



Specialty Medication Administration Site of Care Policy

MEDICAL NECESSITY CRITERIA

- A. 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, settings or supplies when determining least intensive setting.
1. A medication must meet applicable medical necessity criteria for coverage. When coverage criteria are met for the medication, this coverage policy is used to determine the medical necessity of the requested site of care.
 2. 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 an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.
- B. Molina Healthcare, Inc. covers injectable/infused treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite* when the level of care is determined to be medically necessary. Considerations used to determine if an alternative level of care is not suitable may include the following findings:
1. The patient is clinically unstable based on documented medical history and susceptible to complication with drug administration (e.g., cardiopulmonary, or renal dysfunction, risk for fluid overload)
 2. The patient exhibits physical or cognitive impairment, and a capable caregiver is not available to assist with safe administration of prescribed medication in the home.
 3. It is the patient's first dose of the medication, or it is being re-initiated after at least 12 months*
 4. The patient has experienced adverse events with past administration of the drug and cannot be managed by premedication or resources available at a non-hospital facility-based location (NHFBL)
 5. Documented history of difficulty establishing and maintaining patent vascular access, or is not a candidate for a mode of long-term vascular access during the duration of prescribed treatment
 6. The member has received a bone marrow transplant (BMT) or chimeric antigen receptor (CAR) T-cell therapy in the prior 6 months and requires enhanced medical supervision/monitoring at a specialized facility.
- Note: a hospital outpatient setting, or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary*
- C. Molina Healthcare, Inc considers the home setting to be the appropriate setting for delivery of care when:
1. The member's home environment has been assessed as:
 - a. Being accessible to 911 services and urgent care



- b. Having adequate refrigeration.
 - c. Meeting general cleanliness standards determined by an onsite home nursing assessment.
2. The member is medically stable and able to participate in their care; and
 3. The member has reliable venous access.
- D. Benefit design does not dictate site of care. Providers (medical or pharmacy) are expected to bill for payment through the appropriate method for the benefit design and facilitate the medication to be administered through the appropriate site of care.
- E. Only when multiple administrations are required, the **first administration** of the medications subject to this policy may be given at the physician's facility of choice; furthermore, provided that the medication is available and not subject to limited distribution. This includes hospital outpatient facilities, non-hospital outpatient facilities and home care. In the event the therapy is represented by a single administration, the policy applies to the **first administration**. All subsequent doses will be subject to the Molina Healthcare, Inc. Specialty Medication Administration Site of Care policy, which recommends the use of nonhospital outpatient facilities or home infusion services **beyond 6 months of therapy**.**
- F. **When home setting criteria (listed in section C of this policy) have been met, 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.
- G. This policy applies to the specialty medications that require healthcare provider administration listed in table 1.

CODING / BILLING INFORMATION

Specialty Medications: Table 1

Note: 1) This list of codes may not be all-inclusive and is subject to change. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Brand Name	HCPCS	Code Description
Actemra (tocilizumab)	J3262	Injection, tocilizumab, 1 mg
Adakveo (crizanlizumab)	J0791	Injection, crizanlizumab-tmca, 5 mg
Aldurazyme (laronidase)	J1931	Injection, laronidase, 0.1 mg
Alyglo (immune globulin intravenous, human-stwk)	J1552	Injection, immune globulin (alyglo), 500 mg
Alymsys (bevacizumab-maly)	Q5126	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg
Amondys 45 (casimersen)	J1426	Injection, casimersen, 10 mg
Amvuttra (vutrisiran)	J0225	Injection, vutrisiran, 1 mg
Aralast NP (alpha 1-proteinase inhibitor)	J0256	Injection, alpha 1 proteinase inhibitor (human), not otherwise specified, 10 mg



