Provider Administered Drugs – Site of Care

Policy Number: CS2024D0121E
Effective Date: January 1, 2024

Instructions for Use

Table of Contents **Page**

Related Community Plan Policies

- Actemra® (Tocilizumab) Injection for Intravenous Infusion
- Entyvio® (Vedolizumab)
- Ilumya™ (Tildrakizumab-Asmn)
- Infliximab (Avsola®, Inflectra®, Remicade®, & Renflexis®)
- Medical Therapies for Enzyme Deficiencies
- Orencia® (Abatacept) Injection for Intravenous Infusion
- Simponi Aria® (Golimumab) Injection for Intravenous Infusion

Commercial Policy

- Provider Administered Drugs – Site of Care

Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Colorado	None
Kentucky	None
Indiana	None
Louisiana	Provider Administered Drugs – Site of Care (for Louisiana Only)
North Carolina	None
Ohio	Provider Administered Drugs – Site of Care (for Ohio Only)
Pennsylvania	Provider Administered Drugs – Site of Care (for Pennsylvania Only)

The following table outlines the applicability of this policy by medication and state, as differences by state are present:

Drug Name	Applicable States
Actemra® (tocilizumab)	Arizona, Hawaii, Maryland, Nebraska, New Jersey, Tennessee, Texas
Aldurazyme® (laronidase)	Nebraska, New Jersey, Rhode Island
Amondys 45™ (casimersen)	Nebraska, New Jersey, Rhode Island, Tennessee, Texas
Aralast NP® (A1-PI)	Arizona, Nebraska, New Jersey, Rhode Island
Asceniv™ (IV)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Avsola™ (Infliximab-axxq)	Arizona, Hawaii, Maryland, Nebraska, New Jersey, Tennessee, Texas

Drug Name	Applicable States
Bivigam® (IV)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Carimune® NF (IV)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Cutaquig® (SC)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Cuvitru® (SC)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Elaprase® (idursulfase)	Nebraska, New Jersey, Rhode Island
Elfabrio® (pegunigalsidase alfa-iwxj)	Arizona, Nebraska, New Jersey, Rhode Island
Entyvio® (Vedolizumab)	Arizona, Hawaii, Maryland, Nebraska, New Jersey, Tennessee, Texas
Exondys 51® (eteplirsen)	Nebraska, New Jersey, Rhode Island, Tennessee, Texas
Fabrazyme® (agalsidase beta)	Nebraska, New Jersey, Rhode Island
Flebogamma® DIF (IV)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Gammagard® Liquid (IV, SC)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Gammagard® S/D (IV)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Gammaked™ (IV, SC)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Gammaplex® (IV)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Gamunex®-C (IV, SC)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Glassia® (A1-PI)	Arizona, Nebraska, New Jersey, Rhode Island
Hizentra® (SC)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
HyQvia® (SC)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Ilumya™ (tildrakizumab-asmn)	Arizona, California, Florida, Hawaii, Maryland, Michigan, Mississippi, Nebraska, New Jersey, New York, Rhode Island, Tennessee, Texas, Virginia, Washington
Inflectra® (infliximab-dyyb)	Arizona, Hawaii, Maryland, Nebraska, New Jersey, Tennessee, Texas
Kanuma® (sebelipase alfa)	Arizona, Nebraska, New Jersey, Rhode Island
Lamzede® (velmanase alfa-tycv)	Arizona, Nebraska, New Jersey, Rhode Island
Lumizyme® (alglucosidase alfa)	Nebraska, New Jersey, Rhode Island
Mepsevii™ (vestronidase alfa-vjbk)	Arizona, Nebraska, New Jersey, Rhode Island
Naglazyme® (galsulfase)	Arizona, Nebraska, New Jersey, Rhode Island
Nexviazyme™ (avalglucosidase alfa-ngpt)	Arizona, Nebraska, New Jersey, Rhode Island
Octagam® (IV)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Orencia® (Abatacept)	Arizona, Hawaii, Maryland, Nebraska, New Jersey, Tennessee, Texas
Panzyga® (IV)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Privigen® (IV)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Prolastin®-C (A1-PI)	Arizona, Nebraska, New Jersey, Rhode Island
Remicade® (Infliximab)	Arizona, Hawaii, Maryland, Nebraska, New Jersey, Tennessee, Texas
Renflexis® (Infliximab-abda)	Arizona, Hawaii, Maryland, Nebraska, New Jersey, Tennessee, Texas
Revcovi® (elapegademase-lvlr)	Nebraska, New Jersey, Rhode Island
Simponi Aria® (golimumab)	Arizona, Hawaii, Maryland, Nebraska, New Jersey, Tennessee, Texas
Skyrizi® (risankizumab-rzaa)	Arizona, Hawaii, Maryland, Nebraska, New Jersey, Tennessee, Texas
Soliris® (eculizumab)	Nebraska, Rhode Island, New Jersey, Texas
Ultomiris® (ravulizumab-cwvz)	Arizona, Nebraska, New Jersey, Rhode Island, Texas
Viltepso™ (viltolarsen)	Nebraska, New Jersey, Rhode Island, Tennessee, Texas
Vimizim® (elosulfase alfa)	Arizona, Nebraska, New Jersey, Rhode Island
Vyondys 53™ (golodirsen)	Nebraska, New Jersey, Rhode Island, Tennessee, Texas

