



Site of Care Infusion Management Medical Drug Criteria Program Summary

Professional / Institutional
Original Effective Date: January 1, 2019
Latest Review Date: April 25, 2024
Current Effective Date: April 25, 2024

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact [Blue Cross and Blue Shield of Kansas Customer Service](#).

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

FDA APPROVED INDICATIONS AND DOSAGE

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

CLINICAL RATIONALE

Clinical Rationale	<p>The Site of Care Infusion Management Medical Policy outlines the criteria a patient must meet in order to receive an injection in a hospital outpatient facility and will determine medical necessity. The initial administration of the agents included in this policy may be given at the physician’s facility of choice. All subsequent administrations of the agents included in this policy will need to meet the criteria addressed in this policy. Acceptable alternative sites of care include non-hospital outpatient centers, physician/professional offices, infusion suites/ambulatory infusion centers, and home administration.</p> <p>Hospital outpatient facilities are uniquely equipped to handle and support emergency medical situations. It is appropriate for patients, who are medically unstable and in danger of needing medical services only available in a hospital outpatient setting, to have access to administration in these facilities. Guidelines and agencies support first</p>
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	<p>infusions of many drugs in well-controlled settings to ensure immediate access to care to address serious infusion-associated adverse reactions.(1,2) Several studies have demonstrated safety and efficacy of administering several intravenous drugs in alternate sites of care, most notably in the home.(3-8) Although patients and disease states vary, consideration for a patient to transition to home therapy is often considered after six months of no infusion-associated reactions.(9)</p> <p>Center for Medicare and Medicaid Services (CMS) provides defined codes for site of service.(10)</p>
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REFERENCES

Number	Reference
1	American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.
2	Agency for Healthcare Research and Quality. Enzyme-Replacement Therapies for Lysosomal Storage Diseases. Agency for Healthcare Research and Quality. Effective Health Care Program Technical Brief No.12. January 2013.
3	Condino, A., et al. A Home Infliximab Infusion Program. Journal of Pediatric Gastroenterology and Nutrition: January 2005. Volume 40, Issue 1, pp 67-69.
4	National Home Infusion Association. About Infusion Therapy and Medicare Home Infusion Site of Care Act Report. Accessed December 2016.
5	Souayah N, Hasan A, et al. The safety profile of home infusion of intravenous immunoglobulin in patient with neuroimmunologic disorders. J Clin Neuromuscul Dis. 2011. Jun;12 Suppl 4:S1-10.
6	Gerth WC, Betschel SD, Zbrozek AS. Implications to payers of switch from hospital-based intravenous immunoglobulin to home-based subcutaneous immunoglobulin therapy in patients with primary and secondary immunodeficiencies in Canada. Allergy Asthma Clin Immunol. 2014 May 7;10(1)23.
7	Katzberg HD, Rasutis V, Bril V. Home IVIG for CIDP: a focus on patient centered care. Can J Neurol Sci. 2013 May;40(3):384-8.
8	Gardulf A, Nicolay U, et al. Children and adults with primary antibody deficiencies gain quality of life by subcutaneous IgG self-infusions at home. J Allergy Clin Immunol. 2004 Oct;114(4):936-42.
9	Agency for Healthcare Research and Quality. Enzyme-Replacement Therapies for Lysosomal Storage Diseases. Agency for Healthcare Research and Quality. Effective Health Care Program Technical Brief No.12. January 2013.
10	Place of service code set. Center for Medicare and Medicaid Services. Available at: https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html . Accessed on 7/27/23.

OBJECTIVE

The intent of the Site of Care Medical Policy program is to determine medical necessity for patients receiving an outpatient hospital facility-based/owned medication injection. This policy applies after the first administration.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

