THE OHIO STATE UNIVERSITY
HEALTH PLAN

Subject: Site of Care **Revision Date**: 5/25

DESCRIPTION

In an effort to minimize out-of-pocket costs for OSU Health Plan covered persons and to improve cost efficiencies for the overall health care system, prior authorization guidelines have been implemented to ensure services are being provided at the most appropriate location. This includes, but is not limited to, surgical procedures and certain outpatient medications.

In addition to this policy, OSU Health Plan utilizes MCG™ Care Guidelines to assist in determination of appropriate level of care (i.e., inpatient, outpatient, home, etc.).

For covered persons who require infusion or injection therapy services, the place of infusion or injection service, out-of-pocket expenses, safety, time, and convenience are contributing factors that can impact health care value and covered person's satisfaction. Home infusion as a place of service is well established and accepted by physicians. A 2010 home infusion provider survey by the National Home Infusion Association reported providing 1.24 million therapies to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications.

MCG™ Care Guidelines, 22nd edition, 2017, Home Infusion Therapy, CMT: CMT-0009 (SR) addresses criteria for home infusion therapy. Clinical patient characteristics for home suitability include clinical stability, no need for close observation or daily nurse care, and reliable venous access. Additional criteria for home environment, infusion plan and patient ability to participate in care are summarized.

APPLICABILITY

This policy applies to all OSU Health Plan (OSUHP) benefit plans.

DEFINITIONS

Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home.

Infusion therapy is a procedure in which medications are delivered slowly and directly into the bloodstream.

Intravenous (IV) infusion is the administration of fluids into a vein by means of a steel needle or plastic catheter.

Subcutaneous means administered just under the skin.

POLICY

Medications

Certain oral and subcutaneous medications are excluded under the medical benefit. Please review the prior authorization document on the OSU Health Plan website or call OSU Health Plan to determine whether a medication is eligible for reimbursement under the medical benefit. This policy applies to medications that are covered under the medical benefit. It does not apply to medications provided during a medically necessary inpatient hospitalization.

An outpatient intravenous (IV) infusion or injectable therapy is considered medically necessary in a hospital outpatient department or hospital outpatient clinic for covered persons over the age of 12 when **all** of the following are present:

- The inherent complexity or risk of the infusion or injection is such that it can be performed safely and effectively only by or under the general supervision of skilled nursing personnel in a hospital setting; and
- The covered person's medical status or therapy is such that it requires enhanced monitoring beyond that which would routinely be needed; and
- The potential changes in the covered person's clinical condition are such that immediate access to specific services of a medical center/hospital setting, having emergency resuscitation equipment and personnel, and inpatient admission or intensive care is necessary; for example, the covered person is at significant risk of sudden life-threatening changes in medical status based on clinical conditions including but not limited to:
    - Concerns regarding fluid overload status; or
    - History of anaphylaxis to prior infusion therapy with a related pharmacologic or biologic agent; or
    - Acute mental status changes; or
    - Induction[1] of therapy; or
    - Reinduction[1] of therapy after being off therapy for at least 6 months or changing to a different immune globulin product; or
    - Immunoglobulin A (IgA) deficiency with anti-IgA antibodies.

In addition to the above criteria, an outpatient intravenous (IV) infusion or injectable therapy is considered medically necessary in a hospital outpatient department or hospital outpatient clinic for **pediatric** patients ages 12 and younger.

Exceptions to the above criteria may be made if there is no outpatient infusion center within 50 miles of the covered person's home and there is no contracted home infusion agency that will travel to their home.

Medications that are frequently administered safely in a non-hospital outpatient facility, community physician's office, and/or home care include (not an all-inclusive list):

- Actemra (tocilizumab)

- Actimmune (interferon gamma-1b)
- Adagen (pegademase bovine)
- Aldurazyme (laronidase)
- Alglucosidase alfa
- Amvuttra (vutrisiran)
- Aralast NP (Alpha1-Proteinase Inhibitor [Human])
- Avsola (infliximab-axxq)
- Benlysta (belimumab)

---

[1] Induction is defined as all doses administered before the first maintenance dose according to the prescribing guidelines.

