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Kaiser Foundation Health Plan of Washington

Utilization Management Policy
Site of Care: Infusion Therapy and Clinic Administered Medicines

This utilization management policy provides criteria to determine the medical necessity of hospital outpatient administration as the site of care for select specialty medicines. The initial dose(s) of the medicines subject to this policy may be given at the physician's site of choice, see exception doses for further details. All subsequent doses are subject to the Site of Care policy, which require administration in a non-hospital setting. Clinical rationale and documentation must be provided for medical necessity exceptions.

Background

Infusion or Infusion Therapy is when medicine is given directly into the bloodstream through a vein, under the skin (subcutaneous), or into the muscle (intramuscular) by injection. Infusion therapy can be given in many different Sites of Care.

Site of Care refers to the generic type of site or type of setting where the infused drug is administered. Infusions can be given in different settings, including outpatient infusion center located in a hospital, an infusion center that's not in a hospital, a physician's office, or in a member's home.

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente), requires Site of Care prior authorization for select injectable drugs that are given under the medical benefit. All new requests for the select specialty medicines require a medical necessity and a Site of Care review.

See Applicable Codes for a complete list.

Criteria

For Medicare Members

Criteria does not apply.

For Non-Medicare Members

Site of Care for Infusions	Medical Necessity Criteria
Medically necessary sites of care: • **Physician's office** • **Infusion center/suite (outside of a hospital)** • **Home infusion**	These are the preferred sites of care for drugs that meet the following criteria: • A drug has shown low risk for infusion site reactions as determined by medical evidence • The drug manufacturer has identified that the infusion does not require a hospital-based setting
Hospital-based outpatient setting	This site is considered medically necessary for the infusion of drugs on the site of care applicable codes list if **at least one** of the following criteria is met: • Member is 12 years old or younger • Member is medically unstable based upon submitted clinical history ○ Examples include but are, not limited to: cardiopulmonary conditions that may increase risk of adverse reactions, inability to safely tolerate intravenous volume loads, unstable vascular access requiring ultrasound guidance; or • Previous experience of a severe adverse reaction related to requested drug infusion that requires extra monitoring that can only be administered in a hospital setting

	○ Examples include but are not limited to: anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or • Physically and/or cognitively impaired such that a preferred site of care would impact the safety of the infusion; or • The member's home is not eligible for home infusion services, is deemed unsuitable for care by the home infusion provider or the drug cannot be administered by home infusion service providers (if the drug cannot be administered in an infusion center, outside of the hospital) Note: Clinical documentation (e.g., infusion records, medical records) supporting an exception must be included (e.g., dates of prior anaphylactic experience, specific details of adverse reactions and attempts to mitigate). For the hospital site of care reauthorization review timeframe see outpatient hospital reauthorization.

Outpatient Hospital Reauthorization

Medical Necessity Criteria	Authorization Timeframe	Reauthorization of the Site of Care exception
Member is 12 years old or younger	Until date member turns 13 years of age	Any request after the 13th birthday will be subject to a new, full Site of Care exception review
Member is medically unstable based on submitted clinical history	6 months	Authorization shall be reviewed every 6 months to confirm member continues to meet clinical criteria
Previous experience of a severe adverse reaction related to requested drug infusion that requires extra monitoring that can only be administered in a hospital setting	Re-review not needed	N/A
Physically and/or cognitively impaired such that a preferred site of care would impact the safety of the infusion therapy	6 months	Authorization shall be reviewed every 6 months to confirm member continues to meet clinical criteria
The member's home is not eligible for home infusion services, is deemed unsuitable for care by the home infusion provider or the drug cannot be administered by home infusion service providers (if the drug cannot be administered in an infusion center, outside of the hospital)	6 months	Authorization shall be reviewed every 6 months to confirm member's home is still not eligible for home infusion

Exception Doses

For all new coverage requests, Site of Care criteria shall be waived for the administration of the first dose for all drugs, to allow enough time to arrange for a non-hospital outpatient setting for the infusion. Further dose exceptions apply for new start patients or patients reinitiating therapy after 6 months or longer following discontinuation of therapy as identified in applicable codes.*

*This does not include when standard dosing between infusions is 6 months or longer

Oncology exceptions:

For patients transitioning from combination to monotherapy, Site of Care criteria shall be waived for the administration of the first dose. Note: combination therapy exceptions apply to drugs administered under the medical benefit only (e.g., drugs administered orally are not considered). Further dose exceptions are outlined in applicable codes.

