Clinical Policy: Infusion Therapy Site of Care Optimization

Reference Number: AZ. CP.PHAR.493
Effective Date: 02.01.2022
Last Review Date: 01.01.2025
Line of Business: Arizona Medicaid and Arizona HIM

Coding Implications
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. Site of Care is defined as the redirection of administration and/or dispensing of specialty drugs in outpatient facilities. Place of Service codes are listed below:

Place of Service Name	Place of Service Code(s)
Pharmacy	01
Office	11
Home	12
Off Campus-Outpatient Hospital	19
On Campus-Outpatient Hospital	22
End-Stage Renal Disease Treatment Facility	65

FDA Approved Indication(s)
Varies

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation that medically necessary services must be rendered in the least intensive setting that is appropriate for the delivery of the services and supplies. Where applicable, the plan may compare the cost-effectiveness of alternative services, setting or supplies when determining least intensive setting. Alternative less intensive site of care facilities include non-hospital affiliated outpatient infusion (e.g., ambulatory infusion center or physician office), Home Infusion. An injectable medication must meet applicable medical necessity criteria for coverage. When coverage criteria are met for the injectable medication, this coverage policy is used to determine the medical necessity of the requested site of care.

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 health plans affiliated with Centene Corporation® that patient intravenous (IV) or injectable therapy service is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. In-network outpatient hospital or non-hospital outpatient office or facility for Intravenous or Injectable Therapy

1. Request is for a drug applicable for alternative site of care (*see Appendix B*).

2. There is no home infusion provider, ambulatory infusion center lower cost site of care to provide administration and/or specialty pharmacy is not able to provide drug. **AND** one of the following (a, b, c, d, or e):
   a. Request is for the administration of the initial dose of the treatment or restart of treatment after a 6-month disruption for a short duration (e.g., 4 weeks).
      i. Provider must submit request for initial visit with continued administration at home infusion or ambulatory infusion suite.
   b. The FDA-approved indications require outpatient hospital for administration.
   c. Submitted documentation that home based therapy, ambulatory surgical/infusion center is a health risk for the member due to physical or behavioral impairment.
      i. Examples of physical or behavioral health impairment: severe venous access issues and vein finder is not available, member does not have access to a caregiver, cardiopulmonary disorder, unable to tolerate intravenous fluid loads, cognitive concerns that impact patient safety*
   d. Submitted medical records or infusion records that document severe or life-threatening adverse events that were non-responsive to pre-medications, analgesics, steroids, antihistamines (e.g., diphenhydramine), fluids or infusion rate reductions.
      i. Examples severe or life-threatening adverse events: seizures, anaphylaxis with no other therapy options, myocardial infarction, renal failure*
      ii. Non-qualifying examples of medical necessity: trypanophobia (fear of needles), pediatrics, preference/convenience, frequent laboratory monitoring, continuation of services from previous Plan.

      **This is not a complete list of examples*

Approval duration: Up to one year or length of approval for the drug

II. Continued Approval

A. For continuation of services at the requested location, provider must submit medical records or infusion records to reassess the member's site of care and documentation for the need to continue monitoring and advanced treatment capabilities beyond what routinely be needed for the infusion therapy.
Approval duration: Up to one year or length of approval for the drug

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

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

IV. 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****:*

1. AZ Medicaid Reinsurance drugs are excluded from the medical benefit (buy/bill) and must be billed through the pharmacy benefit.

