

Drug and Biologic Coverage Policy



Effective Date 4/1/2021

Next Review Date... 1/1/2022

Coverage Policy Number 1605

Medication Administration Site of Care

Table of Contents

Medical Necessity Criteria	1
General Background.....	2
Coding/ Billing Information.....	4
References	7

Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

Under many benefit plans, 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.

- 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.

A request initiated from a hospital outpatient setting may be subject to a one-time 30 day approval period to facilitate transition an alternative less intensive site of care if medically necessary.

Alternative less intensive site of care facilities include:

- Non-hospital affiliated outpatient infusion (e.g., ambulatory infusion center or physician office)
- Home infusion

Cigna covers injectable treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite* as medically necessary for an individual with ANY of the following:

- The prescribed medication has a site of care restriction for administration per the FDA-approved label

- A documented history of an adverse event warranting a more intense level of care during or following infusion of the prescribed medication unless the adverse event can be appropriately managed by the use of pre-medication(s) or other preventive actions
- A documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or concerns regarding fluid overload status that precludes treatment at an alternative less intensive site of care

* 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.

When the above medical necessity criteria for administration of an injectable medication in a hospital outpatient setting or hospital-affiliated infusion suite are not met, an alternative less intensive site of care should be utilized.

General Background

The following list of drugs is included as part of the Enhanced Specialty Care Options program. This list may not be all-inclusive and is subject to change.

Actemra® (tocilizumab)
Adakveo (crizanlizumab-tmca)
Adagen® (pegademase)
Adcetris (brentuximab vedotin)
Aldurazyme® (laronidase)
Alimta (pemetrexed)
Aranesp® (darbepoetin alfa)
Aralast NP™ [(alpha-1-proteinase inhibitor (human))]
Avastin (bevacizumab)
Aveed® (testosterone undecanoate)
Benlysta® (belimumab)
Berinerit [C1 Esterase Inhibitor (Human)]
Bivigam® (human immunoglobulin g)
Cabenuva™ (cabotegravir/rilpivirine)
Carimune® NF (human immunoglobulin g)
Cerezyme® (imiglucerase)
Cimzia® (certolizumab pegol)
Cinqair® (reslizumab)
Crysvita® (burosumab-twza)
Cinryze® (C1 Esterase Inhibitor [Human])
Cutaquig® (Immune Globulin Subcutaneous [Human] – hipp)
Cuvitru® [immune globulin subcutaneous (human)]
Darzalex Faspro (daratumumab and hyaluronidase-fihj)
Elaprase® (idursulfase)
Elelyso® (taliglucerase)
Entyvio® (vedolizumab)
Evenity™ (romosozumab-aqqg)
Exondys 51™ (eteplirsen)
Fabrazyme® (agalsidase beta)
Fasenra™ (benralizumab)
Flebogamma® [immune globulin (human)]
Fulphila™ (pegfilgrastim-jmdb)
Gamastan (gamma globulin, intramuscular)
Gamifant™ (emapalumab-lzsg)

Gammagard® [immune globulin (human)]
Gammaplex® (human immunoglobulin g)
Gamunex® C [immune globulin (human)]
Givlaari™ (givosiran)
Glassia® (alpha.1-proteinase inhibitor human)
Herceptin (trastuzumab)
Hizentra® (human immunoglobulin g)
Hyqvia® [immune globulin (human)]
Ilaris® (canakinumab)
Ilumya™ (tildrakizumab-asmn)
Imfinzi (durvalumab)
Inflectra™ (infliximab-dyyb)
Kadcyla (ado-trastuzumab emtansine)
Kalbitor® (ecallantide)
Kanuma (sebelipase alfa)
Keytruda (pembrolizumab)
Krystexxa® (pegloticase)
Lemtrada® (alemtuzumab)
Lumizyme® (alglucosidase alfa)
Mepsevii™ (vestronidase alfa-vjbk)
Mircera® (methoxy polyethylene glycol-epoetin beta)
Mvasi (bevacizumab-awwb)
Naglazyme® (galsulfase)
Neulasta® (pegfilgrastim)
Nplate® (romiplostim)
Nucala® (mepolizumab)
Nyvepria™ (pegfilgrastim-apgf)
Ocrevus™ (ocrelizumab)
Octagam® [immune globulin (human)]
Ogivri (trastuzumab-dkst)
Onpattro™ (patisiran sodium)
Opdivo (nivolumab)
Orencia® (abatacept)
Oxlumo™ (lumasiran)
Panzyga® (immune Globulin Intravenous, human-ifas)
Perjeta (pertuzumab)
Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf)
Privigen® (human immunoglobulin g)
Procrit®/Epogen® (epoetin alfa)
Prolastin-C® [alpha-1-proteinase inhibitor (human)]
Prolia® (denosumab)
Radicava™ (edaravone)
Reblozyl® (luspatercept-aamt)
Remicade® (infliximab)
Renflexis™ (infliximab-abda)
Retacrit™ (epoetin alfa-epbx)
Revcovi™ (elapeg ademase-lvlr)
Riabni™ (rituximab-arrx)
Rituxan® (rituximab)
Ruconest® [C1 esterase inhibitor (recombinant)]
Ruxience® (rituximab-pvvr)
Sandostatin® LAR (octreotide)
Signifor® LAR (pasireotide)