Applicable Codes

CPT or HCPC Code	Description				
	Generic Drug Name	Brand Drug Name	Effective Date	New Start Dose Exceptions	Notes
J0129	Abatacept	Orencia	1/15/2017	3	
J0180	Agalsidase beta	Fabrazyme	1/15/2017	4	
J0202	Alemtuzumab	Lemtrada	3/1/2020	5	
J0221, J0220	Alglucosidase alpha	Lumizyme, Myozyme	1/15/2017	4	
J0257, J0256	Alpha 1-proteinase inhibitor	Aralast, Aralast NP, Glassia, Prolastin, Prolastin C, Zemaira	1/15/2017	1	
C9086, J0491	Anifrolumab-fnia	Saphnelo	1/1/2023	1	
C9085, J0219	Avalglucosidase Alfa-ngpt	Nexviazyme	1/1/2023	2	
J0485	Belatacept	Nulojix	2/1/2021	5	Applies to kidney only
J0490	Belimumab	Benlysta	1/15/2017	2	
J0517	Benralizumab	Fasenra	2/1/2021	1	
C9257, J9035	Bevacizumab	Avastin	1/1/2023	Ophthalmology – 1 Oncology - 2 doses within 2 months	Oncology - Applies to monotherapy (new starts and maintenance monotherapy)
Unspecified J3490, J3590	Bevacizumab-adcd	Vegzelma	3/1/2023	Oncology – 2 doses within 2 months	Oncology – Applies to monotherapy (new starts and maintenance monotherapy)
Q5107	Bevacizumab-awwb	Mvasi	1/1/2023	Oncology - 2 doses within 2 months	Oncology - Applies to monotherapy (new starts and maintenance monotherapy)
Q5118	Bevacizumab-bvzr	Zirabev	3/1/2023	Oncology – 2 doses within 2 months	Oncology – Applies to monotherapy (new starts and maintenance monotherapy)
C9142, Q5126	Bevacizumab-maly	Alymsys	1/1/2023	Oncology - 2 doses within 2 months	Oncology - Applies to monotherapy (new starts and maintenance monotherapy)
J9041	Bortezomib	Velcade	9/1/2022	2 doses within 2 months	Applies to monotherapy (new starts and maintenance monotherapy)
J0584	Burosumab-twza	Crysvita	3/1/2020	1	
J0597, J0598, J0596	C1 esterase inhibitor	Berinert, Cinryze, Ruconest	1/15/2017	1	
C9077, J0741	Cabotegravir/Rilpivirine	Cabenuva	1/1/2023	1	
J0638	Canakinumab	Ilaris	3/1/2020	1	
C9075, J1426	Casimersen	Amondys 45	5/20/2021	4	
J0791	Crizanlizumab-tmca	Adakveo	3/2/2020	1	

CPT or HCPC Code	Description				
	Generic Drug Name	Brand Drug Name	Effective Date	New Start Dose Exceptions	Notes
J0850	Cytomegalovirus	Cytogam	1/15/2017	1	
J0897	Denosumab	Prolia	1/1/2023	1	
J0897	Denosumab	Xgeva	9/1/2022	2 doses within 2 months	Applies to monotherapy (new starts and maintenance monotherapy)
C9493, J1301	Edaravone	Radicava	3/1/2020	14	
J1290	Ecallantide	Kalbitor	1/15/2017	1	
J1300	Eculizumab	Soliris	1/15/2017	1	
Unclassified J3490, J3590	Elapegademase-lvlr	Revcovi	1/1/2023	8	
J1322	Elosulfase alpha	Vimizim	1/15/2017	8	
J3032	Eptinezumab-jjmr	Vyepti	12/1/2020	1	
C9484, J1428	Eteplirsen	Exondys 51	3/1/2020	4	
C9079, J1305	Evinacumab-dgnb	Evkeeza	1/1/2023	1	
J1458	Galsulfase	Naglazyme	1/15/2017	8	
J0223	Givosiran	Givlaari	3/2/2020	1	
J1602	Golimumab intravenous injection	Simponi Aria	1/15/2017	2	
J1429	Golodirsen	Vyondys 53	12/1/2020	4	
J1746	Ibalizumab-uiyk	Trogarzo	1/1/2023	2	
J1743	Idursulfase (Elaprase)	Elaprase	1/15/2017	8	
J1786	Imiglucerase	Cerezyme	1/15/2017	2	
J1555	Immunoglobulin subcutaneous	Cuvitru	12/15/2017	1	
J1575	Immune globulin infusion 10% with recombinant hyaluronidase subcutaneous	Hyqvia	1/15/2017	1	
J1823	Inebilizumab-cdon	Uplizna	12/1/2020	1	
J1745	Infliximab	Remicade, Infliximab	1/15/2017	3	
Q5104	Infliximab-abda	Renflexis	4/7/2021		
Q5121	Infliximab-axxq	Avsola	4/7/2021		
Q5103	Infliximab-dyyb	Inflectra	4/1/2018		
Q5109	Infliximab-qbtx	Ixifi	4/7/2021		
J1459, J1554, J1556, J1557, J1561, J1566, J1568, J1569, J1572, J1599	IVIG	Privigen, Bivigam, Gammaplex, Gamunex/Gamunex-C/Gammaked, Other IVIG, Octagam, Gammagard liquid, Flebogamma/ Flebogamma Dif, Other immune globulins IV, Panzyga, Asceniv	1/15/2017	1	
J1931	Laronidase	Aldurazyme	1/15/2017	8	
C9074, J0224	Lumasiran	Oxlumo	1/1/2023	1	
J0896	Luspatercept-aamt	Reblozyl	3/2/2020	1	