Drug Name	Applicable States
Xembify® (SC)	Arizona, Nebraska, New Jersey, Rhode Island, Tennessee, Texas, Washington
Xenpozyme® (olipudase alfa)	Arizona, Nebraska, New Jersey, Rhode Island
Zemaira® (A1-PI)	Arizona, Nebraska, New Jersey, Rhode Island

Coverage Rationale

This policy addresses the criteria for consideration of allowing hospital outpatient facility medication infusion services 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 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.

Outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required):

- Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative Sites of Care as determined by any of the following:
  - The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; **or**
  - The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site of Care; **or**
  - Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; **or**
  - Difficulty establishing and maintaining patent vascular access.

  or
- Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; **or**
- Initial infusion or re-initiation of therapy after more than 6 months for a short duration of time (e.g., 4 weeks); **or**
- **For IVIG or SCIG only**: Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; **or**
- Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy and **both** of the following:
  - The prescriber is unable to infuse in the office setting.
  - There are no ambulatory infusion suite options available for this member.

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.

This policy applies to these specialty medications that require healthcare provider administration:

- Actemra® (tocilizumab)
- Aldurazyme® (laronidase)
- Amondys 45™ (casimersen)
- Aralast NP® (A1-PI)
- Asceniv™ (IV)
- Avsola™ (Infliximab-axxq)
- Bivigam® (IV)
- Carimune® NF (IV)
- Cutaquig® (SC)
- Cuvitru® (SC)
- Elaprase® (idursulfase)
- Elfabrio® (pegunigalsidase alfa-iwxj)
- Entyvio® (Vedolizumab)
- Exondys 51® (eteplirsen)
- Fabrazyme® (agalsidase beta)
- Flebogamma® DIF (IV)
- Gammagard® Liquid (IV, SC)
- Gammagard® S/D (IV)
- Gammaked™ (IV, SC)
- Gammaplex® (IV)
- Gamunex®-C (IV, SC)
- Glassia® (A1-PI)
- Hizentra® (SC)
- HyQvia® (SC)
- Ilumya™ (Tildrakizumab-asmn)
- Inflectra® (Infliximab-dyyb)

- Kanuma® (sebelipase alfa)
- Lamzede® (velmanase alfa-tycv)
- Lumizyme® (alglucosidase alfa)
- Mepsevii™ (vestronidase alfa-vjbk)
- Naglazyme® (galsulfase)
- Nexviazyme™ (avalglucosidase alfa-ngpt)
- Octagam® (IV)
- Orencia® (abatacept)
- Panzyga® (IV)
- Privigen® (IV)
- Prolastin®-C (A1-PI)
- Remicade® (Infliximab)
- Renflexis® (Infliximab-abda)
- Revcovi® (elapegademase-lvlr)
- Simponi Aria® (Golimumab)
- Skyrizi® (risankizumab-rzaa)
- Soliris® (eculizumab)
- Ultomiris® (ravulizumab-cwvz)
- Vimizim® (elosulfase alfa)
- Viltepso™ (viltolarsen)
- Vyondys 53™ (golodirsen)
- Xembify® (SC)
- Xenpozyme® (olipudase alfa)
- Zemaira® (A1-PI)

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 benefit drug policy addresses therapeutic use of Immune Globulin G (IgG) an antibody normally produced by B lymphocytes. References to Immune Globulin within this medical benefit drug 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).

