Policy Name:	Site of Service – Outpatient Infusion and Injection Services	Page:	1 of 7
Department:	Medical Management	Policy Number:	RX.PA.070.MPC
Subsection:	Pharmacy Services Management	Original Effective Date:	04/01/2023
Applies to:	Medicaid Health Plans	Revision Effective Date: 04/2026	

PURPOSE:

The purpose of this policy is to define Maryland Care, Inc., dba Maryland Physicians Care (MPC) business standards for site of care redirection for the administration of an outpatient drug that is typically given by a health care provider in an office or other outpatient clinical setting. This policy defines the criteria for mandatory use of outpatient infusion and injection services for participating and non- participating health professionals in unregulated service settings.

POLICY:

MPC considers alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion, or home infusion services, to be well accepted places of service for medication infusion and injection therapy. MPC members are required to utilize alternative sites of care for outpatient drug infusions and injections unless the member meets criteria for receiving infusion or injection services in regulated service settings.

Requests for outpatient infusion and injection services can be made by participating and non-participating health professionals. Each outpatient infusion and injection must be medically necessary, and member must be enrolled on the date of service(s). Clinical rationale and documentation must be provided for review of medical necessity exceptions.

Infusion and Injection Services Administered in Unregulated Space:

- Site of care prior authorization (PA) is not required for infusion services administered in unregulated space by participating health professionals, home infusion service providers and infusion centers contracted to perform infusion services
- Non-participating providers, home infusion service providers and infusion centers must obtain a site of care PA from PA review team prior to rendering services
- Medications will be subject to separate medical necessity review using clinical criteria specific to the medication requested, regardless of site of care

Infusion and Injection Services Administered in Regulated Space:

- Site of care PA is required for infusion services administered in regulated space for all participating and non-participating health professionals and infusion centers
- Medications will be subject to separate medical necessity review using clinical criteria specific to the medication requested, regardless of site of care

PROCEDURE:

Initial Authorization Criteria

Regulated Infusion and Injection Service Settings:
MPC recognizes that outpatient hospital facility-based infusions or injections may not be appropriate for all members. Outpatient hospital setting will be considered medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required):

- The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting;
  OR
- Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening infusion related adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting;
  OR
- Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting);
  OR
- The prescribed medication has a site of care restriction for administration per the FDA-approved label.

Medication Prior Authorization:
Medications will be subject to separate medical necessity review using clinical criteria specific to the medication requested, regardless of site of care.

Reauthorization Criteria

Regulated Infusion and Injection Service Settings:
All prior authorization renewals are reviewed on an annual basis to determine the medical necessity for continuation of therapy.

- Documentation that the individual remains medically inappropriate for administration of the prescribed medication at the alternative sites of care
- All medications will be subject to separate medical necessity review using clinical criteria specific to the medication requested, regardless of site of care

Limitations

Length of Authorization for Regulated Service Settings (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year

Network Access (COMAR Sec. 31.10.44.04. Travel Distance Standards)
This policy takes into consideration the availability of infusion centers within the geographical access standards required by the member's Plan. Below are the maximum travel distance standards for each geographic area. The travel standards below are applicable for the consideration of infusion center services. Home infusion services are available statewide and will not be subject to network access requirements.
- Rural access distance 1:30 miles
- Suburban distance 1:10 miles
- Urban distance 1:5 miles

Applicable Codes
This policy applies to the following specialty medications that require healthcare provider administration. Please note that this list is subject to change and may not be all inclusive

APPLICABLE CODES:	
CODE	**DESCRIPTION**
J1745	Injection, infliximab, excludes biosimilar (Remicade), 10 mg
Q5103	Injection, infliximab-dyyb, biosimilar (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar (Avsola), 10 mg
J3380	Injection, vedolizumab (Entyvio), 1 mg
J2350	Injection, ocrelizumab (Ocrevus), 1 mg
J2351	Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq
J3032	Injection, eptinezumab-jjmr (Vyepti), 1 mg
J2507	Injection, pegloticase (Krystexxa), 1 mg
J1300	Injection, eculizumab (Soliris), 10 mg
J1303	Injection, ravulizumab-cwvz (Ultomiris), 10 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified (Gammagard), 500 mg
J1551	Injection, immune globulin (Cutaquig), 100 mg
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1561	Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1575	Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg immune globulin

J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg

J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified (Panzyga), 500 mg
J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J2323	Injection, natalizumab (Tysabri), 1 mg
J9332	Injection, efgartigimod alfa-fcab (Vyvgart), 2mg
Q5151	Injection, eculizumab-aagh (epysqli), biosimilar, 2mg
Q5152	Injection, eculizumab-aeeb (bkemv), biosimilar, 2mg
J9334	Injection, efgartigimod alfa, 2mg and hyaluronidase-qvfc

LEGAL/CONTRACT REFERENCES:

ATTACHMENTS:

DEFINITIONS:

COMAR: Code of Maryland Regulation

Drug Compendia: MPC's accepted drug information sources which include Food and Drug Administration (FDA) – approved drug monographs and the following medical pharmacy information sources:

- American Medical Hospital Formulary Service – Drug Information
- Drug Facts and Comparisons
- American Medical Association Drug Evaluations
- United States Pharmacopeia – Drug Information
- Clinical Pharmacology

Medically Necessary/Medical Necessity: This term applies to a service, supply or medicine that is appropriate and necessary for the diagnosis or treatment of the medical condition. Medically necessary care meets the standards of good medical practice within the medical community in the service area; is not primarily for the convenience of the plan member or a plan provider; and should consider the most appropriate level or supply of service which can safely be provided.

Member: Person enrolled in the HealthChoice Medicaid Program by the Maryland Department of Health to MPC, a Medicaid managed care organization.

Prior Authorization (PA), Pre-Authorization or Approval: The approval given prior to the health plan's coverage of a prescribed drug. This approval is based on a review and determination that the drug request is medically necessary, correctly indicated as established by the FDA or as accepted by established drug compendia and covered under the member's pharmacy benefit.

Site of Care: Choice for physical location of infusion administration. Sites of Care include hospital inpatient, hospital outpatient, physician office, ambulatory infusion suite, or home-based setting.

REVISION LOG:

REVISION	***DATE***
New Policy	04/01/2023
Removal of Botox products from restriction	05/22/2023
Annual Review	02/2024
Removal of acute therapy medications – antibiotics, IV iron products and Lemtrada	02/2025
Addition of Eculizumab biosimilar products and Vyvgart Hytrulo	06/2025
Annual Review	02/2026
Addition of Ocrevus Zunovo	04/2026

POLICY AND PROCEDURE APPROVAL:

The electronic approval retained in P&P management software is considered equivalent to a signature.