

Clinical Pharmacy Program Guidelines for Brilinta and Effient

Program	Prior Authorization
Medication	Brilinta (ticagrelor), Effient (prasugrel)
Issue Date	1/2010
Pharmacy and Therapeutics Approval Date	1/2017
Effective Date	11/2017

1. Background:

Brilinta is indicated to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI).

Effient is indicated to reduce the rate of thrombotic cardiovascular (CV) events (including stent thrombosis) in patients with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI) as follows:

- Patients with unstable angina (UA) or non-ST-elevation myocardial infarction (NSTEMI).
- Patients with ST-elevation myocardial infarction (STEMI) when managed with primary or delayed PCI.

2. Coverage Criteria:

A.	<p><u>Brilinta</u></p> <p>1. Brilinta will be approved based the following:</p> <p style="padding-left: 40px;">a. Diagnosis of acute coronary syndrome (ACS) [eg. unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI) or ST-segment elevation myocardial infarction (STEMI)]</p> <p style="text-align: center;">Authorization will issued for 12 months</p>
B.	<p><u>Effient</u></p> <p>1. Effient will be approved based on both of the following:</p> <p style="padding-left: 40px;">a. Diagnosis of acute coronary syndrome (ACS) [eg. unstable angina</p>

(UA), non-ST elevation myocardial infarction (NSTEMI) or ST-segment elevation myocardial infarction (STEMI)]

-AND-

b. Patient managed with percutaneous coronary intervention (PCI)

Authorization will be issued for 12 months.

3. References:

1. Brilinta [package insert]. AstraZeneca LP. Wilmington, DE. September 2016.
2. Wallentin L, Becker RC, Budaj A, et al. Ticagrelor versus clopidogrel in patients with acute coronary syndromes. *N Eng J Med* 2009;361:1045-57.
3. American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2011 ACCF/AHA focused update of the guidelines for the management of patients with unstable angina/non-ST-elevation myocardial infarction (updating the 2007 guideline). *J Am Coll Cardiol.* 2011;57:1920-59.
4. American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2013 focused updates: ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction. *J Am Coll Cardiol.* 2013;61(4):e78-e140.
5. Effient [package insert]. Indianapolis, IN: Eli Lilly and Company; July 2016.
6. American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients With Coronary Artery Disease. *J Am Coll Cardiol.* 2016;68(10).

Program	Prior Authorization
Change Control	
Date	Change
January 2010	New Policy
March 2011	Annual Review
Dec 2011	Added new drug Brilinta to policy.
Dec 2012	Annual Review

March 2015	<p>Updated criteria template</p> <p>Brilinta criteria: added additional criteria that maintenance dose of aspirin should not exceed 100 mg per day</p> <p>Effient criteria removed the following requirements:</p> <ul style="list-style-type: none"> • The patient does not have active pathological bleeding or history of transient ischemic attack or stroke • If patient is ≥ 75 years of age, patient must have diabetes or history of prior MI
November 2016	Annual review, updated policy template
March 2017	Updated Brilinta authorization duration language. Updated references and template.
September 2017	Removed maintenance dose of aspirin requirement for Brilinta to allow for Dx to Rx implementation