**Medical Policy**

BlueCross BlueShield Kansas
An Independent licensee of the
Blue Cross Blue Shield Association

# Title: Site of Care Infusion Management Medical Drug Criteria Program Summary

| **Professional / Institutional** |
|---|
| Original Effective Date: January 1, 2019 |
| Latest Review Date: April 8, 2025 |
| 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 | 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.<br><br>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 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)<br><br>Center for Medicare and Medicaid Services (CMS) provides defined codes for site of service.(10) |

## 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 Gastoenterology 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 | | |
| Q5152 | Bkemv | Eculizumab-aeeb iv soln | 300MG/30ML | M ; N ; O ; Y | N | | |
| J1786 | Cerezyme | imiglucerase for inj | 400 UNIT | M ; N ; O ; Y | N | | |
| J1301 | Edaravone | daravone inj | 60MG/100ML | 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 | | |
| Q5151 | Epysqli | Eculizumab-aagh iv soln | 300MG/30ML | 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-vjbk 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 | | |
| G0138 ; J1203 | 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 | | |

| HCPC Codes | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status |
|---|---|---|---|---|---|---|---|
| | Prolastin-c | alpha1 - proteinase inhibitor | 1000 MG | M ; N ; O ; Y | N | | |
| J1301 | Radicava | edaravone inj | 30 MG/100ML | M ; N ; O ; Y | O ; Y | | |
| | Rivfloza | nedosiran sodium subcutaneous soln | 80 MG/0.5ML | 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 | 1000 MG | Commercial ; HIM ; ResultsRx |
| Aralast np | alpha1 - proteinase inhibitor | 500 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-vjbk iv soln | 10 MG/5ML | Commercial ; HIM ; ResultsRx |
| Naglazyme | galsulfase soln for iv infusion | 1 MG/ML | Commercial ; HIM ; ResultsRx |

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|---|---|---|---|
| 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/20ML | Commercial ; HIM ; ResultsRx |
| Prolastin-c | alpha1 - proteinase inhibitor | 1000 MG | Commercial ; HIM ; ResultsRx |
| Radicava | edaravone inj | 30 MG/100ML | Commercial ; HIM ; ResultsRx |
| Rivfloza | nedosiran sodium subcutaneous soln | 80 MG/0.5ML | Commercial ; HIM ; ResultsRx |
| Rivfloza | nedosiran sodium subcutaneous soln pref syr | 160 MG/ML | Commercial ; HIM ; ResultsRx |
| Rivfloza | nedosiran sodium subcutaneous soln pref syr | 128 MG/0.8ML | Commercial ; HIM ; ResultsRx |
| Soliris | eculizumab iv soln | 300 MG/30ML | Commercial ; HIM ; ResultsRx |
| Ultomiris | ravulizumab-cwvz iv soln | 1100 MG/11ML | Commercial ; HIM ; ResultsRx |
| Ultomiris | ravulizumab-cwvz iv soln | 300 MG/3ML | 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 |
|---|---|
| | **CRITERIA FOR OUTPATIENT HOSPITAL FACILITY-BASED ADMINISTRATION**<br><br>Outpatient hospital facility-based medication injection(s) may be considered medically necessary for persons who meet any one or more of the following criteria:<br><br>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**<br>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: |

| Module | Clinical Criteria for Approval |
|---|---|
| | 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**<br>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**<br>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:<br>1. Clinical history of cardiopulmonary conditions that may cause an increased risk of severe adverse reactions<br>2. An inability to safely tolerate intravenous volume loads, including unstable renal function<br>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)<br>4. Unstable vascular access<br>5. Physical or cognitive impairments such that administration of the requested agent in an alternative site of care would present an unnecessary health risk<br>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**<br>D. The infusion will be given at a designated outpatient hospital facility https://www.bcbsks.com/prescription-drugs/site-of-care<br><br>**Length of Approval:** For initiation or re-initiation, approve for 6 months. All others, approve for up to 12 months maximum per determination |

## PRIOR AUTHORIZATION CLINICAL CRITERIA OPERATIONAL LEVEL OF EVIDENCE REQUIREMENTS

| Module | Ops Set Up | Validation Options | Other Explanation |
|---|---|---|---|
| | Documentation: Requirements as noted within the policy;<br>Validation: Apply Baseline and go to Validation Options | Other (see Other explanation field) | The infusion will be given at a designated outpatient hospital facility |

