

Provider Administered Drugs – Site of Care

Guideline Number: CS155.K
Effective Date: August 1, 2022

[➔ Instructions for Use](#)

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Related Community Plan Policies
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • Provider Administered Drugs – Site of Care

Application

This Utilization Review Guideline does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Kentucky	None
Indiana	None
Louisiana	Provider Administered Drugs – Site of Care (for Louisiana Only)
Mississippi	Provider Administered Drugs – Site of Care (for Mississippi Only)
Nebraska	Provider Administered Drugs – Site of Care (for Nebraska Only)
New Jersey	Provider Administered Drugs – Site of Care (for New Jersey Only)
North Carolina	None
Pennsylvania	Provider Administered Drugs – Site of Care (for Pennsylvania Only)
Tennessee	Provider Administered Drugs – Site of Care (for Tennessee 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, Ohio, Texas
Aldurazyme® (Iaronidase)	Ohio, Rhode Island
Amondys 45™ (casimersen)	Ohio, Rhode Island, Texas
Aralast NP® (A1-PI)	Arizona, Ohio, Rhode Island

Drug Name	Applicable States
Asceniv™ (IV)	Arizona, Ohio, Rhode Island, Texas, Washington
Avsola™ (Infliximab-axxq)	Arizona, Hawaii, Maryland, Ohio, Texas
Bivigam® (IV)	Arizona, Ohio, Rhode Island, Texas, Washington
Carimune® NF (IV)	Arizona, Ohio, Rhode Island, Texas, Washington
Cutaquig® (SC)	Arizona, Ohio, Rhode Island, Texas, Washington
Cuvitru® (SC)	Arizona, Ohio, Rhode Island, Texas, Washington
Elaprase® (idursulfase)	Ohio, Rhode Island
Entyvio® (Vedolizumab)	Arizona, Hawaii, Maryland, Ohio, Texas
Exondys 51® (eteplirsen)	Ohio, Rhode Island, Texas
Fabrazyme® (agalsidase beta)	Ohio, Rhode Island
Flebogamma® DIF (IV)	Arizona, Ohio, Rhode Island, Texas, Washington
Gammagard® Liquid (IV, SC)	Arizona, Ohio, Rhode Island, Texas, Washington
Gammagard® S/D (IV)	Arizona, Ohio, Rhode Island, Texas, Washington
Gammaked™ (IV, SC)	Arizona, Ohio, Rhode Island, Texas, Washington
Gammaplex® (IV)	Arizona, Ohio, Rhode Island, Texas, Washington
Gamunex®-C (IV, SC)	Arizona, Ohio, Rhode Island, Texas, Washington
Glassia® (A1-PI)	Arizona, Ohio, Rhode Island
Hizentra® (SC)	Arizona, Ohio, Rhode Island, Texas, Washington
HyQvia® (SC)	Arizona, Ohio, Rhode Island, Texas, Washington
Ilumya™ (Tildrakizumab-asmn)	Arizona, California, Florida, Hawaii, Maryland, Michigan, New York, Ohio, Rhode Island, Texas, Virginia, Washington
Inflectra® (Infliximab-dyyb)	Arizona, Hawaii, Maryland, Ohio, Texas
Kanuma® (sebelipase alfa)	Arizona, Ohio, Rhode Island
Lumizyme® (alglucosidase alfa)	Ohio, Rhode Island
Mepsevii™ (vestronidase alfa-vjkb)	Arizona, Ohio, Rhode Island
Naglazyme® (galsulfase)	Arizona, Ohio, Rhode Island
Nexviazyme™ (avalglucosidase alfa-ngpt)	Arizona, Ohio, Rhode Island
Octagam® (IV)	Arizona, Ohio, Rhode Island, Texas, Washington
Orencia® (Abatacept)	Arizona, Hawaii, Maryland, Ohio, Texas
Panzyga® (IV)	Arizona, Ohio, Rhode Island, Texas, Washington
Privigen® (IV)	Arizona, Ohio, Rhode Island, Texas, Washington
Prolastin®-C (A1-PI)	Arizona, Ohio, Rhode Island
Remicade® (Infliximab)	Arizona, Hawaii, Maryland, Ohio, Texas
Renflexis® (Infliximab-abda)	Arizona, Hawaii, Maryland, Ohio, Texas
Revcovi® (elapegademase-lvr)	Ohio, Rhode Island
Simponi Aria® (Golimumab)	Arizona, Hawaii, Maryland, Ohio, Texas
Soliris® (eculizumab)	Ohio, Rhode Island, Texas
Ultomiris® (ravulizumab-cwvz)	Arizona, Ohio, Rhode Island, Texas
Viltepso™ (viltolarsen)	Ohio, Rhode Island, Texas
Vimizim® (elosulfase alfa)	Arizona, Ohio, Rhode Island
Vyondys 53™ (golodirsen)	Ohio, Rhode Island, Texas

