



# **Site of Service Policy**

Date of Origin: 1/1/2019

Updated: 3/26/20,6/30/20,11/2/20,6/1/22,1/1/24,5/23/2024, 10/29/2024, 3/17/2025

### I. Background

The Site of Service program, effective January 1, 2019, directs members to the most cost-effective, clinically appropriate location to receive their infusion(s) of select specialty medications as listed in this policy.

#### II. Scope

- A. Applicable to Commercial and Individual Family/Business membership\*
  - 1. New utilizers of these medications on or after January 1, 2019 will be subject to the program requirements.
  - 2. Members currently using these medications will be subject to the program requirements upon prior authorization renewal on or after January 1, 2019.

\*Requests for specialty drugs listed in section IV for members residing in MN and ND will be offered lower cost alternative site of care after prior authorization approval but are exempt from program requirements.

#### **III. Program Requirements**

- A. The Site of Service program will be administered as part of the existing prior authorization program.
  - 1. To submit a prior authorization request, visit gatewayPA.com and select "Providers and Physicians."
  - 2. If this is your first time requesting a prior authorization through the Prime Therapeutics self-service portal, visit gatewayPA.com and select "New Access Request-Provider" on the right side of the home page.
  - 3. All drugs in the Site of Service program require prior authorization.





- B. Requests for select specialty drugs as listed in section IV to be administered in a hospital outpatient setting will be directed to a preferred alternative site of care, such as a home infusion provider or a physician office. Infusions for these medications are excluded from payment when administered in a hospital outpatient infusion center.
- C. To prevent a delay in care and allow adequate transition time for Medica members to an alternate infusion site, Site of Service program requirements will be waived for 60-90 days, depending upon the specific drug, after prior authorization approval so that members can transition to a different infusion site.

#### **IV. Drugs in Scope**

- A. Select infused specialty medications included in the Site of Service program are subject to change.
- B. Changes to the Drugs in Scope

1. If currently available infused specialty medications are added to the Site of Service program medication list, prescribers will receive advanced notification per the terms of the provider contract with Medica.

HCPCS	Brand Name	Generic Name
J3262	ACTEMRA	tocilizumab
J1931	ALDURAZYME	laronidase
Q5121	AVSOLA	infliximab-axxq
J0490	BENLYSTA	belimumab
J0597	BERINERT	C1 esterase inhibitor
J1556	BIVIGAM	intravenous immune globulin
J2329	BRIUMVI	ublituximab-xiiy
J1786	CEREZYME	imiglucerase
J0717	CIMZIA	certolizumab pegol
J2786	CINQAIR	reslizumab
J0598	CINRYZE	C1 esterase inhibitor
J7318	CRYSVITA	burosumab
J1743	ELAPRASE	idursulfase
J3060	ELELYSO	taliglucerase alfa
J3380	ENTYVIO	vedolizumab
J1428	EXONDYS 51	eteplirsen
J0180	FABRAZYME	agalsidase beta





HCPCS	Brand Name	Generic Name
J1744	FIRAZYR	icatibant
J1572	FLEBOGAMMA	intravenous immune globulin
J1569	GAMMAGARD	intravenous immune globulin
J1566	GAMMAGARD S/D	intravenous immune globulin
J1557	GAMMAPLEX	intravenous immune globulin
J1561	GAMUNEX	intravenous immune globulin
Q5103	INFLECTRA	infliximab-dyyb
J1290	KALBITOR	ecallantide
J2840	KANUMA	sebelipase alfa
J2507	KRYSTEXXA	pegloticase
J0202	LEMTRADA	alemtuzumab
J0221	LUMIZYME	alglucosidase alfa
J3397	MEPSEVII	vestronidase alfa-vjbk
J1458	NAGLAZYME	galsulfase
J2182	NUCALA	mepolizumab
J2350	OCREVUS	ocrelizumab
J2351	OCREVUS ZUNOVO	ocrelizumab and hyaluronidase-ocsq
J1568	OCTAGAM	intravenous immune globulin
J0129	ORENCIA	abatacept
J1459	PRIVIGEN	intravenous immune globulin
J1301	RADICAVA	edaravone
J1745	REMICADE	infliximab
Q5104	RENFLEXIS	Infliximab-abda
J0596	RUCONEST	c1 esterase inhibitor recombinant
J1602	SIMPONI ARIA	golimumab
J1300	SOLIRIS	eculizumab
J3357	STELARA	ustekinumab
J1746	TROGARZO	ibalizumab-uiyk
J2323	TYSABRI	natalizumab
J1303	ULTOMIRIS	ravulizumab
J1322	VIMIZIM	elosulfase alfa
J3385	VPRIV	velaglucerase alfa
J2357	XOLAIR	omalizumab





## **V. Exceptions**

- A. Exceptions to the Site of Service program requirements are reviewed through the prior authorization process and may be granted on a case-by-case basis based on medical necessity.
- B. The administration of the infusion and injectable therapy referenced in this policy in a hospital outpatient setting is not considered medically necessary unless the below criteria are met:
  - 1. Hospital outpatient administration of infusion or injectable therapy is considered medically necessary for up to a 60-90-day period for members beginning a new treatment OR initial review of continuation of therapy.
  - 2. An outpatient infusion or injectable therapy service in a hospital outpatient setting is considered medically necessary for the applicable validity period when any of the following are present:
    - 1. Potential changes in the member's clinical condition are such that immediate access to specific services of a hospital setting, having emergency resuscitation equipment and personnel, and inpatient admission or intensive care is necessary. For example, the member is at significant risk of sudden life-threatening changes in medical status based on clinical conditions including but not limited to:
      - a. Intolerable fluid overload, including impaired or unstable renal function, or
      - b. History of anaphylaxis to prior infusion therapy with a related pharmacologic or biologic agent despite standard premedication, or
      - c. Acute mental status/cognitive changes or physical impairment AND no home caregiver available; or
      - d. Vascular access not stable; or
      - e. Documented clinical history of cardiopulmonary conditions that may cause an increased risk of severe adverse reactions (including but not limited to thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress, pulmonary edema, apnea and transfusion associated lung disease); or
      - f. The member does not have access to home infusion AND the nearest office-based provider who can provide that service exceeds the travel distance to the currently-servicing hospital outpatient center.





- 2. Age less than 18 or greater than 64; or
- Home deemed unsafe environment for infusion (e.g., too many pets, esp. birds, aggressive dogs, etc.). The next requirement will be provider office. Requires written documentation; or Member reasoning (e.g., often members don't want children exposed to the medication, etc.). The next requirement will be provider office; or
- 4. Financial impact to member is high in a setting other than hospital outpatient center these are reviewed case by case basis only.