Medical Policy:

Site Of Service Medical Policy – Infusions and Injectables

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.350	March 6, 2024	August 1, 2022

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

This Site of Service policy for infusions and injectable drugs applies to drugs that are in scope for preauthorization. The following preauthorization lists have indicators showing whether a listed drug is covered by this medical policy:

- **ConnectiCare**
- **EmblemHealth**

I. Description

This policy describes coverage criteria outlining principles used to direct administration of select medical drug infusions and injectables to the most cost-effective and clinically-appropriate location, where applicable. The site of care medical policy drug list is subject to change without prior notice.

*A request for administration at an outpatient hospital setting where criteria under the policy are not met, initial coverage for the administration of the requested drug at a non-preferred site of service will be allowed for a one-time 30-day approval period to facilitate transition to a plan-preferred site of care (home infusion, Ambulatory Infusion Suite (non-hospital based), or a prescriber's office in a non-hospital setting)

II. Position Statement

Starting August 1, 2022, the Site of Service Medical Policy will be effect, as follows:

1. Criteria outlined in this policy apply to Commercial and Exchange plan membership.

2. Site of Service codes and definitions[1]:

   - **Preferred place of service codes:**
     - Home (Code 12):
       - Location, other than a hospital or other facility, where the patient receives care in a private residence.
     - Office (Code 11):
       - Includes Ambulatory Infusion Suite (AIS)
       - Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
   - **Non-preferred site of service codes:**
     - Off Campus-Outpatient Hospital (Code 19):
       - A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
     - On Campus-Outpatient Hospital (Code 22):
       - A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

3. Members receiving the listed medications outlined in **III. Policy Criteria** will be subject to the program requirements as described in this policy:

   - Current utilizers: upon prior authorization coverage renewal **OR** within 3 months from policy effective date.
   - New utilizers: on or after March 1, 2021.

III. Policy Criteria

1. All medications in the Site of Service program (called out on our Preauthorization lists) require prior authorization (PA).

2. Preferred site of Service:
   - After the drug-specific PA requirements have been met, EmblemHealth's preferred vendors will coordinate the services for medication administration at a **preferred site of service** (as listed under **II. Position Statement**).

3. Non-Preferred Site of Service:

   - In cases where the patient requires drug administration at a **non-preferred site of service** (as listed under **II. Position Statement**), coverage may be granted when the following criteria are met:

     - Medication-specific prior authorization criteria have been met; **AND**

     - Clinical rationale and complete supportive documentation have been provided to show ONE of the following criteria have been met:

       - Patient is initiating the requested drug therapy; **OR**

       - Patient is re-initiating the requested drug therapy after a 6-month lapse in treatment

         - Re-initiating after a shorter treatment lapse will be considered if another loading protocol is warranted and medically necessary (in accordance with FDA-approved prescribing information and most current disease state guidelines)**; OR**

       - Patient's medical history and medical status OR intended therapy require enhanced monitoring (e.g. telemetry) and services that cannot be provided in the preferred site of service; **OR**

       - Patient's condition is unstable and may potentially require emergency services, therefore the preferred administration sites are not appropriate; **OR**

       - History of a severe drug reaction (e.g. anaphylactic reaction) or significant intolerance to the requested medication or any of its constituents has been documented; **OR**

       - History of a cardiac condition (e.g. symptomatic cardiac arrhythmia), pulmonary condition (e.g. significant respiratory disease, serious obstructive airway disease, %FVC ≤ 40%), fluid overload, or other condition that may increase the risk of an adverse reaction has been documented; **OR**

       - Unstable organ function (e.g. renal, etc.) may be a significant barrier to a preferred site of care administration; **OR**

       - Patient's vascular access is difficult to establish or is unstable; **OR**

       - Patient's physical, cognitive, or mental status is expected to potentially impact the safety of therapy administration at a preferred site of service; **OR**

- Patient's home environment is unstable or not conducive to receiving therapy AND patient is not an appropriate candidate for office or AIS administration (supportive documentation required); **OR**

- Other patient-specific factor(s) deem utilizing the preferred sites of service not suitable or advisable (documentation required; requests will be reviewed on a case-by-case basis).

- Patient is receiving the requested medication in combination with and at the time of administration of their chemotherapy regimen.

IV. Quantity Limitations and Coverage Duration

1. When criteria under **the policy** are not met, initial coverage for the administration of the requested drug at a non-preferred site of service will be allowed for a one-time 30-day approval period to facilitate transition to a plan-preferred site of care; **AND**

2. All subsequent doses will be administered at a plan-preferred site of service (home infusion, Ambulatory Infusion Suite (non-hospital based), or a prescriber's office in a non-hospital setting, coordinated by EmblemHealth's preferred vendors.

NOTE: There is NO dosage limitation OR max coverage duration for patients receiving the requested medication in combination with their chemotherapy regimen

V. Non-preferred Site of Service Coverage Renewal

1. Once the approved number of doses per medication have been exhausted OR the 6-month coverage approval period for administration at a non-preferred site of service has passed:

    - Each request will be reviewed for a non-preferred location coverage continuation on a case-by-case basis to reassess the patient's appropriateness to receive the requested medication's administration at a preferred site of service; **AND**

    - Initial criteria stated under **Policy Criteria** will apply.

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	03/06/2024	Changed the age restriction, expanded drug list, removed the max number of doses and exclusion criteria from medication grid. Added across the board a 30-day auth for all meds given in a non-preferred site of care.
EmblemHealth & ConnectiCare	08/24/2022	Added NOTE: There is NO dosage limitation OR max coverage duration for patients receiving the requested medication in combination with their chemotherapy regimen and Criteria: Patient is receiving the

		requested medication in combination with and at the time of administration of their chemotherapy regimen
EmblemHealth & ConnectiCare	04/26/2022	Transferred policy to new template ** Policy Effective 8/1/2022
EmblemHealth & ConnectiCare	03/01/2021	New Policy approved per P&T 2/2/2021

References

1. Centers for Medicare and Medicaid Services (CMS), Place of Service Code Set. Available at: https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set
2. Centers for Medicare and Medicaid Services (CMS), Medicare Claims Processing Manual. Chapter 12 §20.4.2. Available at: http://www.cms.gov/manuals/downloads/clm104c12.pdf