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PHARMACY – 5.01.657

Medical Necessity Criteria for the Essentials Formulary

Effective Date:	Jan. 1, 2026	RELATED MEDICAL POLICIES: N/A
Last Revised:	Dec. 9, 2025	
Replaces:	N/A	

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Introduction

Prior authorization and step therapy are a way to provide safe and effective drugs. In step therapy, at least one drug on the health plan's list of covered drugs (the formulary) needs to be tried first. A quantity limit is the amount of a specific drug that can be approved for a specific time period. The guideline describes the plan's prior authorization, step therapy, and quantity limits for specific drugs in the plan's formulary. This policy applies to the Essentials formulary (Rx plan E1, E3, and E4). Please refer to the member plan booklet or member ID card to determine if the policy applies.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
• **Eliquis (apixaban) oral** • **Eliquis Sprinkle (apixaban) oral**	**Eliquis (apixaban) and Eliquis Sprinkle (apixaban) may be considered medically necessary when all the following criteria are met:**

Drug	Medical Necessity

	• The individual has had an inadequate response or intolerance to Xarelto (rivaroxaban)
	AND
	• Dose for the first 7 days is limited to 10 mg twice daily and the maintenance dose is limited 5 mg twice daily
	AND
	• Quantity is limited to the following:
	  ○ 0.5 mg tablet: 32 tablets daily
	  ○ 0.15 mg capsule: 4 capsules daily
	  ○ 2.5 mg tablet: 8 tablets daily
	  ○ 5 mg tablet: 4 tablets daily

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews and all other reviews for drugs listed in this policy may be approved up to 12 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for drugs listed in this policy may be approved up to 12 months.**

Documentation Requirements
The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the relevant history and physical evaluation and medication history

Coding

N/A

Related Information

Definition of Terms

Closed formulary benefit: A closed formulary benefit is one that routinely covers only formulary (preferred) drugs. A non-formulary drug may be covered when its use has been determined to be medically necessary after a review of the individual clinical case circumstances.

Formulary: A formulary is a list of drugs approved by the Pharmacy and Therapeutics Committee (P&T) for routine use. A well-designed formulary should provide adequate drug selection to meet the treatment needs of most individuals; however, there will always be exceptional cases where a non-formulary drug may be the best therapeutic choice.

Formulary drug: A formulary drug (also known as a preferred drug) is a drug that is on the formulary list. Drugs that are not on the list are referred to as non-formulary drugs.

Label: Product label refers to the FDA approved prescribing information that is available for every legend drug approved for use in the US. The label includes indications, contraindications, recommended dosing, warnings, precautions, side effects, drug interactions and information on safety in pregnancy and other special populations. The drug's pharmacology, pharmacokinetics, and available dosage forms are also provided. The current format also includes a summary of the pivotal clinical trials that were submitted to FDA in support of the New Drug Application. This prescribing information is included as a package insert with the product and is available on the manufacturer's website.

Quantity limits: A quantity limit is the maximum amount of a medication that may be dispensed during a given calendar period or at one prescription fill without an exception request. Dispensing of a larger quantity may be approved, based on individual case review. A specified larger quantity may be approved when individual-specific circumstances require it, or when published clinical evidence supports a higher dose protocol.

Note: Dispensing quantity limits are not intended to apply in circumstances where logistics may dictate otherwise. These circumstances include but are not limited to member vacation or business travel, disruption of normal prescription supply chains due to adverse weather events or other disasters and members living in remote areas where travel to the nearest pharmacy may sometimes be problematic.

Step therapy: A step therapy edit is a requirement that one or more specified first step agents be tried and failed before coverage will be provided for another second step agent. Step therapy requirements are based upon evidence from published, peer-reviewed clinical studies demonstrating that first-line use of the first step agents is clinically reasonable in most circumstances.

Benefit Application

The drugs addressed in this policy are managed through the pharmacy benefit.

Evidence Review

Eliquis (apixaban)

The EMANATE trial evaluates Eliquis versus standard of care (parental heparin and/or warfarin) in the treatment of atrial fibrillation individuals undergoing cardioversion. Fewer strokes and similar bleeding events were observed in individuals treated with Eliquis 5 mg twice daily (or 2.5 mg in those ≥80 years, ≤60 kg, or with serum creatinine ≥1.5 mg/dl) compared with those treated with parenteral heparin and warfarin. No strokes were reported in the Eliquis-treated group (n=753), compared with six stroked in the warfarin group (n=747). Major bleeding events occurred in 3 individuals treated with Eliquis and 6 treated with warfarin. Like other prospective cardioversion studies, researchers noted that the study was underpowered, but that the results support the use of Eliquis in this population.

Xarelto (rivaroxaban)

The Phase 3 NAVIGATE ESUS study, evaluating Xarelto for the secondary prevention of stroke and systemic embolism in individuals with a recent embolic stroke of undetermined source (ESUS), showed comparable efficacy between rivaroxaban and the standard of care, aspirin, but was determined to have little chance of rivaroxaban showing an overall benefit versus aspirin had the study been completed. While bleeding rates were very low overall, an increase in bleeding was observed in the rivaroxaban arm compared to aspirin.

The EINSTEIN CHOICE study that evaluated Xarelto 10 mg and 20 mg doses compared to 100 mg of aspirin in the extended treatment of VTE. The study concluded that individuals treated with Xarelto at either dose had a lower risk of a recurrent event than with aspirin. Bleeding rates were similar in all three groups with major bleeds in 0.5% and 0.4% of the 20 mg and 10 mg Xarelto groups, respectively. In the aspirin group, the rate of major bleed was 0.3%. A similar trend was also observed in clinically relevant nonmajor bleeding.

The COMPASS study, evaluating rivaroxaban alone or in combination with aspirin compared to aspirin alone for secondary cardiovascular prevention (composite of cardiovascular death, stroke, or myocardial infarction), was halted early due to efficacy, as the primary endpoint reached its pre-specified criteria for superiority. Among individuals with stable atherosclerotic vascular disease, those receiving rivaroxaban 2.5 mg twice daily plus aspirin had better cardiovascular outcomes and more major bleeding than those using aspirin alone. Rivaroxaban alone (5 mg twice daily) did not result in better cardiovascular outcomes than aspirin alone and resulted in more major bleeding events.

References

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3. Funkenstein A, Malowney M, Boyd JW. Insurance Prior Authorization Approval Does Not Substantially Lengthen the Emergency Department Length of Stay for Patients With Psychiatric Conditions Ann Emerg Med 2013;61(5):596-597.
4. Hoadley JF, Merrell K, Hargrave E, et al. In Medicare Part D plans, low or zero copay and other features to encourage the use of generics could save billions. Health Aff (Millwood) 2012;31(10):2266-2275.
5. Lu CY, Law MR, Soumerai SB, et al. Impact of prior authorization on the use and costs of lipid-lowering medications among Michigan and Indiana dual enrollees in Medicaid and Medicare: results of a longitudinal, population-based study. Clin Ther. 2011;33(1):135-44.
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7. 21 CFR 201.5: Labeling Requirements for Prescription Drugs. Adequate Directions for Use. Available at **http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201**. Accessed December 3, 2025.
8. Eliquis (apixaban). Prescribing Information. Bristol-Myers Squibb. Princeton, NJ. Revised May 2025.

History

Date	Comments
01/01/26	New policy, approved December 9, 2025. Added coverage criteria for Eliquis (apixaban).

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.