CPT or HCPC Code	Description		Notes
	Generic Drug Name	Brand Drug Name	
J0129	Abatacept	Orencia	
J0172	Aducanumab-Avwa	Aduhelm	
J0180	agalsidase beta	Fabrazyme	AZ Medicaid Reinsurance (Rx benefit only)
J0202	alemtuzumab	Lemtrada	
J0218	Olipudase Alfa	Xenopozyme	
J0219	Avalglucosidase alfa-ngpt	Nexviazyme	
J0221	algucosidase alfa	Lumizyme	AZ Medicaid Reinsurance (Rx benefit only)
J0222	patisiran	Onpattro	
J0223	givosiran	Givlaari	
J0224	lumasiran	Oxlumo	AZ Medicaid Reinsurance (Rx benefit only)
J0225	vutrisiran	Amvuttra	
J0256	alpha-1 proteinase inhibitor	Aralast NP and Prolastin-C	
J0257	alpha-1 proteinase inhibitor	Glassia	
J0278	amikacin	Amikin	
J0485	belatacept	Nulojix	
J0490	Belimumab	Benlysta IV	
J0517	benralizumab	Fasenra	does not include self-administration
J0565	bezlotoxumab	Zinplava	
J0584	burosumab-twza	Crysvita	
J0597	C1 Esterase Inhibitor, human	BERINERT	
J0598	C1 Esterase Inhibitor, human	Cinryze	
J0638	canakinumab	Ilaris	does not include self-administration
J0695	ceftolozane/tazobactam	Zerbaxa	
J0717	certolizumab pegol	Cimzia	does not include self-administration
J0739	cabotegravir	Apretude	
J0740	cidofovir	Vistide	
J0741	cabotegravir; rilprivine	Cabenuva	
J0791	crizanilzumab-tmca	Adakveo	
J0795	corticorelin	Acthrel	
J0800	corticoptropin gel	Acthar	AZ Medicaid Reinsurance (Rx benefit only)
J0850	cytomegalovirus immune globulin	Cytogam	

J0875	dalbavancin	Dalvance	
J0878	daptomycin	Cubicin	
J0881	darbepoetin alfa (not-esrd)	Aranesp	
J0882	darbepoetin alfa (ESRD)	Aranesp	
J0885	epoetin alfa (non-ESRD)	Epogen	
J0885	epoetin alfa (non-ESRD)	Procrit	
J0887	epoetin beta (ESRD)	Mircera	
J0888	epoetin beta (non-ESRD)	Mircera	
J0895	deferoxamine mesyl	Desferal	
J0896	luspatercept	Reblozyl	
J0897	denosumab	Prolia	
J0897	denosumab	Xgeva	
J1290	ecallantide	Kalbitor	AZ Medicaid Reinsurance (Rx benefit only)
J1300	eculizumab	Soliris (and all biosimilars)	AZ Medicaid Reinsurance (Rx benefit only)
J1301	edaravone	Radicava	
J1303	ravulizumab-cwvz	Ultomiris	AZ Medicaid Reinsurance (Rx benefit only)
J1306	inclisiran	Leqvio	
J1322	elosulfase alfa	Vimizim	
J1324	enfuvirtide	Fuzeon	
J1427	viltolarsen	Viltepso	AZ Medicaid Reinsurance (Rx benefit only)
J1437	ferric derisomaltose	Monoferric	
J1439	ferric carboxymaltose	Injectafer	
J1440	Fecal microbiota, live - jslm, 1 m	Rebyota	
J1442	filgrastim (g-csf)	Neupogen	
J1447	tbo-filgrastim	Granix	
J1458	galsulfase	Naglazyme	
J1459	immune globulin	Privigen	
J1460	immune globulin	Gamastan	
J1551	immune globulin	Cutaquig	
J1554	immune globulin	Asceniv	
J1555	immune globulin	Cuvitru	
J1556	immune globulin	Bivigam	
J1557	immune globulin	Gammaplex	
J1558	immune globulin	Xembify	
J1559	immune globulin	Hizentra	
J1560	immune globulin	Gamastan	
J1561	immune globulin	Gammaked	
J1561	immune globulin	Gamunex-C	
J1566	immune globulin	Carimune NF	

J1566	immune globulin	Gammagard	
J1568	immune globulin	Octagam	
J1569	immune globulin	Gammagard Liquid	
J1570	ganciclovir	Cytovene	
J1571	immune globulin	Hepagam IV	
J1572	immune globulin	Flebogamma	
J1573	immune globulin	Hepagam IM	
J1575	immune globulin	Hyquiva	
J1576	immune globulin	Panzyga	
J1602	golimumab IV	Simponi Aria	
J1626	granisetron	Kytril	
J1628	guselkumab	Tremfya	
J1740	ibandronic acid	Boniva IV	
J1743	idursulfase	Elaprase	AZ Medicaid Reinsurance (Rx benefit only)
J1744	Icatibant	Firazyr	AZ Medicaid Reinsurance (Rx benefit only)
J1745	inflixmab	Remicade/infliximab	includes all biosimilars
J1750	iron dextran	Infed	
J1753	hepatitis b immune globulin	Nabi-HB	
J1756	iron sucrose	Venofer	
J1786	imiglucerase	Cerezyme	
J1823	inebilizumab	Uplizna	
J1833	isavuconazonium sulfate	Cresemba	
J1850	kanamycin A	Kanamycin	
J1931	Laronidase	Aldurazyme	AZ Medicaid Reinsurance (Rx benefit only)
J1942	aripiprazole lauroxil	Aristada	
J1950	leuprolide	Lupron Depot	
J1955	levocarnitine	Carnitine	
J2182	mepolizumab	Nucala	
J2315	naltrexone	Vivitrol	
J2323	natalizumab	Tysabri	Facility must be certified; found approved locations on Tysabri website
J2327	risankizumab-rzaa	Skyrizi	
J2329	ublituximab-xiiy	Briumvi	
J2350	ocrelizumab	Ocrevus	
J2356	tezepelumab-ekko	Tezspire	
J2357	omalizumab	Xolair	
J2406	oritavancin	Kimyrsa	
J2407	oritavancin	Orbactiv	
J2426	paliperidone injection	Invega Sustenna	all strengths

