Clinical Policy: Infusion Therapy Site of Care Optimization

Reference Number: GA.PMN.34
Effective Date: 7/25
Last Review Date: 12/2025
Line of Business: 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. Site of Care is defined as the redirection of administration and/or dispensing of specialty drugs in outpatient facilities such hospitals (Place of Service code 19 or 22), community office (Place of Service Code 11) to home based setting (Place of Service Code 12), ambulatory infusion center, or Ambulatory Infusion Suites (Place of Service Code 24 or 11) or pharmacy (Place of Service Code 01). This definition does not capture every redirection scenario and the noted Place of Service Codes are included to provide context.

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 GA 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. If an individual does not meet criteria below for outpatient hospital infusion, alternative sites of care may be used.

I. Initial Approval Criteria

A. In-network outpatient hospital or non-hospital outpatient office or facility for intravenous or injectable therapy (*see Appendix B*) *

1. There is (i) no home infusion provider, (ii) lower cost site of care to provide administration, and/or (iii) specialty pharmacy cannot provide drug with one of the following (a, b, c, d, or e):

a) FDA approved indications require the administration at an outpatient hospital, office or clinic**;**

b) It is the administration of the initial dose of the treatment or restart of treatment after a 6-month disruption for a short duration of therapy (e.g. 4 weeks);

i. Provider must submit request for initial visit with continued administration at home infusion or ambulatory infusion suite (AIS)**.**

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.

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

**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 outpatient 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 the drug list below.

CPT or HCPC Code	Description		Notes
	Generic Drug Name	Brand Drug Name	
J0129	Abatacept	Orencia	
J0172	Aducanumab-Avwa	Aduhelm	
J0180	agalsidase beta	Fabrazyme	
J0202	alemtuzumab	Lemtrada	
J0218	Olipudase Alfa	Xenopozyme	

J0219	Avalglucosidase alfa-ngpt	Nexviazyme	
J0221	algucosidase alfa	Lumizyme	
J0222	patisiran	Onpattro	
J0223	givosiran	Givlaari	
J0224	lumasiran	Oxlumo	
J0225	vutrisiran	Amvuttra	
J0256	alpha-1 proteinase inhibitor	Aralast NP, Prolastin-C, Zemaira	
J0257	alpha-1 proteinase inhibitor	Glassia	
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
J0717	certolizumab pegol	Cimzia	does not include self-administration
J0791	crizanilzumab-tmca	Adakveo	
J0801	corticotropin gel	Acthar	
J0802	corticotropin gel	Cortrophin	
J0850	cytomegalovirus immune globulin	Cytogam	
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	
J1299	eculizumab	Soliris	
J1301	edaravone	Radicava	
J1303	ravulizumab-cwvz	Ultomiris	
J1306	inclisiran	Leqvio	
J1322	elosulfase alfa	Vimizim	
J1426	Casimersen	Amondys 45	

J1427	viltolarsen	Viltepso	
J1428	Eteplirsen	Exondys 51	
J1429	Golodirsen	Vyondys 53	
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	
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	
J1744	Icatibant	Firazyr	
J1745	infliximab	Remicade/infliximab	includes all biosimilars
J1786	imiglucerase	Cerezyme	
J1823	inebilizumab	Uplizna	
J1833	isavuconazonium sulfate	Cresemba	Not for acute treatment

J1931	Laronidase	Aldurazyme	
J1950	leuprolide	Lupron Depot	
J1955	levocarnitine	Carnitine	
J2182	mepolizumab	Nucala	
J2323	natalizumab	Tysabri	Facility must be certified; found approved locations on Tysabri website
J2327	risankizumab-rzaa	Skyrizi	
J2329	ublituximab-xiiy	Briumvi	
J2350	ocrelizumab	Ocrevus	
J2351	ocrelizumab & hyaluronidase-ocsq	Ocrevus Zunovo	
J2356	tezepelumab-ekko	Tezspire	
J2357	omalizumab	Xolair	
J2430	pamidronate	Aredia	
J2469	palonosetron	Aloxi	
J2501	paricalcitol	Zemplar	
J2506	peg-filgrastim	Neulasta	
J2507	pegloticase	Krystexxa	
J2786	reslizumab	CINQAIR	
J2802	romisplostim	Nplate	
J2820	sargramostim	Leukine	
J2840	sebelipase alfa	Kanuma	
J3032	eptinezumab-jjmr	Vyepti	
J3060	taliglucerase alfa	Elelyso	
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	does not include self-administration
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	
J7177	human fibrinogen concentrate	Fibryga	

