

Provider Administered Drugs – Site of Care

Policy Number: 2025D0121O

Effective Date: May 1, 2025

[Instructions for Use](#)

Table of Contents	Page
Coverage Rationale	1
Documentation Requirements	3
Definitions	6
Applicable Codes	6
Description of Services	8
Benefit Considerations	9
Clinical Evidence	9
References	11
Policy History/Revision Information	12
Instructions for Use	12

Related Commercial Policies

- | | |
|---|---|
| <ul style="list-style-type: none"> • Adakveo® (Crizanlizumab-Tmca) • Adzynma (ADAMTS₁₃, Recombinant-Krh) • Alpha₁-Proteinase Inhibitors • Amondys 45® (Casimersen) • Benlysta® (Belimumab) • Briumvi® (Ublituximab-Xiiy) • Cimzia® (Certolizumab Pegol) • Cosentyx® (Secukinumab) • Crysvita® (Burosumab-Twza) • Complement Inhibitors (PiaSky®, Soliris®, & Ultomiris®) • Enjaymo® (Sutimlimab-Jome) • Entyvio® (Vedolizumab) • Evkeeza® (Evinacumab-Dgnb) • Exondys 51® (Eteplirsen) • Givlaari® (Givosiran) • Home Health, Skilled, and Custodial Care Services (for Commercial Only) • Immune Globulin (IVIG and SCIG) • Ilaris® (Canakinumab) • Ilumya® (Tildrakizumab-Asmn) • Infliximab (Avsola®, Inflectra®, Remicade®, & Renflexis®) • Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease • Long-Acting Injectable Antiretroviral Agents for HIV • Medical Therapies for Enzyme Deficiencies • Neonatal Fc Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo) | <ul style="list-style-type: none"> • Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq) • Omvoh® (Mirikizumab-Mrkz) • Orencia® (Abatacept) Injection for Intravenous Infusion • Oxlumo® (Lumasiran) and Rivfloza™ (Nedosiran) • Radicava® (Edaravone) • Respiratory Interleukins (Cinqair®, Fasentra®, & Nucala®) • RNA-Targeted Therapies (Amvuttra® and Onpattro®) • Ryplazim® (Plasminogen, Human-Tvmh) • Saphnelo® (Anifrolumab-Fnia) • Simponi Aria® (Golimumab) Injection for Intravenous Infusion • Skyrizi® (Risankizumab-Rzaa) • Spevigo® (Spesolimab-Sbzo) • Stelara® (Ustekinumab) • Tepezza® (Teprotumumab-Trbw) • Tezspire® (Tezepelumab-Ekko) • Tocilizumab (Actemra®, Tofidence™, & Tyenne®) Injection for Intravenous Infusion • Tremfya® (Guselkumab) • Uplizna® (Inebilizumab-Cdon) • Veopoz™ (Pozelimab-Bbfg) • Viltepso® (Viltolarsen) • Vyepi® (Eptinezumab-Jjmr) • Vyjuvek® (Beramagene Geperpavec-Svdt) • Vyondys 53® (Golodirsen) • Xolair® (Omalizumab) |
|---|---|

Coverage Rationale

➤ See [Benefit Considerations](#)

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**
- 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) and member is not a viable candidate for long-term vascular access devices such as picc line or port-a-cath; **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 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**
- **For IVIG or SCIG only:** Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; **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

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.

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

- | | | |
|--|-----------------------------|-------------------------------|
| • Actemra® (tocilizumab) | • Amondys 45® (casimersen) | • Benlysta® (belimumab) |
| • Adakveo® (crizanlizumab-tmca) | • Amvuttra™ (vutrisiran) | • Bivigam® (IV) |
| • Adzynma (ADAMTS13, recombinant-krhn) | • Aralast NP® (A1-PI) | • Briumvi® (ublituximab-xiiy) |
| • Aldurazyme® (laronidase) | • Asceniv™ (IV) | • Carimune® NF (IV) |
| • Alyglo™ (IV) | • Avsola™ (infliximab-axxq) | • Cerezyme® (imiglucerase) |

