Health New England - Site of Service Policy

Date of Origin: 01/01/2022

I. Background

The Site of Service program, effective 1/01/2022, 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

1. Applicable to Commercial, fully funded membership.
   a. New utilizers of these medications on or after 01/01/2022 will be subject to the program requirements.
   b. Members currently using these medications will be subject to the program requirements upon prior authorization renewal on or after 01/01/2022.

III. Program Requirements

1. The Site of Service program requirements will be administered as part of the existing prior authorization program.
   a. All drugs in the Site of Service program require prior authorization.

2. 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. Infusions for these medications are excluded from payment when administered in a hospital outpatient infusion center.

3. To prevent a delay in care and allow adequate transition time for Health New England 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

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

2. Changes to the Drugs in Scope
    a. If currently available infused specialty medications are added to the Site of Service program medication list, prescribers will receive advanced notification.

HCPCS	Brand Name	Generic Name
J3262	ACTEMRA	tocilizumab
J1931	ALDURAZYME-	laronidase
J0256/J0257	ARALAST NP	alpha-1 proteinase inhibitor
J1554	ASCENIV	intravenous immune globulin
J0490	BENLYSTA	belimumab
J0597	BERINERT	C1 esterase inhibitor
J1556	BIVIGAM	intravenous immune globulin (IVIG)
J1566	CARIMUNE NF	Intravenous Immune Globulin
J1786	CEREZYME	imiglucerase
J0717	CIMZIA	certolizumab pegol
J0598	CINRYZE	C1 esterase inhibitor
J0584	CRYSVITA	burosumab-twza
J1555	CUVITRU	subcutaneous immune globulin (SCIG)
J1743	ELAPRASE	idursulfase
J3060	ELELYSO	taliglucerase alfa
J3380	ENTYVIO	vedolizumab
J0180	FABRAZYME	agalsidase beta
J1572	FLEBOGAMMA	intravenous immune globulin (IVIG)
J1569	GAMMAGARD	intravenous immune globulin (IVIG)
J1566	GAMMAGARD S/D	intravenous immune globulin (IVIG))
J1561	GAMMAKED	intravenous immune globulin (IVIG)
J1557	GAMMAPLEX	intravenous immune globulin (IVIG)
J1561	GAMUNEX C	intravenous immune globulin (IVIG)
J1559	HIZENTRA	subcutaneous immune globulin (SCIG)
J1575	HYQVIA SQ	subcutaneous immune globulin (SCIG)
Q5103	INFLECTRA	infliximab-dyyb
J0221	LUMIZYME	alglucosidase alfa
J1458	NAGLAZYNME	galsulfase
J2350	OCREVUS	ocrelizumab
J1568	OCTAGAM	intravenous immune globulin (IVIG)
J0129	ORENCIA	abatacept
J1599	PANZYGA	intravenous immune globulin
J1459	PRIVIGEN	intravenous immune globulin (IVIG)
J1745	REMICADE	infliximab
Q5104	RENFLEXIS	Infliximab-abda
J1602	SIMPONI ARIA	golimumab
J1300	SOLIRIS	eculizumab
J3357	STELARA	ustekinumab
J3590	ULTOMIRIS	ravulizumab
J1322	VIMIZIM	elosulfase alfa
J3385	VPRIV	velaglucerase alfa

V. Exceptions

1. 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.

2. 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:
    a. 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.
    b. 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

3. Age less than 18 or greater than 64; or

4. Home deemed unsafe environment for infusion (e.g., too many pets, esp. birds, aggressive dogs, etc.).