HCPC Codes	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
J1931	Aldurazyme	laronidase soln for iv infusion	2.9 MG/5ML	M ; N ; O ; Y	N		
J0256	Aralast np	alpha1 - proteinase inhibitor	500 MG	M ; N ; O ; Y	N		
J0256	Aralast np	alpha1 - proteinase inhibitor	1000 MG	M ; N ; O ; Y	N		
J1786	Cerezyme	imiglucerase for inj	400 UNIT	M ; N ; O ; Y	N		
J1743	Elaprase	idursulfase soln for iv infusion	6 MG/3ML	M ; N ; O ; Y	N		
J3060	Elelyso	taliglucerase alfa for inj	200 UNIT	M ; N ; O ; Y	N		
J2508	Elfabrio	pegunigalsidase alfa-iwxj iv solution	20 MG/10ML	M ; N ; O ; Y	N		
J0180	Fabrazyme	agalsidase beta for iv soln	5 MG	M ; N ; O ; Y	N		
J0180	Fabrazyme	agalsidase beta for iv soln	35 MG	M ; N ; O ; Y	N		
J0257	Glassia	alpha1 - proteinase inhibitor	1000 MG/50ML	M ; N ; O ; Y	N		
J2840	Kanuma	sebelipase alfa iv soln	20 MG/10ML	M ; N ; O ; Y	N		
J0221	Lumizyme	alglucosidase alfa for iv soln	50 MG	M ; N ; O ; Y	N		
J3397	Mepsevii	vestronidase alfa-vjvk iv soln	10 MG/5ML	M ; N ; O ; Y	N		
J1458	Naglazyme	galsulfase soln for iv infusion	1 MG/ML	M ; N ; O ; Y	N		
J0219	Nexviazyme	avalglucosidase alfa-ngpt for iv soln	100 MG	M ; N ; O ; Y	N		
J2350	Ocrevus	ocrelizumab soln for iv infusion	300 MG/10ML	M ; N ; O ; Y	N		
	Pombiliti	cipaglucosidase alfa-atga for iv soln	105 MG	M ; N ; O ; Y	N		
J0256	Prolastin-c	alpha1 - proteinase inhibitor	1000 MG/20ML	M ; N ; O ; Y	N		
J0256	Prolastin-c	alpha1 - proteinase inhibitor	1000 MG	M ; N ; O ; Y	N		

