



## Prior Authorization Approval Criteria

Brilinta (Ticagrelor)

**Generic name:** Ticagrelor

**Brand name:** Brilinta

**Medication class:** Platelet Aggregation Inhibitor

**FDA-approved uses:** Indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (Unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction)

**Available dosage forms:** 90 mg tablets

**Usual dose:** 180 mg (two 90 mg tablets) loading dose with aspirin (usually 325 mg once daily); Continue with 90 mg twice daily with aspirin (75 mg to 100mg once daily)

**Approximate Monthly cost:** \$260.78 (60 tablets)/ \$4.34 unit price  
(Based on AWP 2011)

**Duration of therapy:** To be determined based on patients clinical needs

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must have ACS (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction).
- Must have tried and failed Plavix (clopidogrel)
- Maintenance doses of aspirin must be between 75mg-100mg (aspirin doses greater than 100mg reduce the effectiveness of ticagrelor and should be avoided)

**Caution:**

- **Bleeding risk:** Ticagrelor can cause significant, sometimes fatal, bleeding. Do not use in patients with active pathological bleeding or a history of intracranial hemorrhage. Do not start ticagrelor in patients planned to undergo urgent CABG surgery. When possible, discontinue at least 5 days prior to any surgery.

Suspect bleeding in any patient who is hypotensive and has recently undergone coronary angiography, percutaneous coronary intervention, CABG, or other surgical procedures in the setting of ticagrelor. If possible, manage bleeding without discontinuing ticagrelor. Discontinuing ticagrelor increases the risk of subsequent CV events.

- **Aspirin dose and ticagrelor effectiveness:** Maintenance doses of aspirin above 100 mg reduce the effectiveness of ticagrelor and should be avoided.

**Monitoring:**

- Monitor for bleeding and dyspnea.

**Contraindication:**

- Patients with history of intracranial hemorrhage (ICH) because of high risk of recurrent ICH in this population
- Patients with active pathological bleeding such as peptic ulcers or intracranial hemorrhage
- Patients with severe hepatic impairment because of probable increase in exposure, and it has not been studied in these patients

**Not approved if:**

- If above guidelines are not met
- If the patient has any contraindications to Brilinta

**Special considerations:**

- No adequate and well controlled studies of Brilinta use in pregnant women
- It is not known if active metabolites are excreted in human milk
- Safety and effectiveness of Brilinta in pediatric patients have not been established
- Avoid using with strong inhibitors of CYP3A or potent inducers of CYP3A
- Brilinta achieved more rapid and greater platelet aggregation inhibition than high-loading dose clopidogrel in patients with stable coronary artery disease. However, higher bleeding was observed as compared to clopidogrel

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 12/14/11