

## Medical Policy:

### SITE OF SERVICE MEDICAL POLICY – Infusions and Injectables

POLICY NUMBER	LAST REVIEW	POLICY ORIGINAL EFFECTIVE DATE
MG.MM.PH.350	August 24, 2022	August 1, 2022

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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.

#### **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.

#### **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<sup>1</sup>:

- **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** on or after March 1, 2021.
- New utilizers: on or after March 1, 2021.

**III. Policy Criteria**

1. All medications in the Site of Service program (listed in Table 1) 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 as listed in Table 1 OR in up to 6-month intervals, 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 is 21 years of age or younger; **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  $\leq$  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 **III. Policy Criteria** are met, initial coverage for the administration of the requested drug at a non-preferred site of service will be allowed in accordance with the medication-specific exception stated in Table 1, not to exceed a maximum of 6 months per approval; **AND**
2. All subsequent doses will be administered at a plan-preferred site of service (home infusion, AIS, 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 (stated in **Table 1**) 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 **III. Policy Criteria** will apply.

**When the stated exception criteria under III. Policy Criteria are not met, continued coverage of the requested medication will be denied after the allowed medication trial at a non-preferred site of service has been completed.**

#### Table 1. Medications included in the Site of Service Program\*

Please note: If the patient has already utilized the maximum number of doses allowed at a non-preferred site at the beginning of therapy (as stated in **Table 1**), administration will be expected to continue at a plan-preferred Site of Service, unless policy criteria under **III. Policy Criteria** are met.

(Continued)

J-Code Q-Code	Medication	<u>For NEW Start of Therapy:</u> Maximum Number of Doses Allowed at Non- Preferred Site per Coverage Approval**	<u>Accepted Medication-Specific Exclusions Allowing a 6-Month Coverage Approval</u>	Additional Notes
<b>Filgrastim Agents</b>				
J1447	Granix	Up to 2 doses	Acute Respiratory Distress Syndrome (ARDS), suspected aortitis, capillary leak syndrome, sickle cell crisis, allergic reactions including anaphylaxis.	
J2820	Leukine	Up to 2 doses	History of allergic reactions to human granulocyte-macrophage colony stimulating factor such as sargramostim, yeast-derived products, or any component of the product; serious infusion-related reaction; effusions and capillary leak syndrome; history of cardiac arrhythmias.	
J1442	Neupogen	Up to 2 doses	History of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim; suspected aortitis; splenic rupture; acute respiratory distress syndrome (ARDS); capillary leak syndrome (CLS), sickle cell crisis.	
Q5110	Nivestym	Up to 2 doses	History of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim; suspected aortitis; splenic rupture; acute respiratory distress syndrome (ARDS); capillary leak syndrome (CLS), sickle cell crisis.	
Q5105	Zarxio	Up to 2 doses	History of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim; suspected aortitis; splenic rupture; acute respiratory distress syndrome (ARDS); capillary leak syndrome (CLS), sickle cell crisis.	
<b>Pegfilgrastim Agents</b>				
Q5108	Fulphila	Up to 2 doses	History of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim; suspected aortitis; splenic rupture; acute respiratory distress syndrome (ARDS); capillary leak syndrome (CLS), sickle cell crisis.	

J2505	Neulasta NDC 55513-190-01 (please see Additional Notes)		History of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim; suspected aortitis; splenic rupture; acute respiratory distress syndrome (ARDS); capillary leak syndrome (CLS), sickle cell crisis.	<u>Note:</u> Policy does not apply to Neulasta Onpro® kit NDC 55513-192-01
Q5122	Nyvepria	Up to 2 doses	History of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim; suspected aortitis; splenic rupture; acute respiratory distress syndrome (ARDS); capillary leak syndrome (CLS), sickle cell crisis.	
Q5111	Udenyca	Up to 2 doses	History of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim; suspected aortitis; splenic rupture; acute respiratory distress syndrome (ARDS); capillary leak syndrome (CLS), sickle cell crisis.	
Q5120	Ziextenzo	Up to 2 doses	History of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim; suspected aortitis; splenic rupture; acute respiratory distress syndrome (ARDS); capillary leak syndrome (CLS), sickle cell crisis.	
<b>Erythropoiesis-Stimulating Agents (Non-Dialysis)</b>				
J0881	Aranesp	Up to 2 doses	History of allergic reactions to ESA; uncontrolled hypertension; history of seizures; history of cutaneous reactions (including Erythema multiforme and Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN]).	
J0885	Epogen Procrit	Up to 2 doses	History of allergic reactions to ESA; uncontrolled hypertension; history of seizures; history of cutaneous reactions (including Erythema multiforme and Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN]).	
Q5106	Retacrit	Up to 2 doses	History of allergic reactions to ESA; uncontrolled hypertension; history of seizures; history of cutaneous reactions (including Erythema multiforme and Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN]).	

