

Clinical Pharmacy Program Guidelines for Brilinta and Effient

Program	Prior Authorization
Medication	Brilinta (ticagrelor), Effient (prasugrel)
Markets in Scope	Arizona, CA, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, South Carolina
Issue Date	1/2010
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	1/2021

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). It 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.

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.

Brilinta has black box warnings for bleeding and aspirin coadministration. Effient has a black box warning for bleeding. Please see full prescribing information for additional details.

2. Coverage Criteria:

<p>A. <u>Brilinta</u></p> <p>1. Brilinta will be approved based on one of the following:</p> <p style="padding-left: 40px;">a. Diagnosis of acute coronary syndrome (ACS) [e.g., unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI) or ST-segment elevation myocardial infarction (STEMI)]</p>

-OR-

- b. To reduce the risk of a first myocardial infarction (MI) or stroke in patients with coronary artery disease (CAD) at high risk for such events [e.g., type 2 diabetes mellitus, hypertension, dyslipidemia, multi-vessel CAD, obesity, heart failure, current smoking or chronic kidney disease]

Authorization will be issued for 12 months.

B. Effient

- 1. **Effient** will be approved based on both of the following:
 - a. Diagnosis of acute coronary syndrome (ACS) [e.g., unstable angina (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. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

3. References:

- 1. Brilinta [Package Insert]. Wilmington, DE: AstraZeneca LP; September 2020.
- 2. Effient [Package Insert]. Indianapolis, IN: Eli Lilly and Company; September 2020.

Program	Prior Authorization
Change Control	
Date	Change

1/2010	New Policy
3/2011	Annual Review
12/2011	Added new drug Brilinta to policy.
12/2012	Annual Review
3/2015	<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
11/2016	Annual review, updated policy template
3/2017	Updated Brilinta authorization duration language. Updated references and template.
9/2017	Removed maintenance dose of aspirin requirement for Brilinta to allow for Dx to Rx implementation
10/2018	Annual review. Updated references.
11/2019	Annual review. Updated references.
11/2020	Added new indication for Brilinta for reduction of risk of MI or stroke in patients with CAD and high-risk factors. Updated background and references. Added additional clinical rules section.