Updated 05/2026
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Drug Infusion Site of Care
Website Form – www.highmarkhealthoptions.com

Overview Statement

Highmark Health Options may provide coverage under medical benefits of the Company's Medicaid products for medically necessary infusible drugs in the most appropriate and cost-effective setting. This policy is designed to address medical necessity guidelines that are appropriate for most individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The content of this policy meets the standards of the National Committee for Quality Assurance (NCQA), the Delaware Department of Health and Social Services (DHSS), and all other applicable state and federal regulations.

Terms and Definitions

Site- of-Care (SOC) - Refers to the location where care is provided and is synonymous with "Place of Service." For the purposes of this policy, SOC refers specifically to the site of injectable drug administration and drug infusion therapy.

Highest Level of Care Site - The hospital outpatient facility (Outpatient IV Infusion Department or Hospital-Based Outpatient Clinic Level of Care) setting typically offers the highest-level intensive care ("Highest Level of Care Site"), with access to an emergency equipment and/or services, medical center, intensive care, or inpatient admission if necessary.

Lower Level of Care Site - Physician's offices, specialized infusion centers not affiliated with a hospital, and home infusion services constitute the least intensive setting ("Lower Level of Care Site") for the administration of the medications outlined in this policy.

Home Infusion Therapy (HIT) - The administration of drugs through intravenous, intraspinal, epidural, or subcutaneous routes, under a physician prescribed treatment plan and in a member's home or other appropriate location.

Medically Necessary: The essential need for health care or services which, when delivered by or through authorized and qualified providers, will:

- Be directly related to the prevention, diagnosis and treatment of a member's disease, condition, and/or disorder that results in health impairments and/or disability (the physical or mental functional deficits that characterize the member's condition) and be provided to the member only.
- Be appropriate and effective to the comprehensive profile (e.g., needs, aptitudes, abilities, and environment) of the member and the member's family.

- Be primarily directed to the diagnosed medical condition or the effects of the condition of the member, in all settings for normal activities of daily living (ADLs);
- Be timely, considering the nature and current state of the member's diagnosed condition and its effects, and will be expected to achieve the intended outcomes in a reasonable time.
- Be the least costly, appropriate, available health service alternative, and will represent an effective and appropriate use of funds.
- Be the most appropriate care or service that can be safely and effectively provided to the member and will not duplicate other services provided to the member.
- Be sufficient in amount, scope and duration to reasonably achieve its purpose.
- Be recognized as either the treatment of choice (i.e., prevailing community or Statewide standard) or common medical practice by the practitioner's peer group, or the functional equivalent of other care and services that are commonly provided.
- Be rendered in response to a life-threatening condition or pain, or to treat an injury, illness, or other diagnosed condition, or to treat the effects of a diagnosed condition that has resulted in or could result in a physical or mental limitation, including loss of physical or mental functionality or developmental delay.
- For members enrolled in DSHP Plus LTSS, provide the opportunity for members to have access to the benefits of community living, to achieve person-centered goals, and live and work in the setting of their choice.

- **Ongoing Medication:** A medication that has been previously dispensed to the member for the treatment of an illness that is chronic in nature or for an illness for which the medication is required for a length of time to complete a course of treatment, until the medication is no longer considered
- **Prior Authorization:** A determination made by Highmark Health Options to approve or deny payment for a request to provide a service or course of treatment of a specific duration and scope to a member prior to the provider’s initiation or continuation of the requested service.

Procedure

The medications identified in this policy are considered medically necessary for individuals 18 years of age and older when applicable clinical criteria for individual medication policies are met and when administered in a Lower Level of Care Site.

The Highest Level of Care Site may be considered medically necessary if **ANY** of the following criteria are present, indicating that the member is medically unable to receive drug infusions in a Lower level of Care Site:

- Individual's home is considered unsuitable for care by the home infusion service provider; **or**
- Individual's medical status requires enhanced monitoring beyond that which would routinely be provided at the preferred SOC; **or**
- Individual previously experienced a documented severe adverse reaction (including but not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) during or following administration of drug infusion despite standard pre-medication; **or**
- Individual is concurrently receiving other drugs that require close monitoring with a higher level of care (e.g., cytotoxic chemotherapy or blood products); **or**
- Individual is at high risk for drug infusion complications (e.g., risk of post-transplant complications, risk of infusion reactions due to presence of circulating antibodies, unstable vascular access, cardiopulmonary status with risk of severe adverse reactions, unstable renal function risk with inability to safely tolerate intravenous volume loads, etc.); **or**
- Individual is physically and/or cognitively impaired **AND** a home caregiver is not available and/or unable to comply with the required treatment regimen and schedule.

