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Specialty Medication Administration Site of Care

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Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

NOTE 1: The medical necessity of the pharmacologic or biologic medication may be separately reviewed against the appropriate criteria. This document addresses only the determination of the medical necessity of hospital outpatient setting for the infusion and injectable therapy.

NOTE 2: Not applicable to Illinois regulated plans or Medicare or Medicaid plans.

Requests for select medications (as listed below in Table 1) to be administered in a hospital outpatient setting will be directed to a preferred alternative site of care, such as non-hospital affiliated outpatient facilities (e.g., ambulatory infusion suite or provider office) or home setting.

To prevent a delay in care and allow adequate transition time for members to an alternate site, Specialty Medication Administration Site of Care requirements may be waived for 45 days, after prior authorization approval so that members can transition to a different site. After that time, infusion and injectable therapy must be transitioned to a non-hospital affiliated outpatient facility.

EXCEPTIONS:
An outpatient infusion or injectable therapy service in a hospital outpatient setting **may be considered medically necessary** when all the following are present (medical records required):

- Inherent complexity of the infusion such that it can be performed safely and effectively only by or under the supervision of physician; AND
- Potential changes in the individual's clinical condition are such that immediate access to specific services of a hospital outpatient setting, having emergency resuscitation equipment and personnel, and inpatient admission or intensive care is necessary. For example, the member is at significant risk of sudden life-threatening changes in medical status based on clinical conditions including but not limited to:
    - Intolerable fluid overload, including impaired or unstable renal function; or
    - History of anaphylaxis to prior infusion therapy with a related pharmacologic or biologic agent despite standard premedication; or
    - Acute mental status/cognitive changes or physical impairment AND no home caregiver available; or
    - Vascular access not stable; or
    - Documented clinical history of cardiopulmonary conditions that may cause an increased risk of severe adverse reactions (including but not limited to thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress, pulmonary edema, apnea, and transfusion-associated lung disease); or
    - The member does not have access to home infusion AND the nearest office-based provider or ambulatory infusion suite, who can provide that service exceeds reasonable travel distance to the currently-servicing hospital outpatient setting; or
    - Home deemed unsafe environment for infusion.

All other reasons for administering the infusion and injectable therapy services referenced in this policy in a hospital outpatient setting **are considered not medically necessary.**

Table 1. Medications and Codes

Code	Name	Brand
90283	Immune globulin (IVIG)	
90284	Immune globulin (SCIG)	
J1599	Immune globulin, intravenous, not otherwise specified	
J3262	Tocilizumab	Actemra®

J0791	Crizanlizumab-tmca	Adakveo
J1931	Laronidase	Aldurazyme®
J0225	Vutrisiran	Amvuttra®
J0881	Darbepoetin alfa	Aranesp®
J1554	Immune globulin	Asceniv™
Q5121	Infliximab-axxq	Avsola
J1552	Immune globulin	Alyglo™
J0490	Belimumab	Benlysta®
J1556	Immune globulin	Bivigam
Q5152	Eculizumab-aeeb	Bkemv™
J2329	Ublituximab-xiiy	Briumvi®
J1786	Imiglucerase	Cerezyme®
J0717	Certolizumab pegol	Cimzia®
J2786	Reslizumab	Cinqair®
J0598	C-1 esterase inhibitor (human)	Cinryze®
J3247	Secukinumab	Cosentyx®
J0584	Burosumab-twza	Crysvita
J1551	Immune globulin	Cutaquig®
J1555	Immune globulin	Cuvitru®
J1743	Idursulfase	Elaprase™
J3060	Taliglucerase alfa	Elelyso
J2508	Pegunigalsidase alfa-iwxj	Elfabrio®
J1302	Sutimlimab-jome	Enjaymo®
J3380	Vedolizumab	Entyvio®
J0885	Epoetin alfa	Epogen®
Q5151	Eculizumab-aagh	Epysqli®
J3111	Romosozumab-aqqg	Evenity®
J1305	Evinacumab-dgnb	Evkeeza™
J2361	Depemokimab-ulaa	Exdensur
J0180	Agalsidase beta	Fabrazyme®
J0517	Benralizumab	Fasenra®
J1572	Immune globulin	Flebogamma/Flebogamma dif
J1569	Immune globulin	Gammagard Liquid
J1557	Immune globulin	Gammaplex
J1561	Immune globulin	Gamunex®-C/Gammaked
J0223	Givosiran	Givlaari
J1559	Immune globulin	Hizentra®
J1575	Immune globulin/hyaluronidase	Hyqvia
J0638	Canakinumab	Ilaris
J3245	Tildrakizumab-asmn	Ilumya
J9256	Nipocalimab-aahu	Imaavy™

