



Effective Date: 05/01/2023

Last P&T Approval: 04/2023

Next Review Due By: 04/2024

Policy Number: MHI PHARM 11

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 requested medication is administered as part of a chemotherapy regimen (e.g., anti-neoplastic agent, anti-emetic) for treatment of cancer or with dialysis
 3. 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
 4. It is the patient's first dose of the medication or it is being re-initiated after at least 12 months*
 5. 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)
 6. 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
 7. 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

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
Amondys 45 (casimersen)	J1426	Injection, casimersen, 10 mg
Amvuttra (vutrisiran)	J0225	Injection, vutrisiran, 1 mg
Asceniv (human immunoglobulin g liquid)	J1554	Injection, immune globulin (asceniv), 500 mg
Avsola (infliximab-axxq)	Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
Bavencio (avelumab)	J9023	Injection, avelumab, 10 mg

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare



Benlysta (belimumab)	J0490	Injection, belimumab, 10 mg
Bivigam (immune globulin intravenous (human))	J1556	Injection, immune globulin (bivigam), 500 mg
Cerezyme (imiglucerase for injection)	J1786	Injection, imiglucerase, 10 units
Cinqair (reslizumab)	J2786	Injection, reslizumab, 1 mg
Crysvita (burosumab)	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
Elaprased (idursulfase)	J1743	Injection, idursulfase, 1 mg
Elelyso (taliglucerase alfa)	J3060	Injection, taliglucerase alfa, 10 units
Enjaymo (sutimlimab-jome)	J1302	Injection, sutimlimab-jome, 10 mg
Entyvio (vedolizumab)	J3380	Injection, vedolizumab, 1 mg
Evkeeza (evinacumab-dgnb)	J1305	Injection, evinacumab-dgnb, 5 mg
Exondys 51 (eteplirsén)	J1428	Injection, eteplirsén, 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
Fylnetra (pegfilgrastim-pbbk)	J3590	Unclassified biologics
Gammagard Liquid (immune globulin infusion (human))	J1569	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
Gammaked (immune globulin injection (human))	J1561	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
Gammaflex (immune globulin intravenous (human))	J1557	Injection, immune globulin, (gammaflex), intravenous, non-lyophilized (e.g., liquid), 500 mg
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 (α 1 proteinase inhibitor)	J0257	Injection, alpha 1 proteinase inhibitor (human), (glassia), 10 mg
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
Kanuma (sebelipase alfa)	J2840	Injection, sebelipase alfa, 1 mg
Keytruda (pembrolizumab)	J9271	Injection, pembrolizumab, 1 mg
Krystexxa (pegloticase)	J2507	Injection, pegloticase, 1 mg
Lemtrada (alemtuzumab)	J0202	Injection, alemtuzumab, 1 mg
Libtayo (cemiplimab-rwlc)	J9119	Injection, cemiplimab-rwlc, 1 mg
Lumizyme (alglucosidase alfa)	J0221	Injection, alglucosidase alfa, (lumizyme), 10 mg
Mepsevii (vestronidase alfa-vjbk)	J3397	Injection, vestronidase alfa-vjbk, 1 mg
Naglazyme (galsulfase)	J1458	Injection, galsulfase, 1 mg
Neulasta (pegfilgrastim)	J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare



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
Ocrevus (ocrelizumab)	J2350	Injection, ocrelizumab, 1 mg
Octagam (immune globulin (human))	J1568	Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
Onpattro (patisiran)	J0222	Injection, patisiran, 0.1 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
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
Remodulin (treprostinil sodium)	J3285	Injection, treprostinil, 1 mg
Renflexis (infliximab-abda)	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
Rolvedon (eflapegrastim-xnst)	J3590	Unclassified biologics
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
Skyrizi (risankizumab-rzaa)	J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
Soliris (eculizumab)	J1300	Injection, eculizumab, 10 mg
Stimufend (pegfilgrastim-fpgk)	J3590	Unclassified biologics
Tecentriq (atezolizumab)	J9022	Injection, atezolizumab, 10 mg
Tepezza (teprotumumab-trbw)	J3241	Injection, teprotumumab-trbw, 10 mg
Tezspire (tezepelumab-ekko)	J2356	Injection, tezepelumab-ekko, 1 mg
Trogarzo (ibalizumab-uiyk)	J1746	Injection, ibalizumab-uiyk, 10 mg
Tysabri (natalizumab)	J2323	Injection, natalizumab, 1 mg
Tyvaso (treprostinil)	J7686	Treprostinil, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose form, 1.74 mg
Tzield (teplizumab-mzww)	J3590	Unclassified biologics
Udenyca (pegfilgrastim-cbqv)	Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg
Ultomiris (ravulizumab-cwvz)	J1303	Injection, ravulizumab-cwvz, 10 mg
Uplizna (inebilizumab-cdon)	J1823	Injection, inebilizumab-cdon, 1 mg

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare



Viltepsa (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
Vyepti (eptinezumab-jjmr)	J3032	Injection, eptinezumab-jjmr, 1 mg
Vyondys 53 (golodirsen)	J1429	Injection, golodirsen, 10 mg
Vyvgart (efgartigimod alfa-fcab)	J9332	Injection, efgartigimod alfa-fcab, 2 mg
Xembify (immune globulin subcutaneous (human))	J1558	Injection, immune globulin (xembify), 100 mg
Xenpozyme (olipudase Alfa-rpcp)	J3590	Unclassified biologics
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



REFERENCES AND RESOURCES

1. Frequently Asked Questions: Home Infusion Date of Publication: March 2019 (Published on behalf of the ASHP Section of Ambulatory Care Practitioners Advisory Group on Home Infusion) sections@ashp.org
2. Magellan Rx Management. Medical Pharmacy Trend Report, Tenth edition. 2019.
3. EMD Serono, Inc. Specialty digest: Managed care strategies for specialty pharmaceuticals, 14th edition. Available at: <https://specialtydigestemdserono.com>
4. PolinskiJM,etal.Homeinfusion:Safe,clinicallyeffective,patientpreferred,andcostsaving. Healthcare(2016), <http://dx.doi.org/10.1016/j.hjdsi.2016.04.004>
5. National Home Infusion Association. About infusion therapy. Available at: <http://www.nhia.org/abouthome-infusion.cfm>.
6. Schmidt B, Kennedy PDS. Home infusion therapy: Safety, efficacy, and cost-savings. Patient Safety & Quality Healthcare Available at: <http://www.psqh.com/analysis/home-infusion-therapy-safety-efficacyand-cost-savings/>
7. Centers for Medicare and Medicaid Services. Self- administered Drugs (SADs). Available at: <https://www.cms.gov/medicare-coverage-database/new-search/reports/local-coverage-sad-exclusion-list-report.aspx?contractorName=all&dateOption=current#>