<b>C5 Complement Inhibitors</b>				
J1300	Soliris	Up to 5 doses	Infusion reaction, including anaphylaxis or other hypersensitivity reactions (e.g. cardiovascular instability, respiratory compromise, etc).	<u>Note:</u> Additional supplemental doses may be allowed in the setting of concomitant plasmapheresis or plasma exchange, or fresh frozen plasma infusion, as needed.
J1303	Ultomiris	Up to 3 doses	Anaphylaxis or other hypersensitivity reactions (e.g. cardiovascular instability, respiratory compromise, etc).	
<b>Immunomodulating Agents</b>				
J3262	Actemra	Up to 3 doses	Known hypersensitivity, including anaphylaxis, associated with Actemra.	
J0717	Cimzia	Up to 3 doses	Serious hypersensitivity reaction to Cimzia or to any of the excipients (including angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, urticaria).	
J3380	Entyvio	Up to 3 doses	Known serious hypersensitivity reaction to Entyvio or any of its excipients (including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate).	
J0638	Ilaris	Up to 2 doses	Confirmed hypersensitivity to the active substance in Ilaris or to any of the excipients.	
J3245	Ilumya	Up to 3 doses	Hypersensitivity, including angioedema and urticaria.	
Q5121	Avsola	Up to 3 doses	Hypersensitivity reaction to infliximab or any inactive ingredients of the product or to any murine proteins; anaphylaxis, urticaria, dyspnea, hypotension; serum sickness-like reactions; cardiovascular and cerebrovascular reactions during and after infusion; transient visual loss during or after infusion.	
Q5103	Inflectra			
J1745	Remicade			
Q5104	Renflexis			
J0129	Orencia	Up to 3 doses	Hypersensitivity reactions, including anaphylaxis, hypotension, urticaria, dyspnea.	
J9312	Rituxan (please see Additional Notes)	Up to 3 doses	Hypersensitivity reactions, including anaphylaxis, urticaria, hypotension, angioedema, hypoxia, bronchospasm, pulmonary infiltrates, acute respiratory distress syndrome, myocardial infarction, ventricular fibrillation,	<u>Note:</u> This policy applies to non-oncology indications only.
Q5115	Truxima (please see Additional Notes)			

n/a	Riabni (please see Additional Notes)		cardiogenic shock, anaphylactoid events; severe mucocutaneous reactions (Stephen-Johnson syndrome, lichenoid dermatitis, etc).	
Q5119	Ruxience (please see Additional Notes)			
J1602	Simponi ARIA	Up to 3 doses	Hypersensitivity reactions, including anaphylaxis, hives, pruritus, dyspnea, and nausea.	
<b>Other Immunomodulating Agents</b>				
J0517	Benlysta	Up to 4 doses	Hypersensitivity reaction (including anaphylaxis, angioedema, hypotension, urticaria or other rash, pruritus, dyspnea).	
<b>Transplant</b>				
J0485	Nulojix	Up to 6 doses	Infusion-related reactions (e.g. hypotension, hypertension); anaphylaxis or other hypersensitivity reactions.	
<b>Fabry Disease Agent</b>				
J0180	Fabrazyme	Up to 6 doses	Documented advanced Fabry disease, compromised cardiac function, anaphylaxis, allergic reactions, infusion reactions.	
<b>Gaucher Disease Agents</b>				
J1786	Cerezyme	Up to 4 doses	Hypersensitivity reactions including anaphylaxis; history of or suspected pulmonary hypertension or pneumonia.	Appropriate medical support and emergency medical services should be readily available.
J3060	Elelyso	Up to 4 doses	Hypersensitivity reactions including anaphylaxis.	
J3385	Vpriv	Up to 4 doses	Hypersensitivity reactions including anaphylaxis.	
<b>Agents Affecting Bone Structure and Mineralization</b>				
J3489	Reclast	1 dose for new start therapy	Hypersensitivity reactions including anaphylaxis, urticaria and angioedema.	<b><u>For Reclast, Zoledronic Acid 5 mg, and Prolia NEW starts:</u></b> One dose will be permitted at non-preferred facility of choice, when criteria are met.
	Zoledronic acid 5 mg			
	Zoledronic Acid 4 mg	Up to 4 doses for new start therapy		
J0897	Prolia	1 dose for new start therapy	Hypersensitivity reactions including anaphylaxis, rash, urticaria, facial swelling, and erythema.	
	Xgeva	Up to 4 doses for new start therapy		
<b>Ophthalmic Conditions Agents</b>				
J3241	Tepezza	Up to 2 doses	Severe infusion-related reactions.	