J2430	pamidronate	Aredia	
J2469	palonosetron	Aloxi	
J2501	paricalcitol	Zemplar	
J2506	peg-filgrastim	Neulasta	
J2507	pegloticase	Krystexxa	
J2786	reslizumab	CINQAIR	
J2790	rho(D) immune globulin	Rhogam and Winrho	
J2794	risperidone	Risperdal Consta	
J2796	romisplostim	Nplate	
J2820	sargramostim	Leukine	
J2840	sebelipase alfa	Kanuma	AZ Medicaid Reinsurance (Rx benefit only)
J2916	ferric gluconate	Ferrlecit	
J2997	alteplase	Cathflo activase	
J3032	eptinezumab-jjmr	Vyepti	
J3060	taliglucerase alfa	Elelyso	
J3090	tedizolid	Sivextro	
J3095	telavancin	Vibativ	
J3110	teriparatide	Forteo	
J3111	romosozumab-aqqg	Evenity	
J3240	thyrotropin	Thyrogen	
J3241	teprotumumab-trbw	Tepezza	
J3245	tildrakizumab-asmn	Ilumya	
J3262	tocilizumab	Actemra	
J3315	triptorelin	Trelstar	
J3357	ustekinumab	Stelara SubQ	
J3358	ustekinumab	Stelara IV	
J3380	vedolizumab	Entyvio	
J3385	velaglucerase alfa	Vpriv	
J3485	zidovudine	Retrovi	
J3489	zoledronic acid	Reclast	
J7170	emicizumab-kxwh	Hemlibra	
J7175	coagulation factor X	Coagadex	AZ Medicaid Reinsurance (Rx benefit only)
J7177	human fibrinogen concentrate	Fibryga	
J7178	human fibrinogen concentrate	Riastap	
J7179	von willebrand factor	Vonvendi	AZ Medicaid Reinsurance (Rx benefit only)
J7180	factor XIII concentrate	Corifact	AZ Medicaid Reinsurance (Rx benefit only)
J7181	Factor XIII	Tretten	AZ Medicaid Reinsurance (Rx benefit only)
J7182	antihemophilic factor	Novoeight	AZ Medicaid Reinsurance (Rx benefit only)
J7183	vwf and hemophilia A	Wilate	AZ Medicaid Reinsurance (Rx benefit only)