**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** | |
|---|---|
| 01-01-2019 | Policy added to the bcbsks.com web site on 11-01-2018. Policy effective on 01-01-2019. |
| 01-01-2019 | Policy published 12-19-2018. Policy effective 01-01-2019. |
| | Rationale section updated |
| | References updated |
| 07-01-2019 | Policy published 05-31-2019. Policy effective 07-01-2019. |
| | Header updated to remove link to formulary. |
| | In Description section:<br>▪ Updated to add Mepsevii IV - J3397 to the Enzyme Replacement drugs.<br>▪ Updated links to pharmacy medical policy at myprime.com added. |
| | Rationale section updated |
| | References updated |
| 01-01-2020 | Policy published 12-02-2019. Policy effective 01-01-2020. |
| | In Description section:<br>▪ Added "Amyotrophic lateral sclerosis (ALS) – Radicava IV – J1301" to Target Drugs.<br>▪ Added to Paroxysmal nocturnal hemoglobinuria (PNH)/atypical hemolytic uremic syndrome (aHUS)/Myasthenia Gravis "Ultomiris – J1303" |
| | In Policy section:<br>▪ In Header revised "infusions" to "administration" to read "CRITERIA FOR OUTPATIENT HOSPITAL FACILITY-BASED ADMINISTRATION"<br>▪ Revised "infusion" to "administration of the requested agent" throughout the policy section<br>▪ In Item A removed "intravenous or subcutaneous" and added "injection" to read "Blue Cross and Blue Shield of Kansas will consider an outpatient hospital facility-based medication injection…"<br>▪ Separated previous item 1 which read "The request is for an initial medication infusion or the infusion is a re-initiation after more than 6 months following discontinuation of therapy" into items 1 and 2 and added "(i.e. the patient has never received therapy with the requested agent previously)" to read "1. 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 2. The administration of the requested agent is a re-initiation after more than 6 months following discontinuation of therapy" |
| 05-18-2020 | In Title section:<br>▪ Revised "See Target Drugs Chart for Prior Authorization requirements" to "Site of Care Prior Authorization is required" to clarify the prior authorization requirement for this policy is site of care infusion management.<br>▪ Added "Prior Authorization Form:<br>BCBSKS reviews the Prior Authorization requests for Site of Care Infusion Management " and link to PA form. |
| | In Description section:<br>▪ Removed column of prior authorization and predetermination form links to add clarity that the prior authorization requirement for this policy is site of care infusion management.<br>▪ Added links to myprime.com for access to drug prior authorization information. |
| 01-01-2021 | Target Drugs for Multiple Sclerosis:<br>▪ Added Ocrevus- J2350 |
| 11-19-2021 | In Policy section<br>Deleted: |

| **REVISIONS** | |
|---|---|
| | ▪ The administration of the requested agent is a re-initiation after more than 6 months following discontinuation of therapy<br>Added:<br>▪ 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) |
| 06-01-2022 | In Target Drug Section under Enzyme Replacement<br>▪ Added: Nexviazyme J0219 |
| 07-29-2022 | Added for clarification only:<br>Glassia is a target of this policy when covered under the medical benefit.<br>For policies that cover Glassia through the Pharmacy benefit, Site of Care does not apply |
| 01-09-2024 | Medical Policy Maintained by Prime Therapeutics LLC. |
| | Updated Target Drug Table |
| | Updated Policy Section<br>Added:<br>A. ONE of the following:<br>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)<br>OR<br>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) AND ONE of the following: |
| | Updated Rationale Section |
| | Updated References Section |
| Policy Posted 02-01-2024 Effective 03-01-2024 | Policy converted to Prime format and added to the bcbsks.com web site.<br>▪ Policy maintained by Prime Therapeutics LLC |
| 04-26-2024 | Elfabrio and Pombilit added to the Target Drug list |
| 04-08-2025 | ▪ Bkemv and Epysqli added to the Target Drug list<br>▪ Added PRIOR AUTHORIZATION CLINICAL CRITERIA OPERATIONAL LEVEL OF EVIDENCE REQUIREMENTS section |
| | Medical Policy is Maintained by Prime Therapeutics LLC. |