- Cimzia® (certolizumab pegol)
- Cinqair® (reslizumab)
- Cosentyx® (secukinumab)
- Crysvita® (burosumab-twza)
- Cutaquig® (SC)
- Cuvitru® (SC)
- Elaprase® (idursulfase)
- Elelyso® (taliglucerase)
- Elfabrio® (pegunigalsidase alfa-iwxj)
- Enjaymo® (sutimlimab-jome)
- Entyvio® (vedolizumab)
- Evkeeza® (evinacumab)
- Exondys 51® (eteplirsen)
- Fabrazyme® (agalsidase beta)
- Fasenra® (benralizumab)
- Flebogamma® DIF (IV)
- Gammagard® Liquid (IV, SC)
- Gammagard® S/D (IV)
- Gammaked™ (IV, SC)
- Gammaplex® (IV)
- Gamunex®-C (IV, SC)
- Givlaari® (givosiran)
- Glassia® (A1-PI)
- Hizentra® (SC)
- HyQvia® (SC)
- Ilaris® (canakinumab)
- Ilumya® (tildrakizumab-asmn)
- Inflectra® (infliximab-dyyb)
- Kanuma® (sebelipase alfa)
- Lamzede® (velmanase alfa-tycv)
- Lumizyme® (alglucosidase alfa)
- Mepsevii™ (vestronidase alfa-vjbj)
- Naglazyme® (galsulfase)
- Nexviazyme™ (avalglucosidase alfa-ngpt)
- Nucala® (mepolizumab)
- Nulibry™ (fosdenopterin)
- Ocrevus® (ocrelizumab)
- Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq)
- Octagam® (IV)
- Omvoh® (mirikizumab-mrkz)
- Onpattro® (patisiran)
- Orencia® (abatacept)
- Oxlumo® (lumasiran)
- Panzyga® (IV)
- PiaSky® (crovalimab-akkz)
- Pombiliti™ (cipaglucosidase alfa-atga)
- Privigen® (IV)
- Prolastin®-C™ (A1-PI)
- Pyzchiva® (ustekinumab-ttwe)
- Radicava® (edaravone)
- Remicade® (infliximab)
- Renflexis® (infliximab-abda)
- Revcovi® (elapegademase-lvlr)
- Rivfloza™ (Nedosiran)
- Ryplazim® (plasminogen, human-tvmh)
- Rystiggo® (rozanolixizumab-noli)
- Saphnelo® (anifrolumab-fnia)
- Selarsdi™ (ustekinumab-aekn)
- Simponi Aria® (golimumab)
- Skyrizi® (risankizumab-rzaa)
- Soliris® (eculizumab)
- Spevigo® (spesolimab-sbzo) (SC)
- Stelara® (ustekinumab)
- Tepezza® (teprotumumab-trbw)
- Tezspire™ (tezepelumab-ekko)
- Tofidence™ (tocilizumab-bavi)
- Tremfya® (Guselkumab) (IV)
- Tyenne® (tocilizumab-aazg)
- Ultomiris® (ravulizumab-cwvz)
- Uplizna® (inebilizumab-cdon)
- Veopoz™ (pozelimab-bbfg)
- Viltapso™ (viltolarsen)
- Vimizim® (elosulfase alfa)
- VPRIV® (velaglucerase)
- Vyepiti® (eptinezumab-jjmr)
- Vyjuvek® (beramagene geperpavec-svdt)
- Vyondys 53™ (golodirsen)
- Vyvgart® (efgartigimod)
- Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
- Wezlana™ (ustekinumab-auub)
- Xembify® (SC)
- Xenpozyme™ (olipudase alfa-rpcp)
- Xolair® (Omalizumab)
- Zemaira® (A1-PI)

Documentation Requirements

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 below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

Specialty Medication	HCPs Codes*	Required Clinical Information
Actemra® (tocilizumab)	J3262	Refer to the applicable Medical Benefit Drug Policy.
Adakveo® (crizanlizumab-tmca)	J0791	
Adzyna (ADAMTS13, recombinant-krhn)	J7171	
Aldurazyme® (laronidase)	J1931	
Alyglo™ (IV)	J1552	
Amondys 45® (casimersen)	J1426	
Amvuttra™ (vutrisiran)	J0225	
Aralast NP® (A1-PI)	J0256	
Asceniv™ (IV)	J1554	
Avsola™ (infliximab-axxq)	Q5121	
Benlysta® (belimumab)	J0490	
Bivigam® (IV)	J1556	
Briumvi® (ublituximab-xiyy)	J2329	