In addition to the above exception criteria, individuals receiving an immune checkpoint inhibitor (see drug list below) may have the medication administered in a Highest Level of Care Site if **ANY** of the following criteria are met:

- Individual is on a regimen consisting of combination immune/cytotoxic therapy (unless all drugs in regimen are subject to site of care review); **or**
- Individual is experiencing **ANY** severe toxicity requiring continuous monitoring including but not limited to:
    - Grade 2-4 bullous dermatitis
    - Transaminitis
    - Pneumonitis
    - Stevens-Johnson syndrome
    - Acute pancreatitis
    - Primary adrenal insufficiency

- Aseptic meningitis
- Encephalitis
- Transverse myelitis
- Myocarditis
- Pericarditis
- Arrhythmias
- Impaired ventricular function or conduction abnormalities

Medications in this policy are considered medically necessary when approved through prior authorization and must be administered at the appropriate level of care based on clinical need.

This policy uses a two-step prior authorization process evaluating:

- Medical necessity
- Appropriate level of care

Authorization is approved only if both criteria are met. If either is not satisfied, the request is not approved.

Applicable Drugs and Associated Procedure Codes

HCPCS	Drug Name	Effective Date
J3262	Actemra (tocilizumab)	10/1/2026
J0791	Adakveo (crizanlizumab)	10/1/2026
J1931	Aldurazyme (laronidase)	10/1/2026
J0256	Aralast / Prolastin-C / Zemaira (alpha-1 proteinase inhibitor)	10/1/2026
J1554	Asceniv (immune globulin [human])	10/1/2026
Q5121	Avsola (infliximab-axxq)	10/1/2026
J9023	Bavencio (avelumab)	10/1/2026
J0490	Benlysta (belimumab)	10/1/2026
J0597	Berinert (C1 esterase inhibitor [human])	10/1/2026
J1556	Bivigam (immune globulin [human])	10/1/2026
J1786	Cerezyme (imiglucerase)	10/1/2026
J2786	Cinqair (reslizumab)	10/1/2026
J0598	Cinryze (C1 esterase inhibitor [human])	10/1/2026
J0584	Crysvita (burosumab-twza)	10/1/2026
J1551	Cutaquig (immune globulin [human])	10/1/2026
J1555	Cuvitru (immune globulin [human])	10/1/2026
J1743	Elaprase (idursulfase)	10/1/2026
J3060	Elelyso (taliglucerase alfa)	10/1/2026

J9217	Eligard / Lupron Depot (leuprolide acetate)	10/1/2026
J3380	Entyvio (vedolizumab)	10/1/2026
J3111	Evenity (romosozumab-aqqg)	10/1/2026
J0180	Fabrazyme (agalsidase beta)	10/1/2026
J1951	Fensolvi (leuprolide acetate)	10/1/2026
J1572	Flebogamma (immune globulin [human])	10/1/2026
Q5108	Fulphila (pegfilgrastim-jmdb)	10/1/2026
J1460	Gamastan (immune globulin [human])	10/1/2026
J9210	Gamifant (emapalumab-lzsg)	10/1/2026
J1569	Gammagard Injection (immune globulin [human])	10/1/2026
J1566	Gammagard Intravenous (immune globulin [human])	10/1/2026
J1561	Gammaked / Gamunex / Gamunex-C (immune globulin [human])	10/1/2026
J1557	Gammaplex (immune globulin [human])	10/1/2026
J0223	Givlaari (givosiran)	10/1/2026
J0257	Glassia (alpha-1 proteinase inhibitor [human])	10/1/2026
J1447	Granix (tbo-filgrastim)	10/1/2026
J1559	Hizentra (immune globulin [human])	10/1/2026
J1575	Hyqvia (immune globulin [human]/recombinant human hyaluronidase)	10/1/2026
J0638	Ilaris (canakinumab)	10/1/2026
J3245	Ilumya (tildrakizumab-asmn)	10/1/2026
J9173	Imfinzi (durvalumab)	10/1/2026
J9347	Imjudo (tremelimumab-actl)	10/1/2026
Q5103	Inflectra (infliximab-dyyb)	10/1/2026
J1745	inFLIXimab / Remicade (infliximab)	10/1/2026
J9272	Jemperli (dostarlimab-gxly)	10/1/2026
J2840	Kanuma (sebelipase alfa)	10/1/2026
J9271	Keytruda (pembrolizumab)	10/1/2026
J9277	Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)	10/1/2026
J2507	Krystexxa (pegloticase)	10/1/2026
J1930	Lanreotide / Somatuline (lanreotide)	10/1/2026
J0202	Lemtrada (alemtuzumab)	10/1/2026
J9119	Libtayo (cemiplimab-rwlc)	10/1/2026
J0221	Lumizyme (alglucosidase alfa)	10/1/2026
J1950	Lupron Depot (leuprolide acetate)	10/1/2026
J3397	Mepsevii (vestronidase alfa-vjbk)	10/1/2026
J1458	Naglazyme (galsulfase)	10/1/2026
J2506	Neulasta (pegfilgrastim)	10/1/2026
J1442	Neupogen (filgrastim)	10/1/2026
Q5110	Nivestym (filgrastim-aafi)	10/1/2026
J2802	Nplate (romiplostim)	10/1/2026