Asceniv (human immunoglobulin g liquid)	J1554	Injection, immune globulin (asceniv), 500 mg
Avastin (bevacizumab)	J9035	Injection, bevacizumab, 10 mg
Avsola (infliximab-axxq)	Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
Bavencio (avelumab)	J9023	Injection, avelumab, 10 mg
Benlysta (belimumab)	J0490	Injection, belimumab, 10 mg
Bivigam (immune globulin intravenous (human))	J1556	Injection, immune globulin (bivigam), 500 mg
Bkemv (eculizumab-aeeb)	Q5152	Injection, eculizumab-aeeb (bkemv), biosimilar, 10 mg
Briumvi (ublituximab-xiyy)	J2329	Injection, ublituximab-xiyy, 1mg
Cabenuva (cabotegravir/rilpivirine)	J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg
Cerezyme (imiglucerase for injection)	J1786	Injection, imiglucerase, 10 units
Cimzia (certolizumab pegol)	J0717	Injection, certolizumab pegol, 1 mg
Cinqair (reslizumab)	J2786	Injection, reslizumab, 1 mg
Cosentyx (secukinumab)	J3247	Injection, secukinumab, intravenous, 1 mg
Crysvita (burosumab-twza)	J0584	Injection, burosumab-twza, 1 mg
Cutaquig (immune globulin subcutaneous (human))	J1551	Injection, immune globulin (cutaquig), 100 mg
Cuvitru (immune globulin subcutaneous (human))	J1555	Injection, immune globulin (cuvitru), 100 mg
Elaprase (idursulfase)	J1743	Injection, idursulfase, 1 mg
Elelyso (taliglucerase alfa)	J3060	Injection, taliglucerase alfa, 10 units
Elfabrio (pegunigalsidase alfa-iwxj)	J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg
Enjaymo (sutimlimab-jome)	J1302	Injection, sutimlimab-jome, 10 mg
Entyvio (vedolizumab)	J3380	Injection, vedolizumab, 1 mg
Entyvio SC (vedolizumab SC)	J3590	Unclassified biologics
Evkeeza (evinacumab-dgnb)	J1305	Injection, evinacumab-dgnb, 5 mg
Exondys 51 (eteplirsen)	J1428	Injection, eteplirsen, 10 mg
Fabrazyme (agalsidase beta)	J0180	Injection, agalsidase beta, 1 mg
Fasenra (benralizumab)	J0517	Injection, benralizumab, 1 mg
Flebogamma DIF (immune globulin-human injection, solution)	J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
Fulphila (pegfilgrastim-jmdb)	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg
Furoscix (furosemide)	J1941	Injection, furosemide (furoscix), 20 mg
Fylnetra (pegfilgrastim-pbbk)	Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg
Gammagard Liquid (immune globulin infusion (human))	J1569	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
Gammagard S/D (IVIG lyophilized -- powder)	J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
Gammaked (immune globulin injection (human))	J1561	Injection, immune globulin, (gamunex-c/gammaked), non- lyophilized (e.g., liquid), 500 mg
Gammaplex (immune globulin intravenous (human))	J1557	Injection, immune globulin, (gammaplex), intravenous, non- lyophilized (e.g., liquid), 500 mg

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Gamunex-C (immune globulin injection (human))	J1561	Injection, immune globulin, (gamunex-c/gammaked), non- lyophilized (e.g., liquid), 500 mg
Givlarri (givosiran)	J0223	Injection, givosiran, 0.5 mg
Glassia (α1 proteinase inhibitor)	J0257	Injection, alpha 1 proteinase inhibitor (human), (glassia), 10 mg
Herceptin (Trastuzumab)	J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
Hercessi (trastuzumab-strf)	Q5146	Injection, trastuzumab-strf (hercessi), biosimilar, 10 mg
Herzuma (trastuzumab-pkrb)	Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg
Hizentra (immune globulin subcutaneous)	J1559	Injection, immune globulin (hizentra), 100 mg
Hyqvia (immune globulin infusion 10% (human) with recombinant human hyaluronidase)	J1575	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Ilaris (canakinumab)	J0638	Injection, canakinumab, 1 mg
Ilumya (tildrakizumab-asmn)	J3245	Injection, tildrakizumab, 1 mg
Imfinzi (durvalumab)	J9173	Injection, durvalumab, 10 mg
Inflectra (infliximab-dyyb)	Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Jemperli (dostarlimab-gxly)	J9272	Injection, dostarlimab-gxly, 10 mg
Kanjinti (trastuzumab-anns)	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg
Kanuma (sebelipase alfa)	J2840	Injection, sebelipase alfa, 1 mg
Keytruda (pembrolizumab)	J9271	Injection, pembrolizumab, 1 mg
Krystexxa (pegloticase)	J2507	Injection, pegloticase, 1 mg
Lamzedo (velmanase alfa-tycv)	J0217	Injection, velmanase alfa-tycv, 1 mg
Lemtrada (alemtuzumab)	J0202	Injection, alemtuzumab, 1 mg
Libtayo (cemiplimab-rwlc)	J9119	Injection, cemiplimab-rwlc, 1 mg
Loqtorzi (toripalimab-tpzi)	J3263	Injection, toripalimab-tpzi, 1 mg
Lumizyme (alglucosidase alfa)	J0221	Injection, alglucosidase alfa, (lumizyme), 10 mg
Mepsevii (vestronidase alfa-vjbc)	J3397	Injection, vestronidase alfa-vjbc, 1 mg
Mvasi (bevacizumab-awwb)	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg
Naglazyme (galsulfase)	J1458	Injection, galsulfase, 1 mg
Neulasta (pegfilgrastim)	J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
Nexviazyme (avalglucosidase alfa-ngpt)	J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
Nplate (romiplostim)	J2796	Injection, romiplostim, 10 micrograms
Nucala (mepolizumab)	J2182	Injection, mepolizumab, 1 mg
Nyvepria (pegfilgrastim-apgf)	Q5122	Injection, pegfilgrastim-apgf (nyvepria), biosimilar, 0.5 mg
Ocrevus (ocrelizumab)	J2350	Injection, ocrelizumab, 1 mg
Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq)	J2351	Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq
Octagam (immune globulin (human))	J1568	Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
Ogivri (trastuzumab-dkst)	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg
Onpattro (patisiran)	J0222	Injection, patisiran, 0.1 mg
Ontruzant (trastuzumab-dttb)	Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10