Specialty Medication	HCP Codes*	Required Clinical Information
Carimune® NF (IV)	J1566	Refer to the applicable Medical Benefit Drug Policy.
Cerezyme® (imiglucerase)	J1786	
Cimzia® (certolizumab pegol)	J0717	
Cinqair® (reslizumab)	J2786	
Cosentyx® (Secukinumab)	J3247	
Crysvita® (burosumab-twza)	J0584	
Cutaquig® (SC)	J1551	
Cuvitru® (SC)	J1555	
Elaprase® (idursulfase)	J1743	
Elelyso® (taliglucerase)	J3060	
Elfabrio® (pegunigalsidase alfa-iwxj)	J2508	
Enjaymo® (sutimlimab-jome)	J1302	
Entyvio® (vedolizumab)	J3380	
Evkeeza® (evinacumab)	J1305	
Exondys 51® (eteplirsen)	J1428	
Fabrazyme® (agalsidase beta)	J0180	
Fasenra® (benralizumab)	J0517	
Flebogamma® DIF (IV)	J1572	
Gammagard® Liquid (IV, SC)	J1569	
Gammagard® S/D (IV)	J1566	
Gammaked™ (IV, SC)	J1561	
Gammaplex® (IV)	J1557	
Gamunex® C (IV, SC)	J1561	
Givlaari® (givosiran)	J0223	
Glassia® (A1-PI)	J0257	
Hizentra® (SC)	J1559	
HyQvia® (SC)	J1575	
Ilaris® (canakinumab)	J0638	
Ilumya® (tildrakizumab-asmn)	J3245	
Inflectra® (infliximab-dyyb)	Q5103	
Kanuma® (sebelipase alfa)	J2840	
Lamzed® (velmanase alfa-tycv)	J0217	
Lumizyme® (alglucosidase alfa)	J0221	
Mepsevii™ (vestronidase alfa-vjbk)	J3397	
Naglazyme® (galsulfase)	J1458	
Nexviazyme™ (avalglucosidase alfa-ngpt)	J0219	
Nucala® (mepolizumab)	J2182	
Nulibry™ (fosdenopterin)	C9399, J3490, J3590	
Ocrevus® (ocrelizumab)	J2350	
Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq)	J2351	
Octagam® (IV)	J1568	
Omvo® (mirikizumab-mrkz)	J2267	

Specialty Medication	HCPCS Codes*	Required Clinical Information
Onpattro™ (patisiran)	J0222	Refer to the applicable Medical Benefit Drug Policy.
Orencia® (abatacept)	J0129	
Oxlumo® (lumasiran)	J0224	
Panzyga® (IV)	J1576	
PiaSky® (crovalimab-akkz)	J1307	
Pombiliti™ (cipaglucosidase alfa-atga)	J1203	
Privigen® (IV)	J1459	
Prolastin®-C™ (A1-PI)	J0256	
Pyzchiva® (ustekinumab-ttwe)	Q9996, Q9997	
Radicava® (edaravone)	J1301	
Remicade® (infliximab)	J1745	
Renflexis® (infliximab-abda)	Q5104	
Revcovi® (elapegademase-lvlr)	C9399, J3590	
Rivfloza™ (Nedosiran)	C9399, J3490	
Ryplazim® (plasminogen, human-tvmh)	J2998	
Rystiggo® (rozanolixizumab-noli)	J9333	
Saphnelo® (anifrolumab-fnia)	J0491	
Selarsdi™ (ustekinumab-aekn)	Q9998	
Simponi Aria® (golimumab)	J1602	
Skyrizi® (risankizumab-rzaa)	J2327	
Soliris® (eculizumab)	J1299	
Spevigo® (spesolimab-sbzo) (SC)	J1747**	
Stelara® (ustekinumab)	J3357, J3358	
Tepezza® (teprotumumab-trbw)	J3241	
Tezspire® (tezepelumab-ekko)	J2356	
Tofidence™ (tocilizumab-bavi)	Q5133	
Tremfya® (guselkumab) (IV)	J1628	
Tyenne® (tocilizumab-aazg)	Q5135	
Ultomiris® (ravulizumab-cwvz)	J1303	
Uplizna® (inebilizumab-cdon)	J1823	
Veopoz™ (pozelimab-bbfg)	J9376	
Viltepso® (Viltolarsen)	J1427	
Vimizim® (elosulfase alfa)	J1322	
VPRIV® (velaglucerase)	J3385	
Vyepti® (eptinezumab-jjmr)	J3032	
Vyjuvek™ (beramagene geperpavec-svdt)	J3401	
Vyondys 53® (golodirsen)	J1429	
Vyvgart® (efgartigimod)	J9332	
Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	J9334	
Wezlana™ (ustekinumab-auub)	Q5137, Q5138	
Xembify® (SC)	J1558	
Xenpozyme™ (olipudase alfa-rpcp)	J0218	
Xolair® (Omalizumab)	J2357	

Specialty Medication	HCPSC Codes*	Required Clinical Information
Zemaira® (A1-PI)	J0256	Refer to the applicable Medical Benefit Drug Policy.

