Medical Policy

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

Title: Site of Care Infusion Management

- **See Target Drugs Chart for Prior Authorization requirements**
  Link to Drug List (Formulary):
  https://www.bcbsks.com/drugs/ shtml

Professional
Original Effective Date: January 1, 2019
Revision Date(s): January 1, 2019
Current Effective Date: January 1, 2019

Institutional
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Revision Date(s): January 1, 2019
Current Effective Date: January 1, 2019

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 the following list of intravenous or subcutaneous medication infusions based on the most economical place of service.

Target Drugs

Alpha-1 Proteinase Inhibitors ▪ Aralast NP IV – J0256 ▪ Glassia IV – J0257 ▪ Prolastin-C IV –J0256 ▪ Zemaira IV – J0256	BCBSKS will review Prior Authorization requests Prior Authorization Form: http://www.bcbsks.com/CustomerService/Forms/pdf/15-17_predeterm_request_frm.pdf
Enzyme Replacement ▪ Aldurazyme IV – J1931 ▪ Cerezyme IV – J1786 ▪ Elaprase IV – J1743 ▪ Elelyso IV – J3060 ▪ Fabrazyme IV – J0180 ▪ Kanuma IV – J2840 ▪ Lumizyme IV – J0221 ▪ Naglazyme IV – J1458 ▪ 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.bcbsks.com/CustomerService/Providers/MedicalPolicies/policies/policies/LysosomalStorageDisorders_2018-06-15.pdf
Paroxysmal nocturnal hemoglobinuria (PNH)/atypical hemolytic uremic syndrome (aHUS)/Myasthenia Gravis ▪ Soliris – J1300	Prime will review Prior Authorization requests Prior Authorization Form: (*PA form forthcoming*)

POLICY

CRITERIA FOR OUTPATIENT HOSPITAL FACILITY-BASED INFUSIONS

A. Blue Cross and Blue Shield of Kansas will consider an outpatient hospital facility-based intravenous or subcutaneous medication infusion from the target list of drugs (to include the drug and administration) as **medically necessary** only for persons for whom one of the following criteria have been appropriately substantiated and documented:

1. The request is for an initial medication infusion or the infusion is a re-initiation after more than 6 months following discontinuation of therapy
   OR
2. The patient is medically unstable (based upon submitted 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 infusion. Examples include but are not limited to:
   i. Documented 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 patient has previous experience of a severe adverse event following infusion (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure)
   iv. Unstable vascular access
   v. Physical or cognitive impairments such that infusion in an alternative site of care would present an unnecessary health risk
   vi. The patient has continuing experience of moderate to severe adverse events during/surrounding infusions that cannot be mitigated by pre-medications
   OR
3. The infusion will be given at a designated outpatient hospital facility.

B. Outpatient hospital facility-based intravenous or subcutaneous medication infusion (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.

Duration of approval: up to 12 months maximum per determination

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.[3-9] 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. [10]

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

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.
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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.