Drug Name	Applicable States
Xembify® (SC)	Arizona, Ohio, Rhode Island, Texas, Washington
Zemaira® (A1-PI)	Arizona, Ohio, Rhode Island

Coverage Rationale

This guideline addresses the criteria for consideration of allowing hospital outpatient facility medication infusion services. This includes claim submission for hospital-based services with the following CMS/AMA Place of Service codes:

- 22 On Campus-Outpatient Hospital; and
- 19 Off 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 a patient 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;
- 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 medications that require healthcare provider administration:

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|-----------------------------|--------------------------------|--------------------------------------|
| • Actemra® (Tocilizumab) | • Elaprase® (idursulfase) | • Glassia® (A1-PI) |
| • Aldurazyme® (Iaronidase) | • Entyvio® (Vedolizumab) | • Hizentra® (SC) |
| • Amondys 45™ (casimersen) | • Exondys 51® (eteplirsen) | • HyQvia® (SC) |
| • Aralast NP® (A1-PI) | • Fabrazyme® (agalsidase beta) | • Ilumya™ (Tildrakizumab-asmn) |
| • Asceniv™ (IV) | • Flebogamma® DIF (IV) | • Inflectra® (Infliximab-dyyb) |
| • Avsola™ (Infliximab-axxq) | • Gammagard® Liquid (IV, SC) | • Kanuma® (sebelipase alfa) |
| • Bivigam® (IV) | • Gammagard® S/D (IV) | • Lumizyme® (alglucosidase alfa) |
| • Carimune® NF (IV) | • Gammaked™ (IV, SC) | • Mepsevii™ (vestronidase alfa-vjvk) |
| • Cutaquig® (SC) | • Gammaplex® (IV) | • Naglazyme® (galsulfase) |
| • Cuvitru® (SC) | • Gamunex®-C (IV, SC) | |

- Nexviazyme™ (avalglucosidase alfa-ngpt)
- Octagam® (IV)
- Orenzia® (Abatacept)
- Panzyga® (IV)
- Privigen® (IV)
- Prolastin®-C (A1-PI)
- Remicade® (Infliximab)
- Renflexis® (Infliximab-abda)
- Revcovi® (elapegedemase-lvr)
- Simponi Aria® (Golimumab)
- Soliris® (eculizumab)
- Ultomiris® (ravulizumab-cwvz)
- Vimizim® (elosulfase alfa)
- Viltipso™ (viltolarsen)
- Vyondys 53™ (golodirsen)
- Xembify® (SC)
- Zemaira® (A1-PI)

Definitions

Site of Care: Choice for physical location of infusion administration. Sites of Care include hospital inpatient, hospital outpatient, community 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 SC(Ig), human, for use in subcutaneous infusions, 100 mg, each

CPT® is a registered trademark of the American Medical Association

HCPCS Code	Description
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
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
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

HCPCS Code	Description
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 immunoglobulin
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
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-vjvk, 1 mg
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

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 medications.

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.

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.

References

- Barfield E, Solomon A, Sockolow R. Inflammatory Bowel Disease: A Practical Approach. *Prac Gastroenterol* May 2016, 5:16-23.
- 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.
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- Ducharme J, Pelletier C, Zacharias R. The safety of infliximab infusions in the community setting. *Can J Gastroenterol* 2010;24(5):307-311.
- Phase I: 2010 NHIA Provider Survey Comprehensive Aggregate Analysis Report. National Home Infusion Association. 2011.
- 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.

Guideline History/Revision Information

Date	Summary of Changes
08/01/2022	<p>Related Policies</p> <ul style="list-style-type: none"> Added reference link to the Medical Benefit Drug Policy titled <i>Medical Therapies for Enzyme Deficiencies</i> <p>Application</p> <ul style="list-style-type: none"> Revised list of applicable medications; added: <ul style="list-style-type: none"> Flebogamma® DIF (IV) for the states of Arizona, Texas, and Washington Nexviazyme™ (avalglucosidase alfa-ngpt) for the states of Arizona, Ohio, and Rhode Island <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised medical necessity criteria: <ul style="list-style-type: none"> Removed criterion requiring [outpatient hospital facility-based intravenous medication infusion] is used to initiate or re-initiate products for a short duration (e.g., 4 weeks) Replaced criterion requiring “homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy <i>if</i> the prescriber <i>cannot</i> infuse in the office setting” with “homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy <i>[when]</i> the prescriber <i>is unable to</i> infuse in the office setting <i>and there are no ambulatory infusion suite options available for this member</i>” Revised list of medications that require healthcare provider administration; added Nexviazyme™ (avalglucosidase alfa-ngpt) <p>Applicable Codes</p> <ul style="list-style-type: none"> Added HCPCS code J0219

Date	Summary of Changes
	Supporting Information <ul style="list-style-type: none"> Archived previous policy version CS155.J

Instructions for Use

This Utilization Review Guideline 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 guideline, check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Utilization Review Guideline 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 Utilization Review Guidelines 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.