Balfaxar®
Prothrombin Complex Concentrate, Human-lans

BALFAXAR Reimbursement Information

BALFAXAR Hospital Reimbursement and Coding

Inpatient Setting Reimbursement

Under the Medicare hospital Inpatient Prospective Payment System (IPPS), each inpatient stay is assigned to a single Medicare Severity Diagnosis-Related Group (MS-DRG) depending on[1]:

- Patient's diagnosis
- Procedures performed
- Complicating conditions
- Age
- Sex
- Discharge status

Outpatient Pass-Through Reimbursement

Effective April 1, 2024, the Centers for Medicare and Medicaid Services (CMS) have established a product-specific HCPCS code for BALFAXAR.

Use code ICD-10-PCS when administering BALFAXAR

30283B1 *Transfusion of non-autologous 4-factor prothrombin complex concentrate into vein, percutaneous approach*

Use J-code HCPCS when administering BALFAXAR

J7165 *Injection, prothrombin complex concentrate (human), BALFAXAR, per i.u. of factor IX activity*

BALFAXAR Coding Summary[a]

Code Type	Procedure Code	HCPCS Code	Revenue Code	Diagnosis Code(s)
Hospital Inpatient Setting	ICD-10-CM Procedure Code 30283B1[b]	None	025X	Appropriate ICD-10-CM Diagnosis Code(s)
Hospital Outpatient Setting	Appropriate CPT Code for BALFAXAR admin procedure	April 1, 2024 J-code - J7165	0636 (with J-code) + revenue code for admin CPT	Appropriate ICD-10-CM Diagnosis Code(s)

Indications

BALFAXAR (prothrombin complex concentrate, human-lans) is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with need for an urgent surgery/invasive procedure.

WARNING: ARTERIAL AND VENOUS THROMBOEMBOLIC COMPLICATIONS

Patients being treated with Vitamin K antagonists (VKA) therapy have underlying disease states that predispose them to thromboembolic events. Potential benefits of reversing VKA should be weighed against the potential risks of thromboembolic events, especially in patients with the history of a thromboembolic event. Resumption of anticoagulation should be carefully considered as soon as the risk of thromboembolic events outweighs the risk of acute bleeding. Both fatal and non-fatal arterial and venous thromboembolic complications have been reported with BALFAXAR in clinical trials and post marketing surveillance. Monitor patients receiving BALFAXAR for signs and symptoms of thromboembolic events. BALFAXAR may not be suitable in patients with thromboembolic events in the prior 3 months.

Please see Important Safety Information on the back, and accompanying Full Prescribing Information, including BOXED WARNING.

BALFAXAR Urgently Reverses VKA Therapy[2]

Rapid and Sustained Reduction in INR

BALFAXAR is proven to reduce INR to ≤1.5 at 30 minutes after the end of infusion for up to 24 hours[2]

Quick, Easy, and Convenient Reconstitution

The easy-to-use nextaro® transfer device makes BALFAXAR reconstitution simple[2-4]

Prolonged Stability After Reconstitution

BALFAXAR is stable at room temperature for 8 hours after reconstitution[2,c]

Visit balfaxar.com to request more information

IMPORTANT SAFETY INFORMATION

BALFAXAR is contraindicated in patients with known anaphylactic or severe systemic reactions to BALFAXAR or any of its components. BALFAXAR is also contraindicated in patients with a known allergy to heparin, a history of heparin-induced thrombocytopenia (HIT), and IgA deficient patients with known antibodies against IgA.

In clinical trials, the most frequent (≥3%) adverse reactions observed in subjects receiving BALFAXAR were procedural pain, wound complications, asthenia, anemia, dysuria, procedural vomiting, and catheter-site-related reaction.

BALFAXAR is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

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[a]The treating physician is solely responsible for the determination of the appropriate ICD-10-CM diagnosis codes that describe the patient's condition and are supported by the medical record. All codes provided are for informational purposes and do not constitute an exhaustive list. The provided CPT®, HCPCS, ICD-10-CM, and ICD-10-PCS codes are based on AMA or CMS guidelines. The billing party is solely responsible for the coding services. Please verify current coding requirements directly with the payer being billed, as government and other third-party payer coding requirements may change.

[b]Infusion of 4F-PCC.

[c]BALFAXAR can be stored for up to 36 months at 2°C to 25°C (36°F to 77°F) from the date of manufacture.

References: 1. CMS.gov. Inpatient Prospective Payment System (IPPS). Updated December 7, 2023. Accessed January 18, 2024. https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/ipps **2.** BALFAXAR, Prothrombin Complex Concentrate (Human) Full Prescribing Information. Paramus, NJ: Octapharma USA, Inc. **3.** US Food and Drug Administration. 510K Summary: K183187. March 2019. Accessed January 18, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183187.pdf **4.** Data on File. Octapharma 2023.

Please see accompanying Full Prescribing Information, including BOXED WARNING.

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octapharma

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