Simponi® (golimumab)
Simponi Aria® (golimumab)
Soliris® (eculizumab)
Somatuline® Depot (lanreotide)
Stelara® (ustekinumab)
Synagis® (palivizumab)
Tecentriq (atezolizumab)
Tepezza™ (teprotumumab-trbw)
Trazimera (trastuzumab-qyyp)
Tremfya® (guselkumab)
Triptodur (triptorelin)
Trogarzo™ (ibalizumab-uiyk)
Truxima® (rituximab-abbs)
Tysabri® (natalizumab)
Udenyca™ (pegfilgrastim-cbqv)
Ultomiris™ (ravulizumab-cwvz)
Uplizna™ (inebilizumab-cdon)
Velcade (bortezomib)
Vimizim™ (elosulfase alfa)
Vivaglobin® [immune globulin subcutaneous (human)]
Vpriv® (velaglucerase alfa)
Vyepti™ (eptinezumab-jjmr)
Xgeva® (denosumab)
Xembify™ (immune globulin subcutaneous, human-klhw)
Xolair® (omalizumab)
Yervoy (ipilimumab)
Zemaira® [Alpha1-Proteinase Inhibitor (Human)]
Ziextenzo™ (pegfilgrastim-bmez)
Zirabev (bevacizumab-bvzr)

Coding/ Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each
90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each

HCP Codes	Description
C9399	Unclassified drugs or biologicals
J0129	Injection, abatacept, (Orencia), 10 mg (Code may be used for Medicare when drug administered under direct supervision of a physician, not for use when drug is self-administered)

HCPCS Codes	Description
J0180	Injection, agalsidase beta, (Fabrazyme), 1 mg
J0202	Injection, alemtuzumab, (Lemtrada), 1 mg
J0221	Injection, alglucosidase alfa (Lumizyme), 10 mg
J0222	Injection, patisiran, (Onpattro), 0.1 mg
J0223	injection, givosiran (Givlaari), 0.5 mg
J0256	Injection, alpha 1 proteinase inhibitor (human), not otherwise specified, 10 mg
J0257	Injection, alpha 1 proteinase inhibitor (human), (Glassia), 10 mg
J0490	Injection, belimumab, (Benlysta), 10 mg
J0517	Injection, benralizumab, (Fasenra), 1 mg
J0584	Injection, burosumab-twza, (Crysvita), 1 mg
J0596	Injection, C-1 esterase inhibitor (recombinant), (Ruconest), 10 units
J0597	Injection, C-1 esterase inhibitor (human), (Berinert), 10 units
J0598	Injection, C-1 esterase inhibitor (human), (Cinryze), 10 units
J0638	Injection, canakinumab, (Ilaris), 1 mg
J0717	Injection, certolizumab pegol, (Cimzia), 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when the drug is self-administered)
J0791	infusion, crizanlizumab-tmca, (Adakveo), 5mg
J0881	Injection, darbepoetin alfa, (Aranesp), 1 microgram (non-ESRD use)
J0885	Injection, epoetin alfa, (Procrit/Epogen), (for non-ESRD use), 1000 units
J0888	Injection, epoetin beta, (Mircera),1 microgram, (for non-ESRD use)
J0896	injection, luspatercept-aamt, (Reblozyl) .25 mg
J0897	injection, denosumab, (Xgeva or Prolia) 1 mg
J1290	Injection, ecallantide, (Kalbitor), 1 mg
J1300	Injection, eculizumab, (Soliris), 10 mg
J1301	Injection, edaravone, (Radicava), 1 mg
J1303	injection, ravulizumab-cwvz, (Ultomiris) 10mg
J1322	Injection, elosulfase alfa, (Vimizim), 1 mg
J1428	Injection, eteplirsen, (Exondys 51), 10 mg
J1458	Injection, galsulfase, (Naglazyme), 1 mg
J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1460	injection, gamma globulin, intramuscular, (Gamastan) 1 cc
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1558	injection, immune globulin subcutaneous, human SQ (Xembify) 100 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1560	injection, gamma globulin, intramuscular, over 10 cc
J1561	Injection, immune globulin, (Gamunex-c/Gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562	Injection, immune globulin, subcutaneous, (Vivaglobin), 100 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), intravenous, non-lyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/ Flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, (HyQvia), 100 mg immune globulin

