Medical Policy

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

Title: Site of Care Infusion Management

Prior Authorization of Services may be required by Member's Contract.

Professional / Institutional
Original Effective Date: January 1, 2019
Latest Review Date: January 9, 2024
Current Effective Date: January 9, 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.

DESCRIPTION

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

Target Drugs

Alpha-1 Proteinase Inhibitors ▪ Aralast NP IV – J0256 ▪ Glassia IV – J0257 *** ▪ Prolastin-C IV –J0256 ▪ Zemaira IV – J0256	Prime will review Prior Authorization requests Please refer to the Alpha-1 Proteinase Inhibitors medical policy for the associated prescriber fax form: https://www.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/BCBSKS/Fax_Forms/Alpha1_Proteinase_Inhibitors_KS_PA.pdf
Amyotrophic lateral sclerosis (ALS) ▪ Radicava IV – J1301	Prime will review Prior Authorization requests Please refer to the Radicava medical policy for the associated prescriber fax form: https://www.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/BCBSKS/Fax_Forms/Radicava_KS_PA.pdf
Enzyme Replacement ▪ Aldurazyme IV – J1931 ▪ Cerezyme IV – J1786 ▪ Elaprase IV – J1743 ▪ Elelyso IV – J3060 ▪ Fabrazyme IV – J0180 ▪ Kanuma IV – J2840 ▪ Lumizyme IV – J0221 ▪ Mepsevii IV – J3397 ▪ Naglazyme IV – J1458 ▪ Nexviazyme IV – J0219 ▪ Vimizim IV – J1322 ▪ VPRIV IV – J3385	Prime will review Prior Authorization requests Please refer to the Lysosomal Storage Disorders medical policy for the associated prescriber fax form: https://www.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/BCBSKS/Fax_Forms/Lysosomal_Storage_Disorders_PA_MDC.pdf
Multiple Sclerosis ▪ Ocrevus IV – J2350	Prime will review Prior Authorization requests Please refer to the Healthcare Administered Multiple Sclerosis medical policy for the associated prescriber fax form: https://www.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/BCBSKS/Fax_Forms/Healthcare_Administered_Multiple_Sclerosis_KS_PA_MDC.pdf
Paroxysmal nocturnal hemoglobinuria (PNH)/atypical hemolytic uremic syndrome (aHUS)/Myasthenia Gravis ▪ Soliris IV – J1300 ▪ Ultomiris IV – J1303	Prime will review Prior Authorization requests Please refer to the Soliris and Ultomiris medical policy for the associated prescriber fax form: https://www.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/BCBSKS/Fax_Forms/Soliris_Ultomiris_KS_PA.pdf

*****Glassia is a target of this policy when covered under the medical benefit. For policies that cover Glassia through the Pharmacy benefit, Site of Care does not apply.**

See individual drug policies at the following formularies for prior authorization information.

- BlueCare/EPO Formulary (*off-site link*)
- ResultsRx Formulary (*off-site link*)
- Select Formulary (*off-site link*)

POLICY

CRITERIA FOR OUTPATIENT HOSPITAL FACILITY-BASED ADMINISTRATION

Outpatient hospital facility-based medication injection(s) may be considered medically necessary for persons who meet any one or more of the following criteria:

A. **ONE** of the following:
   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)
      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) **AND** ONE of the following:
      a. The request is for an initial medication administration of the requested agent (i.e., the individual 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 individual 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:
         i. Clinical history of cardiopulmonary conditions that may cause an increased risk of severe adverse reactions
         ii. An inability to safely tolerate intravenous volume loads, including unstable renal function
         iii. The individual has previous experience of a severe adverse event following administration of the requested agent (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure)
         iv. Unstable vascular access
         v. Physical or cognitive impairments such that administration of the requested agent in an alternative site of care would present an unnecessary health risk
         vi. The individual has continuing experience of moderate to severe adverse events during/surrounding administrations of the requested agent that cannot be mitigated by pre-medications
         OR
      d. The infusion will be given at a designated outpatient hospital facility https://www.bcbsks.com/prescription-drugs/site-of-care

B. Outpatient hospital facility-based intravenous or subcutaneous administration of the requested agent (to include the drug and administration) not meeting the above criteria will be considered **not medically necessary** and a different site of drug administration will need to be identified.

Length of Approval: For initiation or re-initiation, approve for 6 months. All others, approve for up to 12 months maximum per determination.

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.

RATIONALE

The Site of Care Infusion Management Medical Policy outlines the criteria a patient must meet in order to receive an infusion in a hospital outpatient facility and will determine medical necessity. The initial infusion of the drugs included in this policy may be given at the physician's facility of choice. All subsequent infusions 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 infusions administered at home.

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 infusions 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 considered after six months of no infusion-associated reactions. [9]

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: ▪ Updated to add Mepsevii IV - J3397 to the Enzyme Replacement drugs. ▪ Updated links to pharmacy medical policy at myprime.com added.
	Rationale section updated
	References updated

REVISIONS	
01-01-2020	Policy published 12-02-2019. Policy effective 01-01-2020.
	In Description section: ▪ Added "Amyotrophic lateral sclerosis (ALS) – Radicava IV – J1301" to Target Drugs. ▪ Added to Paroxysmal nocturnal hemoglobinuria (PNH)/atypical hemolytic uremic syndrome (aHUS)/Myasthenia Gravis "Ultomiris – J1303"
	In Policy section: ▪ In Header revised "infusions" to "administration" to read "CRITERIA FOR OUTPATIENT HOSPITAL FACILITY-BASED ADMINISTRATION" ▪ Revised "infusion" to "administration of the requested agent" throughout the policy section ▪ 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…" ▪ 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: ▪ 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. ▪ Added "Prior Authorization Form: BCBSKS reviews the Prior Authorization requests for Site of Care Infusion Management " and link to PA form.
	In Description section: ▪ 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. ▪ Added links to myprime.com for access to drug prior authorization information.
01-01-2021	Target Drugs for Multiple Sclerosis: ▪ Added Ocrevus- J2350
11-19-2021	In Policy section Deleted: ▪ The administration of the requested agent is a re-initiation after more than 6 months following discontinuation of therapy Added: ▪ 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 ▪ Added: Nexviazyme J0219
07-29-2022	Added for clarification only: Glassia is a target of this policy when covered under the medical benefit. For policies that cover Glassia through the Pharmacy benefit, Site of Care does not apply
01-09-2024	Medical Policy Maintained by Prime Therapeutics
	Updated Target Drug Table

REVISIONS	
	Updated Policy Section Added: A. ONE of the following: 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) 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) AND ONE of the following:
	Updated Rationale Section
	Updated References Section

REFERENCES

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.