Pharmacy Management Drug Policy

SUBJECT: Site of Care Redirection for Medical Specialty Drug Administration
POLICY NUMBER: PHARMACY-118
EFFECTIVE DATE: 10/2024 (select self-funded)
01/2025 (fully insured-select MP, article-47 and exchange excluding essential plan and basic health plan)
LAST REVIEW DATE: 01/01/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☐ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☐ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

The Site of Care Redirection for Medical Specialty Drug Administration policy applies to select healthcare practitioner administered medications covered under the medical benefit. This policy provides medical necessity criteria for the use of select outpatient hospital-based facilities to ensure members receive the most appropriate, cost-effective level of care. Utilization of non-hospital-based facilities (such as prescriber offices and ambulatory infusion suites) as well as home infusion services have been incorporated into standard medical practice.

Compared to infusions in the hospital outpatient setting, home-based infusions have shown to result in better patient care, better health outcomes, and lower costs. Benefits of home-based infusions may include the following:

- Coordination of drug, supplies, and nurses who will monitor the patient for the entire infusion
- Flexible appointment time in the comfort of the patient's home
- Infusion of medications at a time and place convenient for the patient so a patient's life is not 'on hold' with time away for the infusion
- Clinical support available 24/7- nurses are always available with immediate access to the patient's specific care plan and clinical history
- Limited time off work for infusions
- Decreased travel to infusion center
- Limited need to find childcare during infusions
- Local care, even when traveling for part of the year (i.e., spending the winter months in Florida)
- Covid and Flu exposure risk reduction
- Potential for less expensive copays and coinsurance payments (depending on benefit)

A recent systematic review conducted by Polinski et al. sought to better understand the utility and benefits of home-infusion therapy in terms of quality and safety of home infusion, clinical outcomes, quality of life, and costs and length of stay (compared to administration in a hospital-based setting). The 13 articles considered for inclusion in the analysis included a variety of drugs infused and disease states, including antibiotics, including those used for the treatment of cystic fibrosis, chemotherapy regimens, enzyme replacement, and bisphosphonate use. This review found that patients who received home-based infusion therapy were no more likely to experience adverse drug events or side effects (all $p < 0.05$). These patients were noted to have good or better clinical outcomes compared to those who received hospital-based infusion therapy. Cost savings ranged between $1928 and $2974 per treatment course of home-based therapy, with higher patient satisfaction.

Additionally, many home infusion therapy prescribers operate ambulatory infusion suites as an extension of their home services. These suites are managed and operated by registered nurses and pharmacists that are highly skilled in the provision of infusion and injectable drug administration. In addition to providing specialized care, these suites offer services which help eliminate the stress of getting regular infusions for a chronic disease, such as private or semi-private rooms, snacks, and streaming services. They also often provide weeknight and weekend services which a traditional hospital-based outpatient facility may not be able to offer. Alternative sites of care allow for safe, comfortable, and cost-effective care when the home setting is unavailable or suboptimal for administration of infusion or injectable drugs.

For a full list of drugs subject to the Site of Care Redirection for Medical Specialty Drug Administration policy, please see below HCPCS code list. Drug lists will be updated on a quarterly basis.

POLICY:

The Site of Care Redirection for Medical Specialty Drug Administration policy ensures members receive the most appropriate, cost-effective level of care. Preferred sites of care include select outpatient hospital-based facilities, non-hospital-based facilities (e.g., ambulatory infusion center or physician office) or home infusion when clinically appropriate.

Administration in select outpatient **hospital-based** facilities is considered medically necessary when the following criteria are met:

1. Must meet one or more of the following clinical criteria (a, b, c, d or e):
    a. The requested drug is an immune checkpoint inhibitor (e.g., Imfinzi, Jemperli, Keytruda, Opdivo, Opdualag, Tecentriq, Yervoy) **AND**
        i. Must be under the age of 18 **OR**
        ii. Must be receiving the immune checkpoint inhibitor in combination with any cytotoxic chemotherapy that will be administered at the same visit **OR**
    b. The requested drug is an oncology supportive care agent (Nplate, Xgeva, Fulphila, etc) **AND**
        i. Must be under the age of 18 **OR**
        ii. Must be receiving the requested supportive care drug in combination with any cytotoxic chemotherapy that will be administered at the same visit **OR**
    c. Must be clinically unstable defined as any of the following:
        i. Documented cardiac or pulmonary conditions that may increase the risk of an adverse reaction (e.g., cardiopulmonary disorder or fluid overload)
        ii. Unstable renal function resulting in an inability to safely tolerate IV volume loads
        iii. Physical or cognitive impairments or mental status changes which would result in an unsafe condition for home infusion or non-hospital affiliated outpatient infusion site

