention throughout IGIV infusions
- Individuals who have tolerated IGIV therapy without a history of adverse events may be considered for lower levels of supervision during infusions
- Given the options for providing IGIV therapy, specific patient experiences command or exclude specific sites of care (AAAI., 2011)

Hunter Syndrome European Expert Council

European recommendations for the diagnosis and multidisciplinary management of a rare disease published an article reviewing the collective experiences with agalsidase beta home infusion therapy and outlines how safe, patient-centered homecare can be organized in enzyme replacement therapy for patients with Fabry disease. Criteria include that "Patients must have received ERT in hospital for 3-6 months; if patients have previously had IRRs, they must be under control with premedication, and they must not have had an IRR in the 2-8 weeks before homecare is approved, and premedication must be given. If a patient has significant respiratory disease (%FVC, 40% or less; or evidence of serious obstructive airway disease), homecare may not be suitable."

Agency for Healthcare Research and Quality (AHRQ)

The AHRQ publication on Enzyme Replacement Therapy states, "Home infusion of ERT was initially studied in patients with type I Gaucher disease. It has been reported as an option for patients with Fabry disease, MPS I, and MPS II, and MPS VI. However, patients with infantile Pompe disease may not be able to transfer to home care because of an increased risk for serious adverse events during an infusion. In general, the outcomes measured in these studies and the follow-up durations were similar to those reported by disease in the clinical studies summarized under Guiding Question 3. Safety was the main focus of most home infusion studies, as the patients had already been receiving ERT in a more controlled setting."

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Policy History/Revision Information

Date	Summary of Changes
11/01/2026	• Added reference link to the list of *Provider Administered Drugs – Site of Care: Applicable Medications*
10/01/2026	**Coverage Rationale** • Combined and reorganized lists of applicable drug products, documentation requirements, applicable codes, and related policies in the *Provider Administered Drugs – Site of Care: Applicable Medications* list • Added language to indicate a medication will be subject to this *Provider Administered Drugs – Site of Care* policy when the medication is listed on the *Provider Administered Drugs – Site of Care: Applicable Medications* list **Definitions** • Added definition of "Oncology Drugs" **Applicable Codes** • Replaced list of applicable CPT/HCPCS codes with instruction to refer to the *Provider Administered Drugs – Site of Care: Applicable Medications* for the list of applicable codes and corresponding medications • Revised list of Provider Administered Drugs – Site of Care: Applicable Medications; added: ○ Avlayah™ and Loargys® (HCPCS codes C9399, J3490, and J3590) ○ Bosaya® (HCPCS code Q5161) ○ Conexxence® (HCPCS code Q5158) ○ Exdensur™ (HCPCS code J2361) ○ Ospomyv™ (HCPCS code Q5159) ○ Qivigy® (HCPCS code J1577) **Supporting Information** • Archived previous policy version 2026D0121W

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies 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.

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