- Bkemv (eculizumab-aeeb)
- Cabenuva (cabotegravir and rilpivirine)
- Cablivi (caplacizumab-yhdp)
- Cerezyme (imiglucerase)
- Crysvita (burosumab-twza)
- Elaprase (idursulfase)
- Elelyso (taliglucerase alfa)
- Enjaymo (sutimlimab-jome)
- Entyvio (vedolizumab)
- Epysqli (eculizumab-aagh)
- Fabrazyme (agalsidase beta)
- Givlaari (givosiran)
- Glassia (Alpha1-Proteinase Inhibitor [Human])
- Inflectra (infliximab-dyyb)

- IVIG[2], such as:
    - Asceniv
    - Bivigam
    - Carimune NF
    - Flebogamma DIF
    - GamaSTAN S/D
    - Gammagard
    - Gammaked
    - Gammaplex
    - Gamunex-C
    - Octagam
    - Panzyga
    - Privigen
    - Vivaglobin
    - Yimmugo
- IXIFI (infliximab-qbtx)
- Kanuma (sebelipase alfa)
- Krystexxa (pegloticase)
- Lemtrada (alemtuzumab)

---

[2] Subcutaneous immunoglobulin is blocked on the medical benefit. Prior authorization is required for the pharmacy benefit. (e.g., Vivaglobin)

- Leqvio (inclisiran)
- Lumizyme (alglucosidase alfa)
- Mepsevii (vestronidase alfa-vjbk)
- Naglazyme (galsulfase)

- Nexviazyme (avalglucosidase alfa-ngpt)
- Nulojix (belatacept)
- Ocrevus (ocrelizumab)
- Onpattro (patisiran)
- Orencia (abatacept)
- Otulfi (ustekinumab-aauz)
- Phesgo (pertuzumab, trastuzumab and hyaluronidase-zzxf)
- Piasky (crovalimab-akkz)
- Prolastin-C (Alpha1-Proteinase Inhibitor [Human])
- Prolia (denosumab) [non-oncologic]
- Pyzchiva (ustekinumab-ttwe)
- Radicava (edaravone)
- Remicade (infliximab)
- Renflexis (infliximab-abda)
- Rituxan (rituximab) [non-oncologic]
- Rituxan Hyclea (rituximab and hyaluronidase) [non-oncologic]
- Ruxience (rituximab-pvvr)
- Ryplazim (plasminogen, human-tvmh)
- Saphnelo (anifrolumab-fnla)
- Scenesse (afamelanotide)
- Selarsdi (ustekinumab-aekn)
- Simponi Aria (golimumab)
- Skyrizi (risankizumab-rzaa) [IV induction]
- Soliris (eculizumab)
- Stelara (ustekinumab)

- Trogarzo (ibalizumab-uiyk)
- Truxima (rituximab-abbs) [non-oncologic]
- Tysabri (natalizumab)
- Ultomiris (ravulizumab-cwvz)
- Uplizna (inebilizumab-cdon)
- Vimizim (elosulfase alfa)
- VPRIV (velaglucerase alfa)
- Vyepti (eptinezumab-jjmr)
- Vyvgart (efgartigimod alfa-fcab)
- Wezlana (ustekinumab-auub)
- Zemaira (Alpha1-Proteinase Inhibitor [Human])
- Zolgensma (onasemnogene abeparvovec-xioi)

The medical necessity of the medication itself will be separately reviewed against the appropriate criteria.

Hemophilia

Blood-clotting factor is subject to vendor restrictions. Currently, the approved vendor for these medications is Cascade Hemophilia Consortium. For emergent bleeding concerns, the covered person should be directed to the nearest emergency room.

Comprehensive Cancer Centers

OSU Health Plan considers services provided by a Comprehensive Cancer Center (CCC) medically necessary for the prevention, screening, diagnosis, treatment, palliative, and end-of-life care related to

known or suspected malignancy. This includes services for individuals who are at risk for malignancy due to family history or genetic predisposition.

A Comprehensive Cancer Center may also be considered medically necessary for individuals who do not meet the above criteria when the services requested are not available through a non-CCC provider. These cases will be reviewed on an individual basis.

Children's Hospitals

Occasionally adult patients (age 18 and older) require treatment that is only available through a Children's Hospital. OSUHP will review requests for adult patients on a case-by-case basis to determine if the requested service is available at an alternative network hospital. If services can be provided elsewhere, the request for coverage of a Children's Hospital may be denied. Depending on the clinical scenario, a transition period may be authorized based on guidance from the American Academy of Pediatrics (AAP).

Outpatient Surgical Hospital

CMS designates certain CPT codes as office-based procedures or appropriate for an ambulatory surgery center (ASC). These procedures are not covered in an outpatient hospital facility. Any exception requires review by the Medical Director for medical necessity.

PROCEDURES

OSUHP will communicate any site-of-care restrictions to the provider and the covered person. The third-party administrator (TPA) will process claims according to the instructions provided by OSUHP in the care management system.

PRIOR AUTHORIZATION

Prior authorization is required for the medications listed in this policy. Refer to the Medical Prior Authorization Code List for additional prior authorization requirements.

