

Mandatory Site of Service Management Policy

Last Review Date: 08/13/2024

Date of Origin: 07/10/2020

I. Background:

The Provider-Administered Drug Program includes a Mandatory Site of Service program, effective January 1, 2021, which requires members to use the most cost-effective, clinically appropriate location to receive their infusion(s) of select specialty medications as listed in this policy.

II. Scope:

Applicable to all groups and individual health plans that participate in the Provider-Administered Drug Program, have home healthcare benefits, and the Mandatory Site of Service benefit.

- New utilizers of these medications on or after January 1, 2021, will be subject to the program requirements.
- Members currently using these medications will be subject to the program requirements upon prior authorization renewal on or after January 1, 2021.

III. Program Requirements:

- Impacted members will be identified through the existing Provider-Administered Drug prior authorization program and/or through paid claims reporting for identification of current utilizers.
- All drugs in the Mandatory Site of Service Management require prior authorization for the drug requested to ensure medical necessity criteria is met. As part of this review, information concerning the intended place of treatment is obtained and additional criteria may be reviewed based on where the drug is to be administered.
- Members with approved drug prior authorizations and identified as receiving the select specialty drugs (as listed in section V) in a hospital outpatient setting will be referred to Prime Therapeutics' Infusion Referral Center (IRC) as a next internal step in the Site of Service process.
- The IRC will confirm that the following criteria are met in order for the member to be transitioned to an alternate place of treatment, such as a home infusion provider or infusion suite.
- When required, the home infusion provider will obtain all necessary nursing precertification's as specified by the member's benefits.

IV. Exceptions

If it is determined that the administration of the injectable therapy in an outpatient setting is medically necessary, an exception to this site of service program can be made. Reviews to determine the medical necessity for the outpatient facility place of treatment can be performed during the prior authorization process

or at any point during the assessment of the case. Documentation must be submitted to support any exceptions to the Mandatory Site of Service Policy.

The administration of the infusion and injectable therapy referenced in this policy in a hospital outpatient setting may be considered medically necessary if the following criteria are met:

- 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:
 - The member has a higher risk of an adverse reaction due to a co-morbid condition (e.g., renal dysfunction, cardiopulmonary disease, physical/cognitive impairment)- documentation of co-morbid condition, potential adverse reaction, and clinical rationale all must be submitted; or
 - The member has a history of anaphylaxis to prior infusion therapy with a prior infusion therapy with a related pharmacologic or biologic agent despite standard premedication - documentation of previous anaphylaxis reaction noted must be submitted; or
 - The member has intolerable fluid overload, including impaired or unstable renal function; or
 - The member has acute mental status/cognitive changes or physical impairment AND no home caregiver available; documentation of both factors required; or
 - The member's vascular access is not stable, and member has significant, documented venous access issues; submission of documentation required; or
 - The member has 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 with lung disease) - documentation must be submitted; or
 - The member has received a bone marrow transplant (BMT) in the prior 6 months and requires enhanced medical supervision/monitoring at a specialized facility - documentation of the procedure/treatment must be submitted; or
- The member does not have access to home infusion or in-network Ambulatory Infusion Suite AND the nearest office-based provider who can provide the service exceeds the travel distance to the currently-servicing hospital outpatient center- documentation of these factors must be submitted; 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.

V. Drugs in Scope

Select infused specialty medications included in the Site of Service program are subject to change. 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.

HCPCS	Brand Name	Generic Name
J3262	ACTEMRA	tocilizumab
J0791	ADAKVEO	crizanlizumab-tmca
J1931	ALDURAZYME	laronidase
J1554	ASCENIV	intravenous immune globulin
Q5121	AVSOLA	infliximab-axxq
J0490	BENLYSTA	belimumab
J0597	BERINERT	C1 esterase inhibitor
J1556	BIVIGAM	intravenous immune globulin
J1786	CEREZYME	imiglucerase
J0717	CIMZIA	certolizumab pegol
J2786	CINQAIR	reslizumab
J0598	CINRYZE	C1 esterase inhibitor
J1551	CUTAQUIG	subcutaneous immune globulin
J1743	ELAPRASE	idursulfase
J3060	ELELYSO	taliglucerase alfa
J3380	ENTYVIO	vedolizumab
J0517	FASENRA	benralizumab
J0180	FABRAZYME	agalsidase beta
J1572	FLEBOGAMMA	intravenous immune globulin
J1569	GAMMAGARD LIQUID	intravenous immune globulin
J1566	GAMMAGARD S/D, CARIMUNE NF	intravenous immune globulin
J1561	GAMMAKED	intravenous immune globulin
J1557	GAMMAPLEX	intravenous immune globulin
J1561	GAMUNEX	intravenous immune globulin
J1599	IMMUNE GLOBULIN	intravenous immune globulin
Q5103	INFLECTRA	infliximab-dyyb
J2840	KANUMA	sebelipase alfa
J0221	LUMIZYME	alglucosidase alfa
J1458	NAGLAZYME	galsulfase
J2182	NUCALA	mepolizumab
J2350	OCREVUS	ocrelizumab
J1568	OCTAGAM	intravenous immune globulin
J0222	ONPATTRO	patisiran lipid complex
J0129	ORENCIA IV	abatacept
J1576	PANZYGA	intravenous immune globulin
J1459	PRIVIGEN	intravenous immune globulin
J1301	RADICAVA	edaravone
J1745	REMICADE	infliximab
Q5104	RENFLIXIS	infliximab-abda
J9312	RITUXAN (<i>non-oncology diagnosis only</i>)	rituximab
Q5119	RUXIENCE (<i>non-oncology diagnosis only</i>)	rituximab-pvvr
J1602	SIMPONI ARIA	golimumab
J1299	SOLIRIS	eculizumab

J3357	STELARA	ustekinumab
J3241	TEPEZZA	teprotumumab-trbw
J2356	TEZSPIRE	tezepelumab-ekko
J1746	TROGARZO	ibalizumab-uiyk
Q5115	TRUXIMA (<i>non-oncology diagnosis only</i>)	rituximab-abbs
J2323	TYSABRI	natalizumab
J1303	ULTOMIRIS	ravulizumab-cwvz
J3385	VPRIV	velaglucerase alfa
J1322	VIMIZIM	elosulfase alfa
J2357	XOLAIR	omalizumab