CPT or HCPC Code	Description				
	Generic Drug Name	Brand Drug Name	Effective Date	New Start Dose Exceptions	Notes
J2182	Mepolizumab	Nucala	2/1/2021	1	
J2323	Natalizumab	Tysabri	3/1/2020	1	
J9299	Nivolumab	Opdivo	6/1/2021	2 doses within 3 months	Applies to monotherapy (new starts and maintenance monotherapy)
C9494, J2350	Ocrelizumab	Ocrevus	4/1/2018	2	
J2357	Omalizumab	Xolair	2/1/2021	3	
C9036, J0222	Patisiran	Onpattro	3/1/2020	1	
J2507	Pegloticase	Krystexxa	1/15/2017	1	
J9271, C9027	Pembrolizumab	Keytruda	6/1/2021	2 doses within 3 months	Applies to monotherapy (new starts and maintenance monotherapy)
J9306, C9292	Pertuzumab	Perjeta	9/1/2022	2 doses within 2 months	Site of care applies when used in combination with trastuzumab products. Site of Care does not apply if administered in combination with cytotoxic chemotherapy
C9052, J1303	Ravulizumab-cwvz	Ultomiris	10/1/2019	1	
J9310, J9312	Rituximab	Rituxan	4/1/2018	2	Site of care applies only to the indications below: • granulomatosis polyangiitis (GPA or Wegener's) or • microscopic polyangiitis (MPA) who are antineutrophil cytoplasmic antibody (ANCA) positive Note: any oncology indication would not require patients to meet site of care criteria
Q5115	Rituximab-abbs	Truxima	3/1/2020		
Q5123	Rituximab-arrx	Riabni	4/7/2021		
Q5119	Rituximab-pvvr	Ruxience	4/7/2021		
J2796	Romiplostim	Nplate	1/1/2023	4	
J2840	Sebelipase alfa	Kanuma	4/1/2018	8	
J3060	Taliglucerase alfa	Elelyso	4/1/2018	2	
J3241	Teprotumumab-trbw	Tepezza	8/4/2020	1	
J3245	Tildrakizumab-asmn	Ilumya	1/1/2023	1	
J3262	Tocilizumab	Actemra	1/15/2017	2	
J9355	Trastuzumab	Herceptin	3/1/2020	2 doses within 2 months	Applies to monotherapy or when used in combination with pertuzumab
Q5117	Trastuzumab-anns	Kanjinti	3/1/2020		
Q5114	Trastuzumab-dkst	Ogivri	6/1/2020		
Q5112	Trastuzumab-dttb	Ontruzant	4/7/2021		
Q5113	Trastuzumab-pkrb	Herzuma	4/7/2021		
Q5116	Trastuzumab-qyyp	Trazimera	6/1/2020		
J3380	Vedolizumab	Entyvio	1/15/2017	3	

CPT or HCPC Code	Description				
	Generic Drug Name	Brand Drug Name	Effective Date	New Start Dose Exceptions	Notes
J3385	Velaglucerase alfa	Vpriv	1/15/2017	2	
J3397	Vestronidase Alfa-vjbk	Mepsevii	1/1/2023	2	
J1427, C9071	Viltolarsen	Viltepso	12/1/2020	4	

Date Created	Date Reviewed	Date Last Revised
6/26/2020	8/4/2020[MPC], 9/7/2021[MPC]	3/27/2023

Revision History	Description
2/10/2021	Added drug table with CPT code and site of care effective date
4/9/2021	Added rituximab-pvvr, rituximab-arrx, infliximab-qbtx, infliximab-dyyb, infliximab-abda, infliximab-axxq, trastuzumab-dttb, trastuzumab-pkrb, pembrolizumab, nivolumab to drug table.
5/21/2021	Added casimersen
10/4/2021	Added clinical documentation requirements
11/1/2021	Revised hospital site of care criteria Added authorization timeframe Added exception doses
3/30/2022	Added exception doses for ocrelizumab Updated code for Rituximab-arrx Added oncology exceptions Added Trastuzumab diagnosis tables Updated home infusion exception and reauthorization timeframe
4/7/2022	Added monotherapy language to Pembrolizumab and Nivolumab
6/7/2022	Updated abatacept exception dosing from 1 to 3 doses, added Infliximab
7/28/2022	Updated vedolizumab and omalizumab exception dosing from 1 to 3 doses
9/1/2022	Added pertuzumab, bortezomib, denosumab. Removed diagnoses restrictions for trastuzumab products.
1/20/2023	Added anifrolumab-fnia, avalglucosidase alfa-ngpt, bevacizumab, bevacizumab-awwb, bevacizumab-maly, cabotegravir/rilpivirine, denosumab, elapegademase-lvlr, evinacumab-dgnb, ibalizumab-uiyk, lumasiran, romiplostim, tildrakizumab-asmn, vestronidase alfa-vjbk
2/15/2023	Updated exception dosing for casimersen, eteplirsen, golodirsen, viltolarsen Updated codes for casimersen, viltolarsen
3/27/2023	Added bevacizumab-bvzr, bevacizumab-adcd

[MPC] Medical Policy Committee