Coding Resource

INDICATION

ANDEXXA® (coagulation factor Xa [recombinant], inactivated-zhzo) is a recombinant modified human factor Xa (FXa) protein indicated for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

This indication is approved under accelerated approval based on the change from baseline in anti-FXa activity in healthy volunteers. An improvement in hemostasis has not been established. Continued approval for this indication may be contingent upon the results of studies that demonstrate an improvement in hemostasis in patients.

Limitations 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 or rivaroxaban.

The codes identified in this resource may be applicable to ANDEXXA. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of the following codes does not guarantee reimbursement.

National Drug Code (NDC) used to report ANDEXXA as required by some payers[1]

Dosage	10-digit NDC* (Prescribing Information)	11-digit NDC* (Claims forms to payers)
4 single-use vials in 1 carton, each vial containing 200 mg of ANDEXXA	0310-3200-04	00310-3200-04
5 single-use vials in 1 carton, each vial containing 200 mg of ANDEXXA	0310-3200-05	00310-3200-05

*Payers may require 10-digit NDCs to be converted to 11-digit NDCs for claims submissions. Providers are responsible for verifying formatting requirements related to the entry of NDCs on claims with payers.

Hospital Inpatient Coding and Payment

The information in this section details a general understanding of the application of certain codes to ANDEXXA. It is the provider's sole responsibility to determine the appropriate codes for any action taken in billing. This information is not intended to be definitive or exhaustive, and AstraZeneca makes no warranties or guarantees as to the accuracy or appropriateness of this information. Before filing any claim, providers should verify these requirements with specific payers.

Medicare reimbursement

- Medicare classifies each hospital inpatient stay according to a patient's main diagnoses, secondary diagnoses, procedures performed, and other factors. Medicare will then assign the case to a Medicare Severity Diagnosis Related Group (MS-DRG). MS-DRG assignment will vary based on the individual patient's presentation[2]
- Hospitals may be eligible for an outlier payment on qualified ANDEXXA claims under Medicare Part A. Medicare outlier payments do not apply to Commercial claims[3]

Hospital Inpatient Coding and Payment (cont'd)

International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) codes used to report the administration of ANDEXXA across all payers[4]

There are 2 unique ICD-10-PCS codes that may be applicable to the introduction of ANDEXXA.

ICD-10-PCS code	Description
XW03372	Introduction of Inactivated Coagulation Factor Xa into Peripheral Vein, Percutaneous Approach, New Technology Group 2
XW04372	Introduction of Inactivated Coagulation Factor Xa into Central Vein, Percutaneous Approach, New Technology Group 2

Permanent Healthcare Common Procedure Coding System (HCPCS) code used to report ANDEXXA on insurance claims across all payers[5]

ANDEXXA has a permanent HCPCS J-code that may facilitate reimbursement in all hospital inpatient departments, including those in critical access hospitals (CAHs), in the United States.

HCPCS code	Description	NDC[1]	Vial size	Billing units
J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (ANDEXXA), 10 mg	0310-3200-04	200 mg	20 units
		0310-3200-05	200 mg	20 units

IMPORTANT SAFETY INFORMATION FOR ANDEXXA® (coagulation factor Xa [recombinant], inactivated-zhzo)

WARNING: THROMBOEMBOLIC RISKS, ISCHEMIC RISKS, CARDIAC ARREST, AND SUDDEN DEATHS

Treatment with ANDEXXA has been associated with serious and life-threatening adverse events, including:

- **Arterial and venous thromboembolic events**
- **Ischemic events, including myocardial infarction and ischemic stroke**
- **Cardiac arrest**
- **Sudden deaths**

Monitor for thromboembolic events and initiate anticoagulation when medically appropriate. Monitor for symptoms and signs that precede cardiac arrest and provide treatment as needed.

Please see additional Important Safety Information throughout and full Prescribing Information including Boxed WARNING on thromboembolic risks, ischemic risks, cardiac arrest, and sudden death.

Hospital Outpatient Coding and Payment

Permanent HCPCS code used to report ANDEXXA on insurance claims across all payers[5]

ANDEXXA has a permanent HCPCS J-code that may facilitate reimbursement in all hospital outpatient departments, freestanding emergency facilities, and CAHs in the United States.

HCPCS code	Description	NDC[1]	Vial size	Billing units
J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (ANDEXXA), 10 mg	0310-3200-04	200 mg	20 units
		0310-3200-05	200 mg	20 units

HCPCS modifiers used to report an amount of ANDEXXA administered and/or discarded[5,6]

Modifiers provide a means to report or indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code. The modifiers below may be applicable in physician offices and hospital outpatient departments.