iv. The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the alternate Site of Care **OR**

d. Must have previously documented severe or potentially life-threatening adverse reaction or toxicity during or following infusion of the prescribed drug **AND**
   i. The adverse event or toxicity cannot be managed by standard pre-medication, infusion rate reduction or anaphylaxis protocols in the home or physician-based setting (e.g., 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, conduction abnormalities) **OR**

e. Must have determination from a home infusion prescriber that the member's home is not eligible for home-based infusion therapy **AND**
   a) The prescriber is unable to infuse in the office setting **AND**
   b) There are no low-cost facility or ambulatory infusion suite options available for the member within the distance that they are traveling to their current facility **AND**

f. Approval time frame will be determined based on the drug specific prior authorization policy for the requested drug (i.e., if a 1-year approval is granted for the requested drug based on the medical necessity criteria for that drug, then approval for administration in the requested outpatient hospital-based facility will also be 1 year) **OR**

2. Must be new to therapy or reinitiating after not being on therapy for at least 6 months **AND**
   a. Approval time frame will be 3 months **OR**
   b. Approval time frame will be 6 months for the following drugs:
   Aldurazyme, Cerezyme, Elaprase, Elelyso, Fabrazyme, Kanuma, Lamzede, Lumizyme, Mepsevii, Naglazyme, Nexviazyme, Vpriv, Vimizim, Xenpozyme

POLICY GUIDELINES:

1. Administration in all other sites of care (i.e., physician's office, ambulatory infusion center, home, or other outpatient facilities not included above) is considered medically necessary and approval time frame will be determined based on the drug specific prior authorization policy for the requested drug.
2. Continued approval at time of recertification will require documentation that the member continues to meet the requirements for administration in select outpatient hospital-based facilities specified in the above policy.
3. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., prescriber attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the product.
4. For all medical necessity exception requests, clinical rationale and documentation must be provided for review.
5. This guideline is ONLY for determination of the medical necessity of administration at select outpatient hospital-based facilities. The medical necessity of the requested drug may be separately reviewed against the appropriate criteria. Please reference the Clinical Review Prior Authorization policy and drug specific policies for additional requirements which are part of the prior authorization criteria.
   Utilization Management is contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs subject to this policy is contract dependent. Refer to specific contract/benefit language for exclusions.

6. Not all contracts cover all Medical Infusible or Injectable drugs. Refer to specific contract/benefit plan language for exclusions of Infusible or Injectable Medications.
7. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
8. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
9. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key:
Experimental/Investigational = (E/I),
Not medically necessary/ appropriate = (NMN).

HCPCS:

J3262 - **Actemra**
J0791 - **Adakveo**
J1931 - **Aldurazyme**
J7173 - **Alhemo**
J1599 - **Alyglo**
J0225 - **Amvuttra**
J0256 - **Aralast NP**
J1554 - **Asceniv**
Q5156 - **Avtozma**
J0490 - **Benlysta**
J1556 - **Bivigam**
Q5152 - **Bkemv**
Q5158 - **Bomyntra**
J1786 - **Cerezyme**
J0717 - **Cimzia**
J0598 - **Cinryze**
J3247 - **Cosentyx IV**