HCPC Codes	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
J1301	Radicava	edaravone inj	30 MG/100ML	M ; N ; O ; Y	N		
J1300	Soliris	eculizumab iv soln	300 MG/30ML	M ; N ; O ; Y	N		
J1303	Ultomiris	ravulizumab-cwvz iv soln	300 MG/3ML	M ; N ; O ; Y	N		
J1303	Ultomiris	ravulizumab-cwvz iv soln	1100 MG/11ML	M ; N ; O ; Y	N		
J1322	Vimizim	elosulfase alfa soln for iv infusion	5 MG/5ML	M ; N ; O ; Y	N		
J3385	Vpriv	velaglucerase alfa for inj	400 UNIT	M ; N ; O ; Y	N		
J0256	Zemaira	alpha1 - proteinase inhibitor	1000 MG	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Aldurazyme	laronidase soln for iv infusion	2.9 MG/5ML	Commercial ; HIM ; ResultsRx
Aralast np	alpha1 - proteinase inhibitor	500 MG	Commercial ; HIM ; ResultsRx
Aralast np	alpha1 - proteinase inhibitor	1000 MG	Commercial ; HIM ; ResultsRx
Cerezyme	imiglucerase for inj	400 UNIT	Commercial ; HIM ; ResultsRx
Elaprase	idursulfase soln for iv infusion	6 MG/3ML	Commercial ; HIM ; ResultsRx
Elelyso	taliglucerase alfa for inj	200 UNIT	Commercial ; HIM ; ResultsRx
Elfabrio	pegunigalsidase alfa-iwxj iv solution	20 MG/10ML	Commercial ; HIM ; ResultsRx
Fabrazyme	agalsidase beta for iv soln	35 MG	Commercial ; HIM ; ResultsRx
Fabrazyme	agalsidase beta for iv soln	5 MG	Commercial ; HIM ; ResultsRx
Glassia	alpha1 - proteinase inhibitor	1000 MG/50ML	Commercial ; HIM ; ResultsRx
Kanuma	sebelipase alfa iv soln	20 MG/10ML	Commercial ; HIM ; ResultsRx
Lumizyme	alglucosidase alfa for iv soln	50 MG	Commercial ; HIM ; ResultsRx
Mepsevii	vestronidase alfa-vjkb iv soln	10 MG/5ML	Commercial ; HIM ; ResultsRx
Naglazyme	galsulfase soln for iv infusion	1 MG/ML	Commercial ; HIM ; ResultsRx
Nexviazyme	avalglucosidase alfa-ngpt for iv soln	100 MG	Commercial ; HIM ; ResultsRx
Ocrevus	ocrelizumab soln for iv infusion	300 MG/10ML	Commercial ; HIM ; ResultsRx
Pombiliti	cipaglucosidase alfa-atga for iv soln	105 MG	Commercial ; HIM ; ResultsRx
Prolastin-c	alpha1 - proteinase inhibitor	1000 MG	Commercial ; HIM ; ResultsRx
Prolastin-c	alpha1 - proteinase inhibitor	1000 MG/20ML	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Radicava	edaravone inj	30 MG/100ML	Commercial ; HIM ; ResultsRx
Soliris	eculizumab iv soln	300 MG/30ML	Commercial ; HIM ; ResultsRx
Ultomiris	ravulizumab-cwvz iv soln	300 MG/3ML	Commercial ; HIM ; ResultsRx
Ultomiris	ravulizumab-cwvz iv soln	1100 MG/11ML	Commercial ; HIM ; ResultsRx
Vimizim	elosulfase alfa soln for iv infusion	5 MG/5ML	Commercial ; HIM ; ResultsRx
Vpriv	velaglucerase alfa for inj	400 UNIT	Commercial ; HIM ; ResultsRx
Zemaira	alpha1 - proteinase inhibitor	1000 MG	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>CRITERIA FOR OUTPATIENT HOSPITAL FACILITY-BASED ADMINISTRATION</p> <p>Outpatient hospital facility-based medication injection(s) may be considered medically necessary for persons who meet any one or more of the following criteria:</p> <ol style="list-style-type: none"> 1. The request is NOT for service at an off campus-outpatient hospital (place of code service 19) OR on campus-outpatient hospital (place of code service code 22) as defined by Center for Medicare and Medicaid Services (CMS) OR 2. The request is for service at an off campus-outpatient hospital (place of code service 19) OR on campus-outpatient hospital (place of code service 22) as defined by Center for Medicare and Medicaid Services AND ONE of the following: <ol style="list-style-type: none"> A. The request is for an initial medication administration of the requested agent (i.e., the patient has never received therapy with the requested agent previously) OR B. The administration of the requested agent is a re-initiation defined as restarting therapy after at least a 1 month gap in therapy outside of the approved dosing interval (e.g., for an agent requiring every 6 months dosing duration, the requested re-initiation dose will be administered at least 7 months after the previously administered dose) OR C. The patient is medically unstable (based upon provided clinical history) and is in danger of needing medical services only available in a hospital setting (e.g., emergency services/equipment, intensive care, etc.) during/surrounding administration of the requested agent. *Medical records including chart notes are required. Examples include but are not limited to: <ol style="list-style-type: none"> 1. Clinical history of cardiopulmonary conditions that may cause an increased risk of severe adverse reactions 2. An inability to safely tolerate intravenous volume loads, including unstable renal function 3. The patient has previous experience of a severe adverse event following administration of the requested agent (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) 4. Unstable vascular access 5. Physical or cognitive impairments such that administration of the requested agent in an alternative site of care would present an unnecessary health risk 6. The patient has continuing experience of moderate to severe adverse events during/surrounding administrations of the requested agent that cannot be mitigated by pre-medications OR

Module	Clinical Criteria for Approval
	<p>D. The infusion will be given at a designated outpatient hospital facility https://www.bcbsks.com/prescription-drugs/site-of-care</p> <p>Length of Approval: For initiation or re-initiation, approve for 6 months. All others, approve for up to 12 months maximum per determination</p>

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

REVISIONS	
Policy Posted 02-01-2024 Effective 03-01-2024	Policy added to the bcbsks.com web site. <ul style="list-style-type: none"> ▪ Policy maintained by Prime Therapeutics LLC
Posted 3-26-2024 Effective 4-25-2024	In the Target Drug list Added: "Elfabrio and Pombiliti" Policy maintained by Prime Therapeutics LLC