<b>Alpha-1-Proteinase Inhibitors (A1-PI)</b>				
J0256	Aralast	Up to 3 doses	IgA deficient patients with antibodies against IgA (may lead to severe hypersensitivity and anaphylactic reactions); history of a serious infusion-related reaction, anaphylaxis or other severe systemic reaction to Alpha1-PI.	
	Prolastin C	Up to 3 doses		
	Zemaira	Up to 3 doses		
J0257	Glassia	Up to 3 doses		
<b>Somatostatin and analogs</b>				
J2353	Sandostatin LAR	Up to 2 doses		
J2502	Signifor LAR	Up to 2 doses		
J1930	Somatuline Depot	Up to 2 doses	Hypersensitivity to lanreotide (including allergic reactions: angioedema and anaphylaxis).	
<b>Immunotherapies for Reactive and Obstructive Airway Diseases</b>				
J2786	Cinqair	Up to 3 doses	Known hypersensitivity to Cinqair or any of its excipients.	
J0517	Fasenra	Up to 3 doses	Known hypersensitivity to Fasenra or any of its excipients; hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash).	
J2182	Nucala	Up to 3 doses	Known hypersensitivity to Fasenra or any of its excipients; hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash).	
<b>Intravenous Immune Globulins</b>				
J1599	Asceniv	Up to 2 doses	History of anaphylactic or severe systemic reactions to the product or its excipients; IgA-deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions; Transfusion-Related Acute Lung Injury (TRALI).	
J1556	Bivigam	Up to 2 doses		
J1566	Carimune NF	Up to 2 doses		
J1572	Flebogamma	Up to 2 doses		
J1561	Gamunex-C	Up to 2 doses		
J1569	Gammagard Liquid	Up to 2 doses		
J1566	Gammagard S/D	Up to 2 doses		
J1561	Gammaked	Up to 2 doses		
J1557	Gammaplex	Up to 2 doses		
J1568	Octagam	Up to 2 doses	History of anaphylactic or severe systemic reactions to the product or its excipients; IgA-deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions; Transfusion-Related Acute	

			Lung Injury (TRALI); acute hypersensitivity reaction to corn.	
J1459	Privigen	Up to 2 doses	History of anaphylactic or severe systemic reactions to the product or its excipients; IgA-deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions; Transfusion-Related Acute Lung Injury (TRALI).	
J1599	Panzyga	Up to 2 doses		
	Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), not otherwise specified	Up to 2 doses		
<b>Subcutaneous Immune Globulins</b>				
J1555	Cuvitru	Up to 2 doses	History of anaphylactic or severe systemic hypersensitivity reactions to the product or its constituents; serious infusion reactions; IgA-deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions; Transfusion-Related Acute Lung Injury (TRALI).	
J1569	Gammagard Liquid			
J1561	Gammaked			
	Gamunex-C			
J1559	Hizentra			
J1575	Hyqvia			
J1558	Xembify			
<b>Multiple Sclerosis</b>				
J2350	Ocrevus	Up to 3 doses	Hypersensitivity, infusion reactions which can include pruritus, rash, urticaria, erythema, bronchospasm, throat irritation, oropharyngeal pain, dyspnea, pharyngeal or laryngeal edema, flushing, hypotension, pyrexia, fatigue, headache, dizziness, nausea, tachycardia, anaphylaxis.	
J2323	Tysabri	Up to 3 doses	Hypersensitivity reactions: Serious hypersensitivity reactions that may include, anaphylaxis, urticaria, dizziness, fever, rash, rigors, pruritus, nausea, flushing, hypotension, dyspnea, chest pain.	

*\* Subject to change.*

**\*\*Table 1 dosing refers to schedules stated in FDA-approved prescribing information; other sufficiently-supported dosing will be reviewed on a case-by-case basis.**

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/24/2022	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	4/26/2022	Transferred policy to new template ** Policy Effective 8/1/2022
EmblemHealth & ConnectiCare	3/1/2021	New Policy approved per P&T 2/2/2021

## References

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- Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; April 2019.
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- Ellelyso (taliglucerase alfa) [prescribing information]. New York, NY: Pfizer Labs; November 2020.
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- Epogen (epoetin alfa) [prescribing information]. Thousand oaks, CA: Amgen; July 2018.
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- Flebogamma 5% DIF (immune globulin intravenous [human]) [prescribing information]. Barcelona, Spain: Instituto Grifols, SA; September 2019.
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- Gammagard Liquid (immune globulin intravenous and subcutaneous [human]) [prescribing information]. Lexington, MA: Baxalta US Inc; November 2020.
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48. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; March 2020.
49. Retacrit (epoetin alfa-epbx) [prescribing information]. Lake Forest, IL: Hospira, Inc; September 2020.
50. Sandostatin LAR Depot (octreotide injection suspension) [prescribing information]. East Hanover, NJ: Novartis; April 2019.
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