Provider Administered Drugs – Site of Care (for New Jersey Only)

Guideline Number: CS155NJ.H
Effective Date: July 1, 2022

Instructions for Use

Table of Contents Page

Related Policies

- Actemra® (Tocilizumab) Injection for Intravenous Infusion
- Alpha1-Proteinase Inhibitors
- Amondys 45™ (Casimersen) (for New Jersey Only)
- Complement Inhibitors (Soliris® and Ultomiris®)
- Entyvio® (Vedolizumab)
- Exondys 51® (Eteplirsen) (for New Jersey Only)
- Ilumya™ (Tildrakizumab-Asmn)
- Immune Globulin (IVIG and SCIG)
- Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®)
- Medical Therapies for Enzyme Deficiencies
- Orencia® (Abatacept) Injection for Intravenous Infusion
- Simponi Aria® (Golimumab) Injection for Intravenous Infusion
- Vyondys 53™ (Golodirsen) (for New Jersey Only)

Application

This Utilization Review Guideline only applies to the state of New Jersey for the following medications:

- 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)
- 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)
- Lumizyme® (alglucosidase alfa)
- Mepsevii™ (vestronidase alfa-vjbk)
- Naglazyme® (galsulfase)
- Octagam® (IV)
- Orencia® (abatacept)
- Panzyga® (IV)
- Privigen® (IV)
- Prolastin®-C (A1-PI)
- Remicade® (infliximab)
- Renflexis® (infliximab-abda)
- Revcovi® (elapegademase-lvlr)
- Simponi Aria® (golimumab)
- Soliris® (eculizumab)
- Ultomiris® (ravulizumab-cwvz)
- Vimizim® (elosulfase alfa)
- Viltepso™ (viltolarsen)
- Vyondys 53™ (golodirsen)
- Xembify® (SC)
- Zemaira® (A1-PI)

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
  - To initiate or re-initiate products for a short duration (e.g., 4 weeks)

  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 (if the prescriber cannot infuse in the office setting)

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:

- 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)
- Entyvio® (vedolizumab)
- Exondys 51® (eteplirsen)
- Fabrazyme® (agalsidase beta)
- Flebogamma® DIF (IV)
- Gammagard® Liquid (IV, SC)
- Gammagard® S/D (IV)
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- Gammaplex® (IV)
- Gamunex®-C (IV, SC)
- Glassia® (A1-PI)
- Hizentra® (SC)
- HyQvia® (SC)
- Ilumya™ (tildrakizumab-asmn)
- Inflectra® (infliximab-dyyb)
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- Mepsevii™ (vestronidase alfa-vjbk)
- Naglazyme® (galsulfase)
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- Vimizim® (elosulfase alfa)
- Viltepso™ (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. 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
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
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
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

HCPCS Code	Description
J1575	Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg immuneglobulin
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-vjbk, 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 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.

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.

Condino A, Fidanza S Hoffenberg E. A home Infliximab Infusion Program. J Pediatr Gastroenterol Nutr, Vol. 40, No. 1, January 2005.

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

07/01/2022	**Related Policies**
	• Updated reference link to the Medical Benefit Drug Policy titled:
	  ○ *Amondys 45™ (Casimersen) (for New Jersey Only)*
	  ○ *Exondys 51® (Eteplirsen) (for New Jersey Only)*
	  ○ *Vyondys 53™ (Golodirsen) (for New Jersey Only)*
	Applicable Codes
	• Updated list of applicable HCPCS codes to reflect quarterly edits; added J1551
	Supporting Information
	• Archived previous policy version CS155NJ.G

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.