Clinical Policy: Infusion Therapy Site of Care Optimization

Reference Number: AZ.CP.PHAR.493
Effective Date: 2.1.22
Last Review Date: 04.24
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) and Arizona HIM Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Specialty infusion therapy is the intravenous or injectable administration of medication that helps members manage complex and often chronic conditions.

FDA Approved Indication(s)
Varies

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Arizona Complete Health-Complete Care Plan, Care1st, and Arizona HIM that intravenous (IV) or injectable therapy service for a member in an outpatient hospital department or non-hospital outpatient office or facility is **medically necessary** when the following criteria are met:

I. Initial and Continuation Approval Criteria

A. In-network outpatient hospital or non-hospital outpatient office or facility for intravenous or injectable therapy (*see Appendix B*) (must meet one of the following): *

1. There is no home infusion provider, ambulatory infusion center, specialty pharmacy or lower cost site of care to provide services including the medications.
2. It is the administration of the initial dose of the treatment or restart of treatment after a 6-month delay in treatment after expected normal dose (request must meet a or b):
   a. Provider must submit request for initial visit with continued administration at home infusion or ambulatory infusion suite (AIS), OR
   b. For continuation of services at the requested location, provider must submit documentation that monitoring and advanced treatment capabilities must be available beyond what would routinely be needed for infusion therapy due to medical necessity.
      i. Examples of medical necessity – chemotherapy, documented history of a severe or life-threatening acute adverse reaction for this member to the prescribed treatment (and no other drugs are available) and the adverse reaction cannot be managed through premedication in the AIS or home setting.

ii. Non-qualifying examples of medical necessity – fear of needles, pediatrics, preference/convenience, frequent laboratory monitoring, continuation of services from previous Plan.
**This is not a complete list of medical necessity*

3. The member is homeless or resides in a setting which does not meet standards for safe infusion, and there is no ambulatory infusion center, specialty pharmacy or lower cost site of care to provide services.
4. The FDA approved indications require this site of care for administration.

Approval duration: To align with drug approval

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Requests for outpatient IV or injectable therapy not meeting the initial approval criteria should be provided in an alternate less intensive site of care.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
IV: intravenous

Appendix B: Examples of Site of Care Alignment Medical Specialty Drugs – specialty infusion therapies include, ***but are not limited to****:*

Alpha-1 antitrypsin deficiency	J0256 Aralast NP/Prolastin C
	J0257 Glassia
	J0256 Zemaira
Autoimmune disorders	J3262 Actemra
	J3380 Entyvio
	Q5104 Renflexis
	J0129 Orencia
	J1745 Remicade/ unbranded infliximab
	Q5103 Inflectra
	J1602 Simponi Aria
Multiple sclerosis	J0202 Lemtrada
	J2350 Ocrevus
	J2323 Tysabri
Lysosomal Storage Disorders	J1931 Aldurazyme*
	J1786 Cerezyme
	J1743 Elaprase*
	J3060 Elelyso
	J0180Fabrazyme*

Immune deficiencies & related disorders	J2840 Kanuma
	J0221 Lumizyme*
	J1458 Naglazyme
	J1322 Vimizim
	J3385 Vpriv
	J1554 Asceniv
	J1556 Bivigam
	J1555 Cuvitru
	J1572 Flebogamma
	J1569 Gammagard liquid
	J1566 Gammagard S/D
	J1561 Gammaked
	J1557 Gammaplex
	J1561 Gamunex-C
	J1559 Hizentra
	J1575 Hyqvia
	J1568 Octagam
	J1576 Panzyga
	J1459 Privigen
	J1558 Xembify

Paroxysmal nocturnal Hemo-globinuria	J1300 Soliris*
	J1303 Ultomiris*
	J0490 Benlysta

Systemic lupus Erythematosus	

*Reinsurance drugs – Must go through the pharmacy benefit for Arizona Medicaid and may be excluded from Site of Care

IV. Dosage and Administration

Not applicable

V. Product Availability

Not applicable

VI. References

1. Polinski JM, et al. Home infusion: Safe, clinically effective, patient preferred, and cost saving. Healthcare 5 (2017) 68-80.
2. Santillo M, Jenkins, A, Jamieson C. Guidance on the Pharmaceutical Issues concerning OPAT (Outpatient Parenteral Antibiotic Therapy) Services and other Outpatient Intravenous Therapies. Edition 1, April 2018. NHS Pharmaceutical Quality Assurance Committee 2018
3. Nelson, S and Ard, KL. Outpatient Parenteral Antimicrobial Therapy. UpToDate. Accessed October 9, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	06.08.20	08.20
Annual review; no changes.	06.02.21	07.21
Plan-specific policy created; Added examples of medical instability; Added J-codes and notations in Appendix B;	01.13.22	07.22
Added Arizona HIM (Ambetter from Arizona) LOB; clarified that if the request is for chemotherapy or member has a documented history of a severe or life-threatening acute adverse reaction, these reasons meet the medical necessity reasons for in-network outpatient hospital or non-hospital outpatient office or facility for intravenous or injectable therapy as site-of-care; clarified that for new start requests, provider must submit request for initial visit with continued administration at home infusion or ambulatory infusion suite (AIS); Added fear of needles and continuation of services from previous Plan as non-qualifying examples of medical necessity.	01.24.23	01.23

CLINICAL POLICY
Infusion Therapy Site of Care Optimization

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Annual review; Added unbranded infliximab to J1745 Remicade under Appendix B: Examples of Specialty Infusion Drugs.	12.28.23	01.24
Drug Code updates	04.12.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.