Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

☒ **Commercial (Small & Large Group)** ☒ **ASO** ☒ **Exchange/ACA**
☒ **Medicare Advantage (MAPD)**

Site of Service MB2206

Covered Service: Yes

Prior Authorization Required: Yes

Additional Information: None

Medicare Policy: Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and the plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

Wisconsin Medicaid Policy Coverage of prescription drug benefits is administered by the Wisconsin Medicaid program. Coverage of medical drug benefits is administered by the Wisconsin Medicaid fee-for-service program. Medical drugs not paid on a fee-for-service basis by the Wisconsin Medicaid program are covered by the plan with no PA required.

Program requirements:

1.0 The Site of Service program requirements will be administered as part of the existing prior authorization program.

1.1 All drugs in the Site of Service program require prior authorization.

2.0 Requests for select specialty drugs as listed in the list in section ‘Drugs in Scope’ to be administered in a hospital outpatient setting may be directed to a preferred alternative site of care, such as home infusion provider or a physician office.

3.0 To prevent delay in care and allow adequate transition time for the Plan’s 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.

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Drugs in Scope:

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

2.0 Changes to the Drugs in Scope

2.1 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 the Plan.

HCPCS	Brand Name	Generic Name
J3262	ACTEMRA	tocilizumab
J1931	ALDURAZYME	laronidase
Q5121	AVSOLA	infliximab-axxq
J0490	BENLYSTA	belimumab
J1556	BIVIGAM	Intravenous immune globulin (IVIG)
J2329	BRIUMVI	ublituximab-xiiy
J1786	CEREZYME	imiglucerase
J2786	CINQAIR	reslizumab
J7318	CRYSVITA	burosumab
J1743	ELAPRASE	idursulfase
J3060	ELELYSO	taliglucerase alfa
J3380	ENTYVIO	vedolizumab
J0180	FABRAZYME	agalsidase beta
J1744	FIRAZYR	icatibant
J1572	FLEBOGAMMA	IVIG
J1569	GAMMAGARD	IVIG
J1566	GAMMAGARD S/D	IVIG
J1561	GAMMAKED	IVIG
J1557	GAMMAPLEX	IVIG
J1561	GAMUNEX	IVIG
J1599	IMMUNE GLOBULIN IV	IVIG
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	galsufase
J2182	NUCALA	mepolizumab
J2350	OCREVUS	ocrelizumab
J1568	OCTAGAM	IVIG
J0129	ORENCIA	abatacept
J1459	PRIVIGEN	IVIG
J1301	RADICAVA	edaravone
J1745	REMICADE	infliximab
Q5104	RENFLEXIS	infliximab-abda
J1602	SIMPONI ARIA	golimumab
J1300	SOLIRIS	eculizumab
J1746	TROGARZO	ibalizumab-uiyk
J2323	TYSABRI	natalizumab
J1303	ULTOMIRIS	ravulizumab
J1322	VIMIZIM	elosulfase alfa
J3385	VPRIV	velaglucerase alfa
J2357	XOLAIR	omalizumab

Exceptions:

1.0 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 on medical necessity.

2.0 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:

2.1 Hospital outpatient administration of infusion or injectable therapy is considered medically necessary for up to a 60 to 90 day period for members beginning a new treatment OR initial review of continuation of therapy

2.2 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:

2.2.1 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:

2.2.1.1 Intolerable fluid overload, including impaired or unstable renal function, or

2.2.1.2 History of anaphylaxis to prior infusion therapy with a related pharmacologic or biologic age despite standard premedication, or

2.2.1.3 Acute mental status/cognitive changes or physical impairment AND no home caregiver available; or

2.2.1.4 Vascular access not stable; or

2.2.1.5 Documented clinical history of cardiopulmonary conditions that may cause an increased risk of severe adverse react ions (including but not limited to thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress, pulmonary edema, apnea and transfusion associated lung disease); or

2.2.1.6 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.

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

2.2.3 Member reasoning (e.g. often members don't want children exposed to the medication, etc.); or

2.2.4 Financial impact to member is high in a setting other than hospital outpatient center. These are reviewed on a case-by-case basis only.

	Committee/Source	**Date(s)**
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