*For code descriptions, refer to the [Applicable Codes](#) section.

**This policy applies to the Spevigo® (spesolimab-sbzo) prefilled syringe for subcutaneous use.

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).

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. 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 the member specific benefit plan document 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

CPT® is a registered trademark of the American Medical Association

HCPSC 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
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

HCP/CS Code	Description
J0717	Injection, certolizumab pegol, 1 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)
J0791	Injection, crizanlizumab-tmca, 5 mg
J1203	Injection, cipaglucosidase alfa-atga
J1299	Injection, eculizumab, 2 mg
J1301	Injection, edaravone, 1 mg
J1302	Injection, sutimlimab-jome, 10 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
J1305	Injection, evinacumab-dgnb, 5 mg
J1307	Injection, crovalimab-akkz, 10 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
J1552	Injection, immune globulin (Alyglo), 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/ 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 immunoglobulin
J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1628	Injection, guselkumab, 1 mg
J1743	Injection, idursulfase, 1 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J1747**	Injection, spesolimab-sbzo, 1 mg
J1786	Injection, imiglucerase, 10 units
J1823	Injection, inebilizumab-cdon, 1 mg
J1931	Injection, laronidase, 0.1 mg
J2182	Injection, mepolizumab, 1 mg
J2267	Injection, mirikizumab-mrkz, 1 mg

HCPSC Code	Description
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J2329	Injection, ublituximab-xiiy, 1mg
J2351	Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq
J2350	Injection, ocrelizumab, 1 mg
J2356	Injection, tezepelumab-ekko, 1 mg
J2357	Injection, omalizumab, 5 mg
J2508	Injection, pegunigalsidase alfa-iwxj, 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
J3247	Injection, secukinumab, IV, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, IV, 1 mg
J3385	Injection, velaglucerase alfa, 100 units
J3397	Injection, vestronidase alfa-vjbk, 1 mg
J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10 ⁹ PFU/ml vector genomes, per 0.1 ml
J3490	Unclassified drugs
J3590	Unclassified biologics
J7171	Injection, ADAMTS13, recombinant-krhn, 10 IU
J9332	Injection, efgartigimod alfa-fcab, 2 mg
J9333	Injection, rozanolixizumab-noli, 1 mg
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc
J9376	Injection, pozelimab-bbfg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg
Q5137	Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg
Q5138	Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q9996	Injection, ustekinumab-ttwe (pyzchiva), subcutaneous, 1 mg
Q9997	Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg
Q9998	Injection, ustekinumab-aekn (selarsdi), 1 mg

**This policy applies to the Spevigo® (spesolimab-sbzo) prefilled syringe for subcutaneous use.

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).

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.

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. Refer to the Policy and Procedure addressing the treatment of serious rare diseases.

This guideline applies to UnitedHealthcare Commercial plans. This guideline does not apply to Medicare or Medicaid plans.

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 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.

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 (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

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. Available at: <https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/Guidelines-for-the-site-of-care-for-administration-of-IGIV-therapy.pdf>. Accessed September 15, 2022.
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 alfa (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](https://www.aaaai.org/Tools-for-the-Public/Allergy-Asthma-Immunology-Glossary/Immunoglobulin-(IgG)-Replacement-Therapy-Defined). Accessed September 15, 2022.
22. 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.
23. 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.
24. Fisher MD, Puneekar 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
05/01/2025	<p>Related Policies</p> <ul style="list-style-type: none"> Removed reference link to the Medical Benefit Drug Policy titled <i>Tziel[®]</i> (<i>Teplizumab-Mzwv</i>) <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised list of medications that require healthcare provider administration; removed: <ul style="list-style-type: none"> Apretude[™] (cabotegravir) Tziel[™] (teplizumab-mzwv) <p>Documentation Requirements</p> <ul style="list-style-type: none"> Revised list of specialty medications with associated documentation requirements; removed: <ul style="list-style-type: none"> Apretude[™] (cabotegravir) (HCPCS code J0739) Tziel[™] (teplizumab-mzwv) (HCPCS code J9381) <p>Applicable Codes</p> <ul style="list-style-type: none"> Removed HCPCS codes J0739 and J9381 <p>Supporting Information</p> <ul style="list-style-type: none"> Archived previous policy version 2025D0121N

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, please 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.