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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

RETIRED
Effective Date: 10/08/2020

Andexxa® (recombinant coagulation factor Xa, inactivated-zhzo injection)

FDA approval: 05/03/2018

HCPCS: J7169, C9041

Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Reversal of anticoagulation due to life-threatening or uncontrolled bleeding for patients treated with rivaroxaban and apixaban.
- B. Quantity Limitations, Authorization Period and Renewal Criteria:
 - a. FDA labeled dosing

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

- A. **FDA approved indication / Diagnosis**
 - a. Andexxa is indicated when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding for patients treated with rivaroxaban and apixaban.
 - b. Limitation of Use: Andexxa has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban and rivaroxaban.

**Please refer to most recent prescribing information.*

- B. **Background Information**
 - a. A recombinant protein specifically designed to bind to Factor Xa inhibitors and rapidly reverse their anticoagulant effect.
 - b. First and only factor Xa inhibitor antidote for patients treated with apixaban (Eliquis®) and rivaroxaban

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

(Xarelto®).

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: Yes

**Please refer to most recent prescribing information.*

E. Dosing and administration

**Please refer to most recent prescribing information.*

F. How supplied

**Please refer to most recent prescribing information.*

References:

1. Andexxa [prescribing information]. South San Francisco, CA: Portola Pharmaceuticals Inc; 2018
2. Manufacturer press release. Available at: <https://globenewswire.com/news-release/2018/05/04/1496534/0/en/U-S-FDA-Approves-Portola-Pharmaceuticals-Andexxa-First-and-Only-Antidote-for-the-Reversal-of-Factor-Xa-Inhibitors.html>.

Policy History												
#	Date	Change Description										
1.3	Effective Date: 10/08/2020	Retiring policy as this drug is no longer managed with prior authorization										
1.2	Effective Date: 11/07/2019	Annual Review of Medical Policy										
1.1	Effective Date: 08/09/2018	Full Drug Review										
1.0	Effective Date: 08/09/2018	New Policy<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
Line of Business	PA Required (Yes/No)											
BCBS	No											
BCN	No											
MAPPO	No											
BCNA	No											

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

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