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

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Refer to the table outlining applicability of this policy by medication and state to determine the potential applicability of a specific code by the state. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin SCIg), human, for use in subcutaneous infusions, 100 mg, each

HCPCS Code	Description
C9399	Unclassified drugs or biologicals
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 is self-administered)
J0180	Injection, agalsidase beta, 1 mg
J0217	Injection, velmanase alfa-tycv, 1 mg
J0218	Injection, olipudase alfa-rpcp, 1 mg
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
J0221	Injection, alglucosidase alfa, (Lumizyme), 10 mg
J0256	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified
J0257	Injection, alpha 1 proteinase inhibitor (human), (Glassia), 10 mg
J1300	Injection, eculizumab, 10 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
J1322	Injection, elosulfase alfa, 1 mg

HCPCS Code	Description
J1426	Injection, casimersen, 10 mg
J1427	Injection, viltolarsen, 10 mg
J1428	Injection, eteplirsen, 10 mg
J1429	Injection, golodirsen, 10 mg
J1458	Injection, galsulfase, 1 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), 100mg
J1556	Injection, immune globulin (Bivigam), 500 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-C/Gammaked), intravenous, 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), intravenous, 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, (Hyqvia), 100 mg immune globulin
J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1743	Injection, idursulfase, 1 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J1931	Injection, laronidase, 0.1 mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg
J2840	Injection, sebelipase alfa, 1 mg
J3245	Injection, tildrakizumab, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3380	Injection, vedolizumab, 1 mg
J3397	Injection, vestronidase alfa-vjbk, 1 mg
J3490	Unclassified drugs
J3590	Unclassified biologics
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg

Description of Services

According to the American Academy of Allergy Asthma and Immunology (AAAI), 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).

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 (AAAI., 2011).

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 ($p = .46$) but was significantly better than 30 similar patients managed before eculizumab ($p = .030$). 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; $p < .001$). 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 transfusion requirement reduced from 19.3 units before eculizumab to 5.0 units in the most recent 12 months on eculizumab ($p < .001$). 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 3,161 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.

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).

Clinical Practice Guidelines

American Academy of Allergy Asthma and Immunology

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

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."

References

1. 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.
2. American Academy of Allergy Asthma and Immunology. Guidelines for the site of care for administration of IGIV therapy. December 2011.
3. Bagewadi S, Roberts J, Mercer J, et al. Home treatment with elaprase and naglazyme is safe in patients with mucopolysaccharidoses types II and VI, respectively. J Inherit Metab Dis. 2008 Dec;31(6):733-7.
4. Barfield E, Solomon A, Sockolow R. Inflammatory Bowel Disease: A Practical Approach. Prac Gastroenterol May 2016, 5:16-23.
5. Burton BK, Guffon N, Roberts J, et al. Home treatment with intravenous enzyme replacement therapy with idursulfase for mucopolysaccharidosis type II data from the Hunter Outcome Survey. Mol Genet Metab. 2010 Oct-Nov;101(2-3):123-9.
6. 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.html. Accessed September 28, 2022.
7. Condino A, Fidanza S Hoffenberg E. A home Infliximab Infusion Program. J Pediatr Gastroenterol Nutr, Vol. 40, No. 1, January 2005.
8. Cox-Brinkman J, Timmermans RG, Wijburg FA, et al. Home treatment with enzyme replacement therapy for mucopolysaccharidosis type I is feasible and safe. J Inherit Metab Dis. 2007 Nov;30(6):984.
9. Ducharme J, Pelletier C, Zacharias R. The safety of infliximab infusions in the community setting. Can J Gastroenterol 2010;24(5):307-311.
10. Elstein D, Abrahamov A, Oz A, et al. 13,845 home therapy infusions with velaglucerase alfa exemplify safety of velaglucerase alfa and increased compliance to every-other-week intravenous enzyme replacement therapy for Gaucher disease. Blood Cells Mol Dis. 2015 Dec;55(4):415-8.
11. Elstein D, Burrow TA, Charrow J, et al. Home infusion of intravenous velaglucerase alfa: Experience from pooled clinical studies in 104 patients with type 1 Gaucher disease. Mol Genet Metab. 2017 Jan-Feb;120(1-2):111-115.
12. Finnigan N, Roberts J, Mercer J, Jones SA. Home infusion with elosulfase alpha (Vimizim®) in a UK paediatric setting. Mol Genet Metab Rep. 2017 Nov 5;14:15-18.
13. Kelly RJ, Hill A, Arnold LM, et al. Long-term treatment with eculizumab in paroxysmal nocturnal hemoglobinuria: sustained efficacy and improved survival. Blood. 2011;117(25):6786-92.
14. Kisinovsky I, Cáceres G, Coronel C, Reisin R. Home infusion program for Fabry disease: experience with agalsidase alfa in Argentina. Medicina (B Aires). 2013;73(1):31-4.
15. Petrache I, Hajjar J, Campos M. Safety and efficacy of alpha-1-antitrypsin augmentation therapy in the treatment of patients with alpha-1-antitrypsin deficiency. Biologics. 2009; 3: 193-204.
16. Phase I: 2010 NHIA Provider Survey Comprehensive Aggregate Analysis Report. National Home Infusion Association. 2011.