EXCLUSION

OSU Health Plan does not cover the following services:

- Administration of an IV infusion or injectable therapy services in the hospital outpatient department or hospital outpatient clinic is not medically necessary when the criteria specified in this policy are not met.
- Any service provided by a Comprehensive Cancer Center when the criteria specified in this policy are not met.

CODES

The medication portion of this policy applies to claims for medications that are submitted with the following CMS/AMA Place of Service codes:

- 22 On-Campus - Outpatient Hospital; and
- 19 Off-Campus - Outpatient Hospital

Codes related to this policy (not all-inclusive):

HCPCS Code	**Description**
C9047	Injection, caplacizumab-yhdp, 1 mg
C9090	Injection, plasminogen, human-tvmh, 1 mg
C9399	Unclassified drugs or biologicals
J0129	Injection, abatacept, 10 mg
J0180	Injection agalsidase beta, 1mg
J0202	Injection, alemtuzumab, 1 mg
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg

J0220	Injection, alglucosidase alfa, 10 mg, not otherwise specified
J0221	Injection, alglucosidase alfa, (Lumizyme), 10 mg
J0222	Injection, patisiran, 0.1 mg
J0223	Injection, givosiran, 0.5 mg
J0225	Injection, vutrisiran, 1 mg
J0256	Injection, alpha 1 proteinase inhibitor (human), not otherwise specified, 10 mg
J0257	Injection, alpha 1 proteinase inhibitor (human), (GLASSIA), 10 mg
J0485	Injection, belatacept, 1 mg
J0490	Injection, belimumab, 10 mg
J0491	Injection, anifrolumab-fnla, 1 mg
J0584	Injection, burosumab-twza, 1 mg
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg
J0897	Injection, denosumab, 1 mg (Prolia)
J1299	Injection, eculizumab, 2 mg
J1301	Injection, edaravone, 1 mg
J1302	Injection, sutimlimab-jome, 10 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
J1306	Injection, inclisiran, 1 mg
J1307	Injection, crovalimab-akkz, 10 mg
J1322	Injection, elosulfase alfa, 1 mg
J1458	Injection, galsulfase, 1 mg
J1459	Injection, immune globulin, intravenous, nonlyophilized (e.g.,liquid), 500 mg
J1460	Injection, gamma globulin, intramuscular, 1 cc
J1554	Injection, immune globulin (Asceniv), 500 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), 500 mg
J1560	Injection, gamma globulin, intramuscular, over 10cc
J1561	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), 500 mg
J1562	Injection, immune globulin (Vivaglobin), 100 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg

J1568	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid) 500 mg
J1569	Injection, immune globulin, intravenous, nonlyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), 500 mg
J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1743	Injection, idursulfase, 1 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J1746	Injection, ibalizumab-uiyk, 10 mg
J1786	Injection, imiglucerase, 10 units
J1823	Injection, inebilizumab-cdon, 1 mg
J1931	Injection, laronidase, 0.1 mg
J2323	Injection, natalizumab, 1 mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J2350	Injection, ocrelizumab, 1 mg
J2504	Injection, pegademase bovine, 25 IU
J2507	Injection, pegloticase, 1 mg
J2840	Injection, sebelipase alfa, 1 mg
J2998	Injection, plasminogen, human-tvmh, 1 mg
J3032	Injection, eptinezumab-jjmr, 1 mg
J3060	Injection, taliglucerase alfa, 10 units
J3262	Injection, tocilizumab, 1 mg
J3358	Ustekinumab for intravenous injection, 1 mg
J3380	Injection, vedolizumab, 1 mg
J3385	Injection, velaglucerase alfa, 100 units
J3397	Injection, vestronidase alfa-vjbk, 1 mg
J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10
J3490	Unclassified drugs
J3590	Unclassified biologics

J7352	Afamelanotide implant, 1 mg
J9216	Injection, interferon, gamma 1-b, 3 million units
J9311	Injection, rituximab 10 mg and hyaluronidase [non-oncologic]
J9312	Injection, rituximab, 10 mg [non-oncologic]
J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg
J9332	Injection, efgartigimod alfa-fcab, 2 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, 10 mg
Q5109	Injection, infliximab-qbtx, biosimilar, (Ixifi), 10 mg
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg [non-oncologic]
Q5119	Injection, rituximab-pvvr, biosimilar, (RUXIENCE), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg
Q5138	Injection, ustekinumab-auub (Wezlana), biosimilar, IV, 1 mg
Q5151	Injection, eculizumab-aagh (Epysqli), biosimilar, 2 mg
Q5152	Injection, eculizumab-aeeb (Bkemv), biosimilar, 2 mg
Q9997	Injection, ustekinumab-ttwe (Pyzchiva), intravenous, 1 mg
Q9998	Injection, ustekinumab-aekn (Selarski), 1 mg
Q9999	Injection, ustekinumab-aauz (Otulfi), biosimilar, 1 mg