Modifier	Description	Indication and placement
JW	Drug or biological amount discarded/not administered to any patient	Unused drug remains after the applicable dose is administered from a single-use vial • Centers for Medicare & Medicaid Services (CMS) has issued a discarded drug policy requiring use of the JW modifier; other payer requirements may vary • Typically, the modifier is appended to the drug HCPCS code on a line separate from that reporting the administered dose
JZ	Zero drug amount discarded/not administered to any patient	Modifier used to report no wastage from single-use vials • CMS claims should include the JZ modifier when no wastage has occurred; other payer requirements may vary • Typically, the modifier is appended to the drug HCPCS code on the same line

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

- Arterial and venous thromboembolic events, ischemic events, and cardiac events, including sudden death, have occurred during treatment with ANDEXXA. To reduce thromboembolic risk, resume anticoagulant therapy as soon as medically appropriate following treatment with ANDEXXA. The safety of ANDEXXA has not been evaluated in subjects who experienced thromboembolic events or disseminated intravascular coagulation within two weeks prior to the life-threatening bleeding event requiring treatment with ANDEXXA. Safety of ANDEXXA also has not been evaluated in subjects who received prothrombin complex concentrates, recombinant factor VIIa, or whole blood products within seven days prior to the bleeding event.

Please see additional Important Safety Information throughout and full Prescribing Information including Boxed WARNING on thromboembolic risks, ischemic risks, cardiac arrest, and sudden death.

Hospital Outpatient Coding and Payment (cont'd)

Current Procedural Terminology (CPT®) codes used to report the administration of ANDEXXA across all payers[7]

Multiple coding options are available to report the administration of ANDEXXA. The intravenous (IV) injection and IV infusion of ANDEXXA may be reported with 1 or more of the following CPT codes in hospital outpatient sites of care, including CAHs.

Submitting accurate codes and claims is important to ensure proper reimbursement of services. The table below lists **potential** CPT codes for your reference when submitting claims for ANDEXXA. Review the individual payer's policy to obtain appropriate administration codes.

Code	Description
XXXXX	Check payer's policy to obtain appropriate administration code.
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
96375*	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366*	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour
96367*	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour

*Add-on codes must be reported with the appropriate base procedure. Please review the *CPT 2023 Professional Edition* code book and consult with individual payers for appropriate reporting requirements.

Hospitals and physicians are responsible for compliance with Medicare and other payer rules and requirements and for the information submitted with all claims and appeals. Before any claims or appeals are submitted, hospitals and physicians should review official payer instructions and requirements, confirm the accuracy of their coding or billing practices with these payers, and use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient as documented in the electronic medical record.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- Re-elevation or incomplete reversal of anticoagulant activity can occur.
- ANDEXXA may interfere with the anticoagulant effect of heparin. If anticoagulation is needed, use an alternative anticoagulant to heparin.

Please see additional Important Safety Information throughout and full Prescribing Information including Boxed WARNING on thromboembolic risks, ischemic risks, cardiac arrest, and sudden death.

ANDEXXA Dosing: Calculation of Billing Units[1]

ANDEXXA has 2 dosing regimens, both of which require an initial IV bolus followed by a continuous IV infusion.

ANDEXXA low dose

Initial IV bolus: **400 mg** Continuous IV infusion: **480 mg**	Total number of 200-mg vials: **5** **(2 vials IV bolus + 3 vials IV infusion)**	**5 vials × 20 units/vial = 100 BILLING UNITS*** 880 mg of administered drug = J7169 × 88 billing units 120 mg of discarded drug = J7169-JW × 12 billing units

ANDEXXA high dose

Initial IV bolus: **800 mg** Continuous IV infusion: **960 mg**	Total number of 200-mg vials: **9** **(4 vials IV bolus + 5 vials IV infusion)**	**9 vials × 20 units/vial = 180 BILLING UNITS*** 1760 mg of administered drug = J7169 × 176 billing units 40 mg of discarded drug = J7169-JW × 4 billing units

*Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on services performed within the medical facility.

IMPORTANT SAFETY INFORMATION (cont'd)