17. Scarpa M, Almássy Z, Beck M, et al. European recommendations for the diagnosis and multidisciplinary management of a rare disease. Orphanet J Rare Dis. 2011;6:72. Mucopolysaccharidosis type II: Hunter Syndrome European Expert Council.
18. Sheikh SZ, Hammer AE, Fox NL, et al. Evaluation of a novel autoinjector for subcutaneous self-administration of belimumab in systemic lupus erythematosus. Int J Clin Pharmacol Ther. 2016 Nov;54(11):914-922.
19. Smid BE, Hoogendijk SL, Wijburg FA, et al. A revised home treatment algorithm for Fabry disease: Influence of antibody formation. Mol Genet Metab. 2013 Feb;108(2):132-7.
20. Smith S, Curry, K, Rout T, et al. Adverse drug events in infliximab patients infused in the home care setting: a retrospective chart review. Poster presented at the National Home Infusion Association Annual Conference and Exhibition; 2016 March 21-24; New Orleans, La.
21. American Academy of Allergy Asthma and Immunology. Immunoglobulin (IgG) replacement therapy defined. 2022. Available at: https://www.aaaai.org/Tools-for-the-Public/Allergy,-Asthma-Immunology-Glossary/Immunoglobulin-(IgG)-Replacement-Therapy-Defined. Accessed September 15, 2022.
22. 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 21, 2022.
23. Wasserman RL, Ito D, Xiong Y, et al. Impact of site of care on infection rates among patients with primary immunodeficiency diseases receiving intravenous immunoglobulin therapy. J Clin Immunol. 2017 Feb; 37(2): 180–186.
24. Hopson S, Casebeer A, Stemkowski S, et al. Does site-of-care for oncology infusion therapy influence treatment patterns, cost, and quality in the United States? J Med Econ. 2018 Feb;21(2):152-162. doi: 10.1080/13696998.2017.1384736. Epub 2017 Oct 17. PMID: 28945163.
25. Fisher MD, Punekar R, Yim YM, et al. Differences in Health Care Use and Costs Among Patients With Cancer Receiving Intravenous Chemotherapy in Physician Offices Versus in Hospital Outpatient Settings. J Oncol Pract. 2017 Jan;13(1):e37-e46. doi: 10.1200/JOP.2016.012930. Epub 2016 Nov 15. PMID: 27845870.

Policy History/Revision Information

Date	Summary of Changes
01/01/2024	**Applicable Codes** • Updated list of applicable HCPCS codes to reflect annual edits; added J0217 and J2508 **Supporting Information** • Archived previous policy version CS2023D0121D

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. 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.

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