REFERENCES

Aetna. (2018). Drug infusion site of care policy. Retrieved March 27, 2018, from https://www.aetna.com/health-care-professionals/utilization-management/drug-infusion-site-of- care-policy.html

Anthem. (2017). Level of Care: Specialty Pharmaceuticals [CG-DRUG-47]. Retrieved March 27, 2018, from https://www.anthem.com/medicalpolicies/guidelines/gl_pw_c183201.htm

American Academy of Allergy, Asthma, and Immunology. Guidelines for the Site of Care for Administration of IVIG therapy. December 2011.

Arnold, L., Stephenson, J., Kelly, R., Buchanan, D., Jones, G., & Hillmen, P. (2008). Home infusion of eculizumab: a unique and innovative model of drug delivery to reduce treatment-associated

burden and enhance quality of life for patients with PNH. *Blood, 112*(11), 4671.

Chataway, J., Porter, B., Riazi, A., et al. (2006) Home versus outpatient administration of intravenous steroids for multiple-sclerosis relapses: a randomized controlled trial. *Lancet Neurol, 5*(7), 565-571.

Cousins, A., et al. (2008). Home-based infusion therapy for patients with fabry disease. *Br J Nurs, 17*(10), 653-657.

Exondys 51 [prescribing information]. Cambridge, MA: Sarepta Therapeutics, Inc.; Sept. 2016.

Gupta, S., et al. (2019). A quality improvement approach to external infliximab infusions in pediatric inflammatory bowel disease. JPGN, 69(5), 544-550. DOI: 10.1097/MPG.0000000000002422

Inflectra [prescribing information]. Lake Forest, IL: Celltrion, Inc.; Nov. 2016.

Katzberg, H., Rasutis, V., & Bril, V. (2013). Home IVIG for CIDP: a focus on patient centered care. *Canadian Journal of Neurological Sciences / Journal Canadien Des Sciences Neurologiques, 40*(3), 384-388. DOI:10.1017/S0317167100014359

Lemtrada [prescribing information]. Cambridge, MA: Genzyme Corp.; Nov. 2014.

Linthorst, G., Vedder, A., Ormel, E., Aerts, J., & Hollak, C. (2006). Home treatment for fabry disease: practice guidelines based on 3 years' experience in The Netherlands. *Nephrol Dial Transplant, 21*(2), 355-360.

MCG Care Guidelines, 22nd Edition, 2018, Home Infusion Therapy: CMT: CMT-0009.

Milligan, A., Hughes, D., Goodwin, S., Richfield, L., & Mehta, A. (2006). Intravenous enzyme replacement therapy: better in home or hospital? *Br J Nurs, 15*(6), 330-333.

Ocrevus [prescribing information]. San Francisco, CA: Genentech, Inc.: March 2017.

Premera. (2018). Site of Service: Infusion Drugs and Biologic Agents. Retrieved March 27, 2018, from https://www.anthem.com/medicalpolicies/guidelines/gl_pw_c183201.htm

Radicava [prescribing information]. Jersey City, NJ: MT Pharma America, Inc.; May 2017.

Remicade [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; Oct. 2015.

Renflexis [prescribing information]. Kenilworth, NJ: Merck & Co., Inc.; April 2017.

the Multiple Sclerosis Relapse Management Scale (MSRMS). *Health and Quality of Life Outcomes* 2011 9:80.

Rigas, M., Tandan, R., & Sterling, R. (2008). Safety of Liquid Intravenous Immunoglobulin for Neuroimmunologic Disorders in the Home Setting: A retrospective Analysis of 1085 Infusions. *Journal of Clinical Neuromuscular Disease, 10*(2), 52-55. DOI: 10.1097/CND.0b013e31818b2aef

Souayah, N., Hasan, A., Khan, H., Yacoub, H., & Jafri, M. (2011). The Safety Profile of Home Infusion of Intravenous Immunoglobulin in Patients with Neuroimmunologic Disorders. *Journal of Clinical Neuromuscular Disease, 12*, S1-S10. DOI: 10.1097/CND.0b013e3182212589

Tysabri [prescribing information]. Cambridge, MA: Biogen Idec, Inc.: May 2016.

White, P.H., et. al. (2018). Supporting the health care transition from adolescence to adulthood in the medical home. *Pediatrics, 142*(5), https://doi.org/10.1542/peds.2018-2587.