

## Infusion Site of Care Drug Management Program

<b>Policy ID:</b>	HHO-DE-RP-1149
<b>Approved By:</b>	Highmark Health Options – Market Leadership
<b>Provider Notice Date:</b>	09/01/2023
<b>Original Effective Date:</b>	10/01/2023
<b>Annual Approval Date:</b>	07/26/2023
<b>Last Revision Date:</b>	07/26/2023
<b>Products:</b>	Medicaid
<b>Application:</b>	All participating hospitals and providers
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### Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### POLICY 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 the majority of 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 qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

### DEFINITIONS

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children program (DHCP) and Diamond State Health Plan Plus members.

**Site of care** – Refers to the location in which care is provided. It is synonymous with “Place of Service.” For the purposes of this policy, it will refer specifically to the site of injectable drug administration and drug infusion therapy.

**Home infusion therapy** – 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 approved by HHO. In the case of Long-Term Supports and Services (LTSS) or Home and Community Based Services (HCBS) the site of care is considered a “home” setting. If or when that member is residing (either long term or temporarily) in an institutional setting such as a hospital, rehab, or LTSS residential care program, those services are inclusive in the institutional rate and should not be billed separately.

## PROCEDURES

Medications and site of care identified below require prior authorization.

### Site of Care Drug Management Program

HHO's order of preference for site of infusion therapy is as follows:

1. Home
2. Doctor's office-professional billing only
3. Infusion Center
4. Outpatient hospital IV infusion department or hospital-based outpatient clinical level of care

The medications identified in this policy may be 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 physician's office not affiliated with a hospital, specialized infusion centers not affiliated with a hospital or in the home.

Infusion centers and outpatient facility (Outpatient Hospital IV Infusion Department or Hospital-based Outpatient Clinical Level of Care) administration may be considered medically necessary if **ANY** of the following criteria are present to indicate the member is medically unstable for infusions in settings other than an outpatient facility setting:

- Member's home is considered unsuitable for care by the home infusion provider; **or**
- Individual's medical status requires enhanced monitoring beyond that which would routinely be needed for infusion therapy; **or**
- Previous severe adverse reaction (including but not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) during or following administration of prescribed medication despite standard pre-medication; **or**
- Individual is receiving other medications that require close monitoring with a higher level of care (e.g., cytotoxic chemotherapy or blood products); **or**
- Individual is at high risk for complications due to medication administration (e.g., at risk for post-transplant complications, increased risk of infusion reactions due to presence of circulating antibodies, unstable vascular access, cardiopulmonary condition at risk for severe adverse reactions, unstable renal function with inability to safely tolerate IV volume loads, etc.); **or**
- Individual is initiating therapy or re-initiating therapy after a period of at least 6 months with no therapy; **or**
- Physically and/or cognitively impaired **AND** a home caregiver is not available to comply with the required treatment regimen and schedule.

Administration that occurs in an unapproved hospital outpatient or infusion setting when an approved site of care (home or doctor's office) exists, will result in "no payment" for the provider.

All drugs in the program were clinically evaluated to verify they can be given with the same level of safety by a provider that's not affiliated with a hospital.

Privacy, reduced travel time, scheduling flexibility, personalized care for members, and reduced risk of exposure to hospital and clinic-acquired illnesses.

Several studies and US government reports have documented the occupational safety and health (OSH) challenges of HHC work. OSH hazards in HHC include but are not limited to bloodborne pathogen (BBP)

exposures, demanding patient mobilization and transfer tasks, threat of violence and other personal safety issues, exposure to secondhand tobacco smoke and cleaning and other household chemicals, long-distance driving, and the presence of pets.

### Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

### Medical Specialty Products Requiring Authorization

HCPCS	Generic (Brand Name)	Effective Date
J0129	abatacept (Orencia)	01/01/2019
J0180	agalsidase beta (Fabrazyme)	01/01/2019
J0221	alglucosidase alfa (Lumizyme)	01/01/2019
J0222	patisiran (Onpattro)	05/01/2020
J0256	alpha 1- proteinase inhibitor (human)(Aralast)	01/01/2019
J0257	alpha 1 proteinase inhibitor (Glassia)	01/01/2019
J0490	belimumab (Benlysta)	01/01/2019
J0596	c1 esterase inhibitor recombinant (Ruconest)	10/01/2019
J0597	c-1 esterase inhibitor human (Berinert)	01/01/2019
J0598	c-1 esterase inhibitor human (Cinryze)	10/01/2019
J0791	crizanlizumab-tmca (Adakveo)	11/01/2020
J1300	eculizumab (Soliris)	01/01/2019
J1301	edaravone (Radicava)	10/01/2019
J1303	ravulizumab-cwvz (Ultomiris)	05/01/2020
J1322	elosulfase alfa (Vimizim)	01/01/2019
J1458	galsulfase (Naglazyme)	10/01/2019
J1459	immune globulin (Privigen)	01/01/2019
J1554	Immune globulin (Asceniv)	05/01/2020
J1556	immune globulin (Bivigam)	01/01/2019
J1557	immune globulin (Gammaplex)	01/01/2019
J1561	immune globulin (Gamunex)	01/01/2019
J1566	immune globulin (Gamagard S/D, Carimune)	01/01/2019
J1568	immune globulin (Octagam)	01/01/2019
J1569	immune globulin (Gammagard)	01/01/2019
J1572	immune globulin (Flebogamma)	01/01/2019
J1599	immune globulin (Panzyga)	05/01/2020
J1602	golimumab (Simponi)	01/01/2019

J1743	idursulfase (Elaprase)	01/01/2019
J1745	infliximab (Remicade)	01/01/2019
J1786	imiglucerase (Cerezyme)	01/01/2019
J1823	inebilizumab-cdon (Uplizna)	06/01/2021
J1931	laronidase (Aldurazyme)	10/01/2019
J2350	ocrelizumab (Ocrevus)	10/01/2019
J2840	sebelipase alfa (Kanuma)	10/01/2019
J3032	eptinezumab-jjmr (Vyepiti)	02/01/2021
J3060	taliglucerase alfa (Elelyso)	10/01/2019
J3241	teprotumumab-trbw (Tepezza)	02/01/2021
J3262	tocilizumab (Actemra)	01/01/2019
J3380	vedolizumab (Entyvio)	01/01/2019
J3385	velaglucerase alfa (Vpriv)	01/01/2019
J3397	vestronidase alfa-vjvk (Mepsevii)	11/01/2020

## REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

## Reference

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.

## POLICY UPDATE HISTORY

07/26/2023	Approved in Governance
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