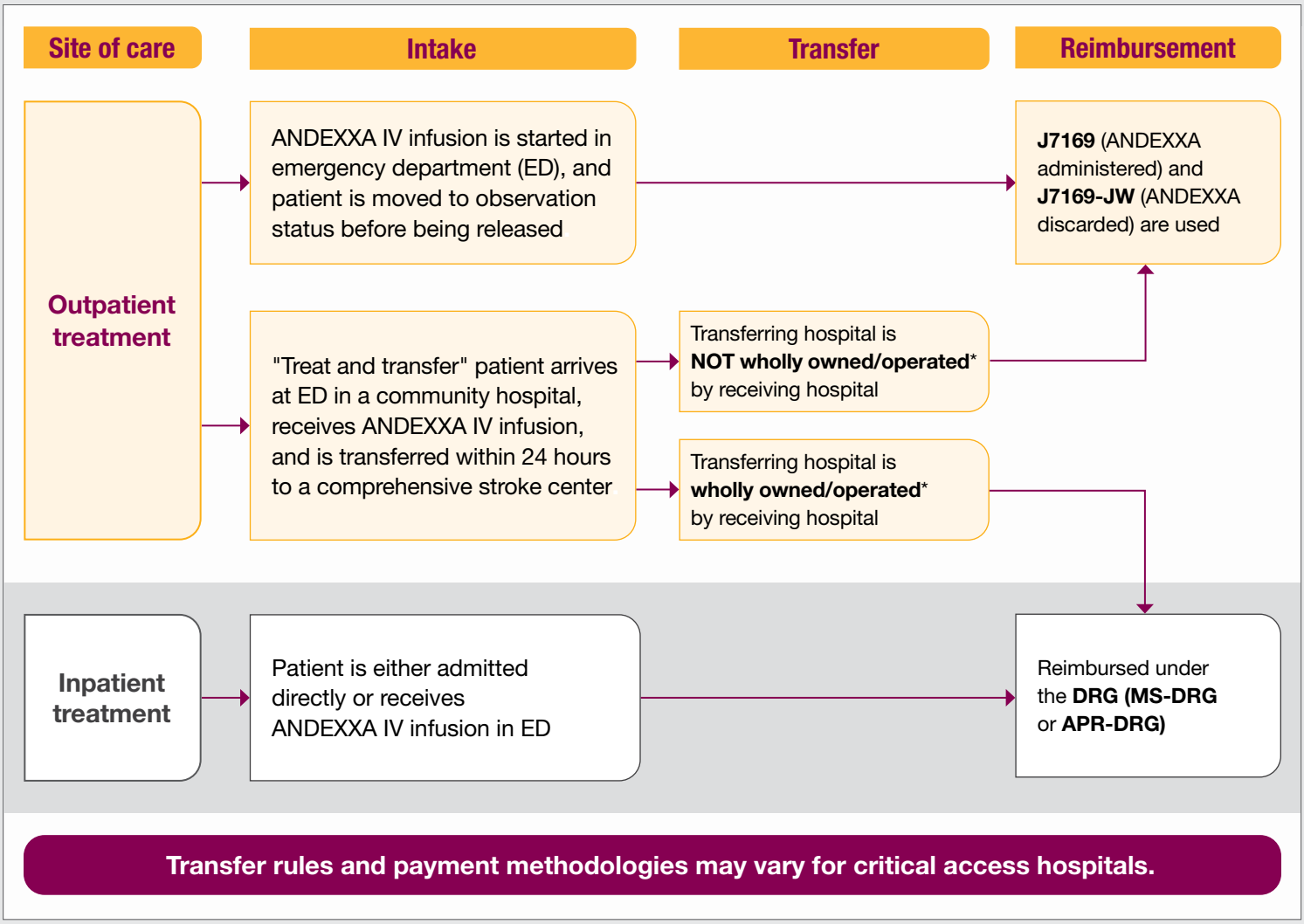
ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) in bleeding subjects receiving ANDEXXA were urinary tract infections and pneumonia. The most common adverse reactions (≥ 3%) in healthy volunteers treated with ANDEXXA were infusion-related reactions.

Please see additional Important Safety Information throughout and full Prescribing Information including Boxed WARNING on thromboembolic risks, ischemic risks, cardiac arrest, and sudden death.

Hospital Reimbursement

Examples of the hospital reimbursement process for ANDEXXA



*The transferring hospital/entity is wholly owned by the receiving hospital if the receiving hospital is the sole owner of the entity. The transferring hospital/entity is wholly operated by the receiving hospital if the receiving hospital has exclusive responsibility for conducting and overseeing the entity's routine operations.[8]

Individual payers, including Medicare, may have their own coverage pathways. Facilities, hospitals, and physicians should review official payer instructions and requirements as it is up to the facility, hospital, and/or physician to confirm accuracy of their coding or billing practices with the respective payer.

APR-DRG=All Patient Refined Diagnosis Related Group.

IMPORTANT SAFETY INFORMATION (cont'd)

INDICATION

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IMPORTANT SAFETY INFORMATION (cont'd)

INDICATION (cont'd)

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Limitations 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 or rivaroxaban.

Please see additional Important Safety Information throughout and full Prescribing Information including Boxed WARNING on thromboembolic risks, ischemic risks, cardiac arrest, and sudden death.

You may report side effects related to AstraZeneca products.

For 24/7 clinical and reconstitution support for ANDEXXA, call 1-866-ANDEXXA.

For more information, please contact AstraZeneca Access 360™ at **1-844-ASK-A360**, Monday through Friday, 8 AM - 6 PM ET.

1-844-ASK-A360 (1-844-275-2360)

www.MyAccess360.com

1-844-FAX-A360 (1-844-329-2360)

Access360@AstraZeneca.com

One MedImmune Way, Gaithersburg, MD 20878

References: 1. ANDEXXA® (coagulation factor Xa [recombinant], inactivated-zhzo) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2023. **2.** Centers for Medicare & Medicaid Services. MS-DRG classifications and software. Accessed March 20, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/ms-drg-classifications-and-software **3.** Centers for Medicare & Medicaid Services. Outlier payments. Accessed March 20, 2023. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier **4.** Centers for Medicare & Medicaid Services. 2023 ICD-10-PCS Codes. Accessed March 20, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-pcs **5.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. Accessed March 20, 2023. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update **6.** Centers for Medicare & Medicaid Services. JW modifier: drug/biological amount discarded/not administered to any patient frequently asked questions. Accessed March 20, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **7.** American Medical Association. *CPT 2023 Professional Edition*. 2022. **8.** Centers for Medicare & Medicaid Services. Frequently asked questions CR 7502. Accessed March 20, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/downloads/cr7502-faq.pdf