Pharmacy Medical Necessity Guidelines:
Platelet Aggregation Inhibitors

Effective: November 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Brilinta (ticagrelor) is a $P2Y_{12}$ platelet inhibitor indicated to reduce the rate of cardiovascular death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI. For at least 12 months following ACS, it is superior to clopidogrel. Brilinta (ticagrelor) also reduces the rate of stent thrombosis in patients who have been stented for treatment of ACS.

Brilinta is also indicated to reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. While use is not limited to this setting, the efficacy of Brilinta was established in a population with type 2 diabetes (T2DM).

Additionally, Brilinta is indicated to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤5) or high-risk transient ischemic attack (TIA).

Zontivity (vorapaxar) is a protease-activity receptor-1 (PAR-1) antagonist indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease. Zontivity has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization. Zontivity should be used in combination with clopidogrel and/or aspirin according to their indications or standard of care. There is limited clinical experience with other antiplatelet drugs and none with Zontivity as the only antiplatelet agent.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred platelet aggregation inhibitor for Members, when **ALL** of the following criteria are met:

Ticagrelor (Brilinta)

Acute Coronary Syndrome

1. The Member meets one of the following:
    a. The Member is diagnosed with acute coronary syndrome or has a history of myocardial infarction

    OR

    b. Documentation the Member has been stented for treatment of acute coronary syndrome

    AND

2. Member has been started and stabilized on ticagrelor in the hospital

    OR

    Member had an inadequate response, intolerance, or contraindication to a trial with one of the following: clopidogrel or prasugrel

Coronary Artery Disease (CAD)

1. The Member has a diagnosis of coronary artery disease (CAD)

    AND

2. The Member is at high risk of myocardial infarction (MI) or stroke

Acute Ischemic Stroke or Transient Ischemic Attack

1. The Member has had an acute ischemic stroke or a transient ischemic attack (TIA)

Zontivity (vorapaxar)

1. Member has a diagnosis of either acute coronary syndrome or peripheral arterial disease

AND

2. Zontivity is being used in combination with ONE of the following: clopidogrel or aspirin

LIMITATIONS

1. Requests for brand-name products, with AB-rated generics, will also be reviewed according to the Brand name criteria.

CODES

None

REFERENCES

1. Brilinta (ticagrelor) [prescribing information]. Wilmington, DE: AstraZeneca LP.; March 2024 .
2. Cutlip D, Lincoff AM. Acute non-ST-elevation acute coronary syndromes: early platelet therapy. UpToDate. www.uptodate.com. Accessed 7 August 2023.
3. Jneid H, Anderson JL, Wright RS, et al. 2012 ACCF/AHA focused update of the guideline for the management of patients with unstable angina/non-ST-elevation myocardial infarction (updating the 2007 guideline and replacing the 2011 focused update): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2012 Aug 14;60(7):645-81.
4. Levine GN, Bates ER, Bittl JA, et al. 2016 ACC/AHA guideline focused update on duration of dual antiplatelet therapy in patients with coronary artery disease. *Circulation.* 2016;134(10):e123-e155.
5. Lincoff AM, Cutlip D. Acute ST-elevation myocardial infarction: antiplatelet therapy. UpToDate. Available at: www.uptodate.com. Accessed 7 August 2023.
6. Smith SC Jr, Benjamin EJ, Bonow RO, et al. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: a guideline from the American Heart Association and American College of Cardiology Foundation endorsed by the World Health Federation and the Preventive Cardiovascular Nurses Association. *J AM Coll Cardiol*. 2011 Nov 29;58(23):2432-46.
7. Wallentin L, Becker RC, Budaj A, et al. Ticagrelor versus clopidogrel in patients with acute coronary syndromes. *N Engl J Med* 2009;361:1045-57.
8. Vandvik PO, Lincoff AM, Gore JM, et al. Primary and secondary prevention of cardiovascular disease: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians. *Chest*. 2012;141:2 suppl e637S-e668S.
9. Zontivity (voraxapar) [prescribing information]. Ridgeland, MS: WraSer Pharmaceuticals; October 2022.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: No changes.
2. September 10, 2024: Administrative update to overview and fax number update.
3. September 9, 2025: No changes
4. October 13, 2026: Effective November 1, 2026, updated MNG to reflect generic availability of Brilinta by referencing of generic name throughout the coverage criteria and adding the following statement to Limitations, "Requests for brand-name products, with AB-rated generics, will also be reviewed according to the Brand name criteria".

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic. Provider Services