Subject: Site of Care Policy

Effective Date: 01/2019

DESCRIPTION

In an effort to minimize out-of-pocket costs for OSU Health Plan members 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 members 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 member 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.

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.

Administration of medications under the medical benefit will be covered in the most appropriate, safe and cost effective site. The preferred sites of service are non-hospital outpatient facility or home care.

An outpatient intravenous (IV) infusion or injectable therapy is considered medically necessary in a hospital outpatient department or hospital outpatient clinic 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 individual'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 individual'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 individual 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
    - Initiation of therapy; or
    - Reinitiating 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.

Exceptions to the above criteria may be made if there is no outpatient infusion center within 50 miles of the member'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)
- Adagen (pegademase bovine)
- Aldurazyme (laronidase)
- Aralast NP (Alpha1-Proteinase Inhibitor [Human])
- Benlysta (belimumab)
- Cerezyme (imiglucerase)
- Crysvita (burosumab-twza)
- Elaprase (idursulfase)
- Elelyso (taliglucerase alfa)
- Entyvio (vedolizumab)
- Exondys 51 (eteplirsen)
- Fabrazyme (agalsidase beta)
- Glassia (Alpha1-Proteinase Inhibitor [Human])
- Inflectra (infliximab-dyyb)
- IVIG, such as:
    - Bivigam
    - Carimune NF
    - Flebogamma DIF
    - GamaSTAN S/D
    - Gammagard
    - Gammaked
    - Gammaplex
    - Gamunex-C
    - Hizentra
    - Octagam
    - Privigen
- IXIFI (infliximab-qbtx)
- Kanuma (sebelipase alfa)

- Lemtrada (alemtuzumab)
- Lumizyme (alglucosidase alfa)
- Mepsevii (vestronidase alfa-vjbk)
- Naglazyme (galsulfase)
- Nulojix (belatacept)
- Ocrevus (ocrelizumab)
- Orencia (abatacept)
- Prolastin-C (Alpha1-Proteinase Inhibitor [Human])
- Prolia (denosumab)
- Radicava (edaravone)
- Remicade (infliximab)
- Renflexis (infliximab-abda)
- Replagal (agalsidase alfa)
- Rituxan (rituximab) [non-oncologic]
- Simponi Aria (golimumab)
- Soliris (eculizumab)
- Stelara (ustekinumab)
- Trogarzo (ibalizumab-uiyk)
- Tysabri (natalizumab)
- Vimizim (elosulfase alfa)
- VPRIV (velaglucerase alfa)
- Zemaira (Alpha1-Proteinase Inhibitor [Human])

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

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 a 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.

EXCLUSION

The following services are not covered by OSU Health Plan:

- 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*
C9399	Unclassified drugs or biologicals
J0129	Injection, abatacept, 10 mg
J0180	Injection agalsidase beta, 1mg
J0202	Injection, alemtuzumab, 1 mg
J0220	Injection, alglucosidase alfa, 10 mg, not otherwise specified
J0221	Injection, alglucosidase alfa, (Lumizyme), 10 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
J0897	Injection, denosumab, 1 mg
J1300	Injection, eculizumab, 10 mg
J1301	Injection, edaravone, 1 mg
J1322	Injection, elosulfase alfa, 1 mg
J1428	Injection, eteplirsen, 10 mg
J1458	Injection, galsulfase, 1 mg
J1459	Injection, immune globulin, intravenous, nonlyophilized (e.g.,liquid), 500 mg
J1460	Injection, gamma globulin, intramuscular, 1 cc
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), 500 mg
J1559	Injection, immune globulin (Hizentra), 100 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
J1575	Injection, immune globulin/hyaluronidase, 100 mg immuneglobulin
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
J1931	Injection, laronidase, 0.1 mg
J2323	Injection, natalizumab, 1 mg
J2350	Injection, ocrelizumab, 1 mg
J2504	Injection, pegademase bovine, 25 IU
J2840	Injection, sebelipase alfa, 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
J3490	Unclassified drugs
J3590	Unclassified biologics
J9312	Injection, rituximab, 10 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, 10 mg
Q5109	Injection, infliximab-qbtx, biosimilar, (Ixifi), 10 mg

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