

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: 03/06/2025

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:	<input checked="" type="checkbox"/> Commercial Group (e.g., EPO, HMO, POS, PPO)	<input type="checkbox"/> Medicare Advantage
	<input checked="" type="checkbox"/> On Exchange Qualified Health Plans (QHP)	<input type="checkbox"/> Medicare Part D
	<input checked="" type="checkbox"/> Off Exchange Direct Pay	<input type="checkbox"/> Essential Plan (EP)
	<input type="checkbox"/> Medicaid & Health and Recovery Plans (MMC/HARP)	<input type="checkbox"/> Child Health Plus (CHP)
	<input type="checkbox"/> Federal Employee Program (FEP)	<input type="checkbox"/> Ancillary Services
	<input type="checkbox"/> 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 that members receive the most appropriate, cost-effective level of care. Utilization of non-hospital-based facilities (such as physician offices and ambulatory infusion suites) as well as home infusion services has 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)

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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 providers 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 that 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 that a traditional hospital-based outpatient facility may not be able to offer. Alternative sites of care such these 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 that 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 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, Eleyso, Fabrazyme, Kanuma, Lumizyme, Mepsevii, Naglazyme, Nexviazyme, Vpriv, Vimizim, Xenpozyme **OR**
2. Must be an existing user of the requested drug and meet one or more of the following clinical criteria:
 - a. For members receiving an immune checkpoint inhibitor (e.g., Imfinzi, Jemperli, Keytruda, Opdivo, Opdualag, Tecentriq, Yervoy):
 - i. Must be under the age of 18 **OR**
 - ii. Must be receiving in combination (administered at the same visit) with any cytotoxic chemotherapy (e.g., Keytruda in combination with pemetrexed for NSCLC) **OR**
 - b. 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

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- 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**
- c. 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**
- d. Must have determination from a home infusion provider that the member's home is not eligible for home-based infusion therapy **AND**
 - i. The prescriber is unable to infuse in the office setting **AND**
 - ii. 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**
- e. 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).

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., provider 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. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website

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at <https://www.cms.gov/medicare-coverage-database/search.aspx>. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.

9. 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.

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).

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HCPCS:

J3262	-	Actemra
J0791	-	Adakveo
J1931	-	Aldurazyme
J1599	-	Alyglo
J0225	-	Amvuttra
J0256	-	Aralast NP
J1554	-	Asceniv
J0490	-	Benlysta
J1556	-	Bivigam
J1786	-	Cerezyme
J0717	-	Cimzia
J0598	-	Cinryze
J0584	-	Crysvita
J1551	-	Cutaquig
J1555	-	Cuvitru
J1743	-	Elaprase
J3060	-	Elelyso
J2508	-	Elfabrio
J3380	-	Entyvio
J1325	-	Epoprostenol
J3111	-	Evenity
J0180	-	Fabrazyme
J0517	-	Fasenra
J1572	-	Flebogamma

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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
J1575	-	Hyqvia
J0638	-	Ilaris
J3245	-	Ilumya
J9173	-	Imfinzi
J1745	-	Infliximab
J9272	-	Jemperli
J2840	-	Kanuma
J9271	-	Keytruda
J2507	-	Krystexxa
J0221	-	Lumizyme
J3397	-	Mepsevii
J1458	-	Naglazyme
J1442	-	Neupogen
J0219	-	Nexviazyme
Q5110	-	Nivestym
J2802	-	Nplate
J2182	-	Nucala
Q5122	-	Nyvepria
J2350	-	Ocrevus
J1568	-	Octagam
J0222	-	Onpattro
J9299	-	Opdivo
J9298	-	Opdualag
J0129	-	Orencia
J1576	-	Panzyga
J1459	-	Privigen
J0256	-	Prolastin-C
J1745	-	Remicade
J3285	-	Remodulin
Q5104	-	Renflexis
J2353	-	Sandostatin LAR(R) Depot
J0491	-	Saphnelo
J1602	-	Simponi Aria
J1300	-	Soliris
J3357	-	Stelara
J9022	-	Tecentriq
J3241	-	Tepezza
J2356	-	Tezspire

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J3285	-	Treprostinil
J1303	-	Ultomiris
J1823	-	Uplizna
J1325	-	Veletri
Q4074	-	Ventavis
J1322	-	Vimizim
J3385	-	Vpriv
J3032	-	Vyepti
J9332	-	Vyvgart
J9334	-	Vyvgart Hytrulo
J1558	-	Xembify
J0218	-	Xenpozyme
J0897	-	Xgeva
J2357	-	Xolair
J9228	-	Yervoy
J0256	-	Zemaira
Q5120	-	Ziextenzo

UPDATES:

Date	Revision
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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5. Smith S, Curry, K, Rout T, et al. Adverse drug events in infliximab patients infused in the home care setting: a retrospective chart review. Poster presented at the National Home Infusion Association Annual Conference and Exhibition; 2016 March 21-24; New Orleans, La.
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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.