HCPCS Codes	Description
J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg
J1602	infusion, golimumab (Simponi Aria), 1mg (IV)
J1602	injection, golimumab (Simponi), 100 mg/1ml (SQ)
J1628	injection, guselkumab, (Tremfya), 1mg
J1743	Injection, idursulfase, (Elaprase), 1 mg
J1745	Injection, infliximab, (Remicade), excludes biosimilar, 10 mg
J1746	Injection, ibalizumab-uiyk, (Trogarzo), 10 mg
J1786	Injection, imiglucerase, (Cerezyme), 10 units
J1930	Injection, lanreotide, (Somatuline® Depot), 1 mg
J1931	Injection, laronidase, (Aldurazyme), 0.1 mg
J2182	Injection, mepolizumab, (Nucala), 1 mg
J2323	Injection, natalizumab, (Tysabri), 1 mg
J2350	Injection, ocrelizumab, (Ocrevus), 1 mg
J2353	Injection, octreotide, depot form for intramuscular injection, (Sandostatin LAR), 1 mg
J2357	Injection, omalizumab, (Xolair), 5 mg
J2502	Injection, pasireotide long acting, (Signifor LAR), 1 mg
J2504	Injection, pegademase bovine, (Adagen), 25 IU
J2505	Injection, pegfilgrastim, (Neulasta), 6 mg
J2507	Injection, pegloticase, (Krystexxa), 1 mg
J2786	Injection, reslizumab, (Cinqair), 1 mg
J2796	Injection, romiplostim, (Nplate), 10 micrograms
J2840	Injection, sebelipase alfa, (Kanuma), 1 mg
J3032	infusion, eptinezumab-jjmr, (Vyepti), 1 mg
J3060	Injection, taliglucerase alfa, (Elelyso), 10 units
J3111	injection, romosozumab-aqqg (Evenity), 1 mg
J3145	Injection, testosterone undecanoate, (Aveed), 1 mg
J3241	infusion, teprotumumab-trbw, (Tepezza), 10 mg
J3245	Injection, tildrakizumab, (Ilumya), 1 mg
J3262	Injection, tocilizumab, (Actemra), 1 mg
J3315	injection, triptorelin pamoate (Triptodur), 3.75 mg
J3316	Injection, triptorelin, (Triptodur) extended-release, 3.75 mg
J3357	Ustekinumab (Stelara), for subcutaneous injection, 1 mg
J3358	injection, ustekinumab (Stelara), 1mg (IV)
J3380	Injection, vedolizumab, (Vpriv), 1 mg
J3385	Injection, velaglucerase alfa, 100 units
J3397	Injection, vestronidase alfa-vjbk, (Mepsevii), 1 mg
J3490	Unclassified drugs
J3590	Unclassified biologics
J9022	Injection, atezolizumab (Tecentriq)
J9035	Injection, bevacizumab (Avastin), 10 mg
J9041	Injection, bortezomib (Velcade),
J9042	Injection, brentuximab vedotin (Adcetris)
J9173	Injection, durvalumab (Imfinzi), 10 mg
J9210	Injection, emapalumab-lzsg, (Gamifant), 1 mg
J9228	Injection, ipilimumab (Yervoy)
J9271	Injection, pembrolizumab (Keytruda), 1 mg
J9299	Injection nivolumab (Opdivo), 1 mg

HCP Codes	Description
J9305	Injection, pemetrexed, not otherwise specified, 10 mg (Alimta)
J9306	Injection, pertuzumab (Perjeta), 1 mg
J9354	Injection, ado-trastuzumab emt (Kadcyla), 10 mg
J9355	Injection, trastuzumab (Herceptin)
J9312	Injection, rituximab, (Rituxan), 10 mg
J9999	Antineoplastic drug (Darzalex Faspro)
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units
Q5107	Injection, bevacizumab-awwb (Mvasi), 10 mg
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg
Q5114	Injection, trastuzumab-dkst (Ogivri), 10 mg
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5116	Injection, trastuzumab-qyyp (Trazimera), 10 mg
Q5118	Injection, bevacizumab-bvzr (Zirabev), 10 mg
Q5119	Injection, rituximab-pvvr, rituximab biosimilar, (Ruxience), 10 mg
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg

*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

References

1. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.
2. U.S. Food and Drug Administration. Licensed Biological Products with Supporting Documents. U.S. Department of Health & Human Services: <http://www.fda.gov/BiologicsBloodVaccines/ucm133705.htm>.

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., QualCare, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2021 Cigna.