J7178	human fibrinogen concentrate	Riastap	
J7179	von willebrand factor	Vonvendi	
J7180	factor XIII concentrate	Corifact	
J7181	Factor XIII	Tretten	
J7182	antihemophilic factor	Novoeight	
J7183	vwf and hemophilia A	Wilate	
J7185	antihemophilic factor	Xyntha	
J7186	vwf and hemophilia A	Alphanate	
J7187	von willebrand factor	Humate-P	
J7188	factor VIII	Obizur	
J7189	factor VIIa	NovoSeven	
J7190	factor VIII	Hemofil M	
J7190	factor VIII	Koate	
J7190	factor VIII	Monoclate-O	
J7192	factor VIII	ADVATE	
J7192	factor VIII	Refacto	
J7193	factor IX	AlphaNine	
J7193	Monovine	MONONINE	
J7194	factor IX	Bebulin	
J7194	factor IX	Profilnine	
J7195	factor IX	BeneFIX & Benefix RT	
J7195	factor IX	Ixinity	
J7197	antihrombin III	Thrombate	
J7200	factor IX	Rixubis	
J7201	factor IX	Alprolix	
J7202	factor IX	Idelvion	
J7203	factor IX	Rebinyn	
J7204	factor VIII	Esperoct	
J7205	efmoroctocog alfa	Eloctate	
J7207	factor VIII	Adynovate	
J7208	damoctocog alfa pegol	Jivi	
J7209	factor VIII	Nuwiq	
J7210	factor VIII	Afstyla	
J7211	factor VIII	Kovaltry	
J7212	factor VIII	Sevenfact	
J3303	factor VIII	Aristospan	
J9035	Bevacizumab	Avastin	• Concurrent chemotherapy is an exemption to policy

			• Ophthalmic indications excluded
J9217	leuprolide	Lupron	
J9218	leuprolide	lupron	
J9271	Pembrolizumab	Keytruda	• Maintenance Therapy, only • Concurrent chemotherapy is an exemption to policy
J9299	Nivolumab	Opdivo	• Maintenance Therapy, only • Concurrent chemotherapy is an exemption to policy
J9312	rituximab	Rituxan	• 1st visit in AIS • Concurrent chemotherapy is an exemption to policy
J9332	efgartigimod alfa	Vyvgart	
J9334	efgartigimod alfa and hyaluronidase-qvfc	Vyvgart Hytrulo	
Q0138	Ferumoxytol	Feraheme	
Q5100	Ustekinumab-kfce	Yesintek	
Q5101	filgrastim-sndz	Zarxio	
Q5103	infliximab	Inflectra	
Q5104	infliximab	Renflexis	
Q5106	epoetin alfa-epbx	Retacrit	
Q5107	bevacizumab-awwb	Mvasi	• Concurrent chemotherapy is an exemption to policy • Ophthalmic indications excluded
Q5108	pegfilgrastim-jmdb	Fulphila	
Q5109	infliximab-qbtx	Ixifi	
Q5111	pegfilgastrim-cbqv	Udenyca	
Q5115	rituximab	Truxima	• 1st visit in AIS • Concurrent chemotherapy is an exemption to policy

Q5118	Bevacizumab-bvzr	Zirabev	• Concurrent chemotherapy is an exemption to policy • Ophthalmic indications excluded
Q5119	rituximab	Ruxience	• 1st visit in AIS • Concurrent chemotherapy is an exemption to policy
Q5120	pegfilgrastim-bmez	Ziextenzo	
Q5121	infliximab	Avsola	
Q5122	pegfilgrastim-apgf	Nyvepria	
Q5123	Rituximab-arrx	Riabni	• 1st visit in AIS • Concurrent chemotherapy is an exemption to policy
Q5125	filgrastim-ayow	Releuko	
Q5126	bevacizumab-maly	Alymsys	• Concurrent chemotherapy is an exemption to policy • Ophthalmic indications excluded
Q5127	pegfilgrastim-fpgk	Stimufend	
Q5129	bevacizumab-adcd (vegzelma)	Vegzelma	• Concurrent chemotherapy is an exemption to policy • Ophthalmic indications excluded
Q5133	tocilizumab-bavi	Tofidence	
Q5134	natalizumab-sztn	Tyruko	
Q5135	Tocilizumab-aazg	Tyenne	
Q5137	ustekinumab-auub	Wezlana SubQ	
Q5138	ustekinumab-auub	Wezlana IV	
Q5151	Eculizumab	Epysqli	
Q5152	Eculizumab	Bkemv	

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	Approval Date
Policy created.	6/2025	6/2025
Updated policy description. Initial Criteria-Section 1A modified for clarity. Continuation Criteria – Updated to reflect meeting initial criteria. Drug List & important notes modified. Clinical Policy note removed Medicaid language and replaced with state legislative/regulatory language.	12/2025	12/2025

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:
When a specific State's legislation and/or regulation conflicts with the coverage provisions in this clinical policy, state provisions take precedence. Please refer to each State's Insurance laws and rules for any coverage provisions pertaining to this clinical policy.