J1566	Immune globulin	Immune globulin
Q5098	Ustekinumab-srlf	Imuldosa®
Q5103	Infliximab-dyyb	Inflectra®
Q5109	Infliximab-qbtx	Ixifi™
J1290	Ecallantide	Kalbitor®
J2840	Sebelipase alfa	Kanuma™
J0175	Donanemab-azbt	Kisunla™
J2507	Pegloticase	Krystexxa®
J0174	Lecanemab-irmb	Leqembi®
J1306	Inclisiran	Leqvio®
J0221	Alglucosidase alfa	Lumizyme™
J3397	Vestronidase alfa-vjbk	Mepsevii
J0888	Epoetin beta	Mircera®
J1458	Galsulfase	Naglazyme®
J0219	Avalglucosidase alfa-ngpt	Nexviazyme®
J2802	Romiplostim	Nplate®
J0485	Belatacept	Nulojix®
J2182	Mepolizumab	Nucala®
J2350	Ocrelizumab	Ocrevus®
J2351	Ocrelizumab and hyaluronidase-ocsq	Ocrevus Zunovo™
J1568	Immune globulin	Octagam®
J0222	Patisiran	Onpattro
J0129	Abatacept	Orencia®
Q9999	Ustekinumab-aauz	Otulfi™
J0224	Lumasiran	Oxlumo®
J1576	Immune Globulin	Panzyga®
J1459	Immune globulin	Privigen®
Q9997	Ustekinumab-ttwe	Pyzchiva®
J1577	Immune globulin	Qivigy®
J1301	Edaravone	Radicava™
J1745	Infliximab	Remicade®
Q5104	Infliximab-abda	Renflexis®
Q5106	Epoetin alfa-epbx	Retacrit®
Q5123	Rituximab-arrx	Riabni®
J9312	Rituximab	Rituxan®
Q5119	Rituximab-pvvr	Ruxience®
J9333	Rozanolixizumab-noli	Rystiggo®
J2353	Octreotide (depot)	Sandostatin LAR®
J2354	Octreotide (non-depot)	Sandostatin®
J0491	Anifrolumab-fnia	Saphnelo®
Q9998	Ustekinumab-aekn	Selarsdi™

J1602	Golimumab	Simponi Aria®
J1299	Eculizumab	Soliris®
J1930	Lanreotide	Somatuline Depot®
Q5164	Ustekinumab-hmny	Starjemza®
J3358	Ustekinumab	Stelara®
Q5099	Ustekinumab-stba	Steqeyma®
J3241	Teprotumumab-trbw	Tepezza
J2356	Tezepelumab-ekko	Tezspire®
Q5133	Tocilizumab-bavi	Tofidence™
J1746	Ibalizumab-uiyk	Trogarzo
Q5115	Rituximab-abbs	Truxima®
Q5135	Tocilizumab-aazg	Tyenne®
Q5134	Natalizumab-sztn	Tyruko®
J2323	Natalizumab	Tysabri®
J1303	Ravulizumab-cwvz	Ultomiris
J1823	Inebilizumab-cdon	Uplizna®
J9376	Pozelimab-bbfg	Veopoz™
J1322	Elosulfase alfa	Vimizim™
J1562	Immune globulin	Vivaglobin®
J3385	Velaglucerase alfa	VPRIV
J3032	Eptinezumab-jjmr	Vyepti
J9332	Efgartigimod alfa-fcab	Vyvgart®
J9334	Efgartigimod alfa and hyaluronidase-qvfc	Vyvgart Hytrulo®
Q5138	Ustekinumab-auub	Wezlana™
J7183	Von willebrand factor complex	Wilate®
J1558	Immune globulin	Xembify
J0218	Olipudase alfa-rpcp	Xenpozyme®
J2357	Omalizumab	Xolair®
J1289	Narsoplimab-wuug	Yartemlea®
Q5100	Ustekinumab-kfce	Yesintek™
J1553	Immune globulin	Yimmugo®