J2182	Nucala (mepolizumab)	10/1/2026
J2350	Ocrevus (ocrelizumab)	10/1/2026
J1568	Octagam (immune globulin [human])	10/1/2026
J2354	Octreotide / Sandostatin (octreotide acetate)	10/1/2026
J0222	Onpattro (patisiran)	10/1/2026
J9299	Opdivo (nivolumab)	10/1/2026
J9289	Opdivo Qvantig (nivolumab and hyaluronidase-nvhy)	10/1/2026
J9298	Opdualag (nivolumab and relatlimab-rmbw)	10/1/2026
J0129	Orencia (abatacept)	10/1/2026
J1576	Panzyga (immune globulin [human])	10/1/2026
J1459	Privigen (immune globulin [human])	10/1/2026
J0897	Prolia (denosumab)	10/1/2026
J1301	Radicava (edaravone)	10/1/2026
J0896	Reblozyl (luspatercept-aamt)	10/1/2026
Q5125	Releuko (filgrastim-ayow)	10/1/2026
Q5104	Renflexis (infliximab-abda)	10/1/2026
J0596	Ruconest (C1 esterase inhibitor [recombinant])	10/1/2026
J1602	Simponi (golimumab)	10/1/2026
J1300	Soliris (eculizumab)	10/1/2026
J3358	Stelara Intravenous (ustekinumab)	10/1/2026
J3357	Stelara Subcutaneous (ustekinumab)	10/1/2026
J9022	Tecentriq Intravenous (atezolizumab)	10/1/2026
J9024	Tecentriq Subcutaneous (atezolizumab)	10/1/2026
J3241	Tepezza (teprotumumab-trbw)	10/1/2026
J1746	Trogarzo (ibalizumab-uiyk)	10/1/2026
J2323	Tysabri (natalizumab)	10/1/2026
J1303	Ultomiris (ravulizumab-cwvz)	10/1/2026
J1823	Uplizna (inebilizumab-cdon)	10/1/2026
J1322	Vimizim (elosulfase alfa)	10/1/2026
J3385	Vpriv (velaglucerase alfa)	10/1/2026
J3032	Vyepti (eptinezumab-jjmr)	10/1/2026
J1558	Xembify (immune globulin [human])	10/1/2026
J2357	Xolair (omalizumab)	10/1/2026
J9228	Yervoy (ipilimumab)	10/1/2026
Q5101	Zarxio (filgrastim-sndz)	10/1/2026
Q5120	Ziextenzo (pegfilgrastim-bmez)	10/1/2026
J9345	Zynyz (retifanlimab-dlwr)	10/1/2026

Additional References

Markkanen P, Galligan C, Quinn M. Safety Risks Among Home Infusion Nurses and Other Home Health Care Providers. J Infus Nurs. 2017 Jul/Aug;40(4):215-223. doi: 10.1097/NAN.0000000000000227. PMID: 28683000; PMCID: PMC5502120.