J7185	antihemophilic factor	Xyntha	AZ Medicaid Reinsurance (Rx benefit only)
J7186	vwf and hemophilia A	Alphanate	AZ Medicaid Reinsurance (Rx benefit only)
J7187	von willebrand factor	Humate-P	AZ Medicaid Reinsurance (Rx benefit only)
J7188	factor VIII	Obizur	AZ Medicaid Reinsurance (Rx benefit only)
J7189	factor VIIa	NovoSeven	AZ Medicaid Reinsurance (Rx benefit only)
J7190	factor VIII	Hemofil M	AZ Medicaid Reinsurance (Rx benefit only)
J7190	factor VIII	Koate	AZ Medicaid Reinsurance (Rx benefit only)
J7190	factor VIII	Monoclate-O	AZ Medicaid Reinsurance (Rx benefit only)
J7192	factor VIII	ADVATE	AZ Medicaid Reinsurance (Rx benefit only)
J7192	factor VIII	Refacto	AZ Medicaid Reinsurance (Rx benefit only)
J7193	factor IX	AlphaNine	AZ Medicaid Reinsurance (Rx benefit only)
J7193	Monovine	MONONINE	AZ Medicaid Reinsurance (Rx benefit only)
J7194	factor IX	Bebulin	AZ Medicaid Reinsurance (Rx benefit only)
J7194	factor IX	Profilnine	AZ Medicaid Reinsurance (Rx benefit only)
J7195	factor IX	BeneFIX & Benefix RT	AZ Medicaid Reinsurance (Rx benefit only)
J7195	factor IX	Ixinity	AZ Medicaid Reinsurance (Rx benefit only)
J7197	antihrombin III	Thrombate	AZ Medicaid Reinsurance (Rx benefit only)
J7200	factor IX	Rixubis	AZ Medicaid Reinsurance (Rx benefit only)
J7201	factor IX	Alprolix	AZ Medicaid Reinsurance (Rx benefit only)
J7202	factor IX	Idelvion	AZ Medicaid Reinsurance (Rx benefit only)
J7203	factor IX	Rebinyn	AZ Medicaid Reinsurance (Rx benefit only)
J7204	factor VIII	Esperoct	AZ Medicaid Reinsurance (Rx benefit only)
J7205	efmoroctocog alfa	Eloctate	AZ Medicaid Reinsurance (Rx benefit only)
J7207	factor VIII	Adynovate	AZ Medicaid Reinsurance (Rx benefit only)
J7208	damoctocog alfa pegol	Jivi	AZ Medicaid Reinsurance (Rx benefit only)
J7209	factor VIII	Nuwiq	AZ Medicaid Reinsurance (Rx benefit only)
J7210	factor VIII	Afstyla	AZ Medicaid Reinsurance (Rx benefit only)
J7211	factor VIII	Kovaltry	AZ Medicaid Reinsurance (Rx benefit only)
J7212	factor VIII	Sevenfact	AZ Medicaid Reinsurance (Rx benefit only)
J3303	factor VIII	Aristospan	AZ Medicaid Reinsurance (Rx benefit only)
J9217	leuprolide	Lupron	
J9218	leuprolide	lupron	
J9312	rituximab	Rituxan	1st visit in AIS; includes biosimilars
J9332	efgartigimod alfa	Vyvgart	
J9334	efgartigimod alfa and hyaluronidase-qvfc	Vyvgart Hytrulo	
Q0138	Ferumoxytol	Feraheme	
Q2023	factor VIII	Xyntha	
Q5101	filgrastim-sndz	Zarxio	

Q5103	infliximab	Inflectra	
Q5104	infliximab	Renflexis	
Q5106	epoetin alfa-epbx	Retacrit	
Q5108	pegfilgrastim-jmdb	Fulphila	
Q5109	infliximab-qbtx	Ixifi	
Q5111	pegfilgastrim-cbqv	Udenyca	
Q5115	rituximab	Truxima	
Q5119	rituximab	Ruxience	
Q5121	infliximab	Avsola	
Q5123	rituximab	Riabni	

V. Dosage and Administration

Please see FDA approval or package insert.

VI. Product Availability

Not applicable

VII. 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;	01.13.23	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	01.24.23	01.23

Reviews, Revisions, and Approvals	Date	P&T Approval Date
of services from previous Plan as non-qualifying examples of medical necessity.		
Annual review; Added unbranded infliximab to J1745 Remicade under Appendix B: Examples of Specialty Infusion Drugs.	12.28.23	01.24
Updated description to include Place of Service Codes for OP billing include home, office, pharmacy, and hospital for medical billing. Updated the Initial Approval Criteria section A.1 to include FDA approval for SOC, drug availability at a specialty pharmacy and member setting is safe for infusion. Updated Section 2i-iii to include specialty pharmacy as a source for the drug if the provider member needs to be at outpatient hospital or office. 2.ii.ii included specific BH impairments including cognitive issues; 2.iii.iii. added trypanophobia as a non-qualifying example. Approval duration clarified to one year or approval for the drug. Added Continued approval portion that was not previously provided. Appendix B was expanded to include more drugs and the link for SharePoint for access to the full list of drugs as well the locations where the drugs can be administered.	09.30.24	10.24
In Section I.A.1 updated OR to AND to clarify that both 1 and a or b or c or d or e when reviewing. Also added a chart for place of service locations and place of service codes. Some minor grammar updates.	01.25	1.2025

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.