Policy Guidelines

None.

Description

Site of care refers to the choice for physical location for infusion administration of medications, and can include the following settings: inpatient hospital, outpatient hospital, provider office, ambulatory infusion suite or home.

New technologies and pharmaceuticals allow therapeutic services, such as infusion therapy, to be administered safely and effectively outside of hospital-based infusion centers. Sites of care such as physician offices, ambulatory infusion centers and home infusion services are well accepted places of service for medication infusion services.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	90283, 90284
HCPCS Codes	J0129, J0174, J0175, J0180, J0218, J0219, J0221, J0222, J0223, J0224, J0225, J0485, J0490, J0491, J0517, J0584, J0598, J0638, J0717, J0791, J0881, J0885, J0888, J1289, J1290, J1299, J1301, J1302, J1303, J1305, J1306, J1322, J1458, J1459, J1551, J1552, J1553, J1554, J1555, J1556, J1557, J1558, J1559, J1561, J1562, J1566, J1568, J1569, J1572, J1575, J1576, J1577, J1599, J1602, J1743, J1745, J1746, J1786, J1823, J1930, J1931, J2182, J2323, J2329, J2350, J2351, J2353, J2354, J2356, J2357, J2361, J2507, J2508, J2786, J2802, J2840, J3032, J3060, J3111, J3241, J3245, J3247, J3262, J3358, J3380, J3385, J3397, J7183, J9256, J9312, J9332, J9333, J9334, J9376, Q5098, Q5099, Q5100, Q5103, Q5104, Q5106, Q5109, Q5115, Q5119, Q5121, Q5123, Q5133, Q5134, Q5135, Q5138, Q5151, Q5152, Q5164, Q9997, Q9998, Q9999, [Deleted 1/2025: J2796], [Deleted 4/2025: J1300]

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
01/01/2026	Document updated. The following changes were made to Coverage: 1) Modified conditional site of care criteria; 2) Changed code for Nplate from J2796 to J2802; and 3) Added the following codes with associated products to the coverage table: J0225, J2329, J3247, J2508, Q5098, Q5109, J0175, J0174, J0888, J9333, Q5099, J9376, J9334, J0218, and Q5100.
07/01/2025	Document updated. The following changes were made to Coverage table: 1) Changed code for Soliris from J1300 to J1299; 2) Added the following codes with associated products – 90283, 90284, J1552, J1599, J1562, J1576, J2351, Q5133, Q5134, Q5135, Q5138, Q5151, Q5152, Q9997, Q9998, and Q9999.
02/01/2025	Document updated. The following change was made to Coverage: Added EXCEPTION language regarding drug shortages/recalls. No new references added.
10/01/2024	Document updated. The following change was made to Coverage: Removed J0585 Onabotulinumtoxin A (Botox®), J0586 Abobotulinumtoxin A (Dysport®), J0587 rimabotulinumtoxin B (Myobloc®), and J0588 Incobotulinumtoxin A (Xeomin®) from Medications and Codes table.
06/01/2024	New medical document originating from medical policy RX501.096. Coverage unchanged.