J0584 - **Crysvita**
J1551 - **Cutaquig**
J1555 - **Cuvitru**
J1743 - **Elaprase**
J3060 - **Elelyso**
J2508 - **Elfabrio**
J3380 - **Entyvio**
J1325 - **Epoprostenol**
Q5151 - **Epysqli**
J3111 - **Evenity**
J0180 - **Fabrazyme**
J0517 - **Fasenra**
J1572 - **Flebogamma**
J1325 - **Flolan (epoprostenol)**
Q5108 - **Fulphila**
J1569 - **Gammagard Liquid**
J1566 - **Gammagard S-D**
J1557 - **Gammaplex**
J1561 - **Gammaked**
J1561 - **Gamunex-C**
J0223 - **Givlaari**
J0257 - **Glassia**
J1447 - **Granix**
J7170 - **Hemlibra**
J1559 - **Hizentra**
J7172 - **Hympavzi**
J1575 - **Hyqvia**
J0638 - **Ilaris**
J3245 - **Ilumya**
J9256 - **Imaavy**
J9173 - **Imfinzi**
Q5098 - **Imuldosa PFS**
J1745 - **Infliximab**
J9272 - **Jemperli**
J2840 - **Kanuma**
J9271 - **Keytruda**
J2507 - **Krystexxa**
J0217 - **Lamzede**
J3263 - **Loqtorzi**
J0221 - **Lumizyme**
J3397 - **Mepsevii**
J1458 - **Naglazyme**
J1442 - **Neupogen**
J0219 - **Nexviazyme**
J9038 - **Niktimvo**
Q5110 - **Nivestym**
J2802 - **Nplate**
J2182 - **Nucala**
Q5122 - **Nyvepria**
J2350 - **Ocrevus**

J2351 - **Ocrevus Zunovo**
J1568 - **Octagam**
J0222 - **Onpattro**
J9299 - **Opdivo**
J9289 - **Opdivo Qvantig**
J9298 - **Opdualag**
J0129 - **Orencia**
Q5157 - **Osenvelt**
Q9999 - **Otulfi**
J1576 - **Panzyga**
J1307 - **PiaSky**
J1459 - **Privigen**
J0256 - **Prolastin-C**
Q9997 - **Pyzchiva**
Q9996 - **Pyzchiva autoinjector**
J1745 - **Remicade**
J3285 - **Remodulin**
Q5104 - **Renflexis**
J9333 - **Rystiggo**
J0870 - **Rytelo**
J9361 - **Ryzneuta**
J2353 - **Sandostatin LAR(R) Depot**
J0491 - **Saphnelo**
Q9998 - **Selarsdi**
J1602 - **Simponi Aria**
J1299 - **Soliris**
J3357 - **Stelara**
Q5099 - **Steqeyma**
J9022 - **Tecentriq**
J9024 - **Tecentriq Hybreza**
J3241 - **Tepezza**
J9329 - **Tevimbra**
J2356 - **Tezspire**
Q5133 - **Tofidence**
J3285 - **Treprostinil**
Q5135 - **Tyenne**
J1303 - **Ultomiris**
J1823 - **Uplizna**
J3357 - **ustekinumab**
Q9998 - **ustekinumab-aekn**
Q9996 - **ustekinumab-ttwe**
J1325 - **Veletri**
J1322 - **Vimizim**
J3385 - **Vpriv**
J3032 - **Vyepti**
J9332 - **Vyvgart**
J9334 - **Vyvgart Hytrulo**
Q5137 - **Wezlana**
Q5136 - **Wyost**
J1558 - **Xembify**

J0218 - **Xenpozyme**
J0897 - **Xgeva**
J2357 - **Xolair**
J9228 - **Yervoy**
Q5100 - **Yesintek**
J0256 - **Zemaira**
Q5120 - **Ziextenzo**

UPDATES:

Date	Revision
01/01/2026	Revised
11/19/2025	Revised
09/23/2025	Revised
07/31/2025	Revised
07/01/2025	Revised
05/21/2025	Revised
05/08/2025	Reviewed / P&T Committee Approved
04/01/2025	Revised
03/06/2025	Revised
02/01/2025	Revised
01/01/2025	Revised
09/30/2024	Revised
09/13/2024	Revised
07/12/2024	Revised
06/20/2024	Revised
05/09/2024	Policy Implemented
05/09/2024	P&T Committee Approval

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6. Walgreens Medical Benefit Drug Management – Excellus Site of Care Program 6/19/2017. Walgreens, Option Care Presentation
7. Rigas M, Tandan R, Sterling RJ. Safety of liquid intravenous immunoglobulin for neuroimmunologic disorders in the home setting: a retrospective analysis of 1085 infusions. *Journal of clinical neuromuscular disease.* Dec 2008;10(2):52-55.