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		mg
Opdivo (nivolumab)	J9299	Injection, nivolumab, 1 mg
Opdualag (nivolumab-relatlimab-rmbw)	J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg
Orencia (abatacept)	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)
Oxlumo (lumasiran sodium)	J0224	Injection, lumasiran, 0.5 mg
Panzyga (immune globulin intravenous (human))	J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg
Pombiliti (cipaglucoisidase alfa-atga)	J1203	Injection, cipaglucoisidase alfa-atga, 5 mg
Privigen (immune globulin intravenous (human))	J1459	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
Prolastin C (Alpha 1 Proteinase Inhibitor)	J0256	Injection, alpha 1 proteinase inhibitor (human), not otherwise specified, 10 mg
Radicava (edaravone)	J1301	Injection, edaravone, 1 mg
Reblozyl (luspatercept-aamt)	J0896	Injection, luspatercept-aamt, 0.25 mg
Remicade (infliximab)	J1745	Injection, infliximab, excludes biosimilar, 10 mg
Renflexis (infliximab-abda)	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
Riabni (rituximab-arrx)	Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg
Rituxan (rituximab)	J9312	Injection, rituximab, 10 mg
Rolvedon (eflapegrastim-xnst)	J1449	Injection, eflapegrastim-xnst, 0.1 mg
Ruxience (rituximab-pvvr)	Q5119	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg
Rystiggo (rozanolixizumab-noli)	J9333	Injection, rozanolixizumab-noli, 1 mg
Sandostatin (octreotide)	J2354	Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg
Sandostatin LAR (octreotide)	J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg
Saphnelo (anifrolumab-fnia)	J0491	Injection, anifrolumab-fnia, 1 mg
Simponi Aria (golimumab)	J1602	Injection, golimumab, 1 mg, for intravenous use
Soliris (eculizumab)	J1300	Injection, eculizumab, 10 mg
Stimufend (pegfilgrastim-fpgk)	Q5127	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Tecentriq (atezolizumab)	J9022	Injection, atezolizumab, 10 mg
Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs)	J9999	Not otherwise classified, antineoplastic drugs
Tepezza (teprotumumab-trbw)	J3241	Injection, teprotumumab-trbw, 10 mg
Tevimbra (tislelizumab-jsgr)	J9329	Injection, tislelizumab-jsgr, 1mg
Tezspire (tezepelumab-ekko)	J2356	Injection, tezepelumab-ekko, 1 mg
Tofidence (tocilizumab-bavi)	Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Trazimera (trastuzumab-qyyp)	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg
Trogarzo (ibaluzimab-uyk)	J1746	Injection, ibalizumab-uyk, 10 mg
Truxima (rituximab-abbs)	Q5115	Injection, rituximab-abbs, biosimilar, (truxima), 10 mg
Tyenne (tocilizumab-aazg)	Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg

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Tyruko (natalizumab-sztn)	Q5134	Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg
Tysabri (natalizumab)	J2323	Injection, natalizumab, 1 mg
Tziel (teplizumab-mzww)	J9381	Injection, teplizumab-mzww, 5 mcg
Udenyca (pegfilgrastim-cbqv)	Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenycya), 0.5 mg
Ultomiris (ravulizumab-cwvz)	J1303	Injection, ravulizumab-cwvz, 10 mg
Uplizna (inebilizumab-cdon)	J1823	Injection, inebilizumab-cdon, 1 mg
Vegzelma (bevacizumab-adcd)	Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg
Viltepso (viltolarsen)	J1427	Injection, viltolarsen, 10 mg
Vimizim (elosulfase alfa)	J1322	Injection, elosulfase alfa, 1 mg
Vpriv (velaglucerase alfa for injection)	J3385	Injection, velaglucerase alfa, 100 units
Vyalev [foscarbidopa and foslevodopa (administration with VYAFUSER pump)]	J3490	Unclassified drugs
Vyepti (eptinezumab-jjmr)	J3032	Injection, eptinezumab-jjmr, 1 mg
Vyjuvek Topical (beremagene geperpavec-svdt topical)	J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5×10^9 pfu/ml vector genomes, per 0.1 ml
Vyondys 53 (golodirsen)	J1429	Injection, golodirsen, 10 mg
Vyvgart (efgartigimod alfa-fcab)	J9332	Injection, efgartigimod alfa-fcab, 2 mg
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc
Xembify (immune globulin subcutaneous (human))	J1558	Injection, immune globulin (xembify), 100 mg
Xenpozyme (olipudase Alfa-rpcp)	J0218	Injection, olipudase alfa-rpcp, 1 mg
Xolair (omalizumab)	J2357	Injection, omalizumab, 5 mg
Yervoy (ipilimumab)	J9228	Injection, ipilimumab, 1 mg
Zemaira (α 1 proteinase inhibitor)	J0256	Injection, alpha 1 proteinase inhibitor (human), not otherwise specified, 10 mg
Ziextenzo (pegfilgrastim-bmez injection)	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg
Zirabev (bevacizumab-bvzr)	Q5118	Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg



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