



## Prior Authorization Approval Criteria

### *Effient (prasugrel)*

**Generic name:** prasugrel

**Brand name:** Effient

**Medication class:** antiplatelet agents, aggregation inhibitor

**FDA-approved uses:** Platelet inhibitor indicated for the reduction of thrombotic cardiovascular 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 or, non-ST-elevation myocardial infarction (NSTEMI) or patients with ST-elevation myocardial infarction (STEMI) when managed with either primary or delayed PCI.

**Available dosage forms:** 5mg and 10mg tablets

**Usual dose:** 60mg loading dose. Continue at 10mg once daily. Patients that weigh less than 60kg may need 5mg once daily. Patients should also take aspirin 75mg-325mg daily.

**Approximate monthly cost:** 10mg once daily \$196.20/month  
(based on AWP 2009)

**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 and are going to be managed with PCI as follows:
  - Patients with unstable angina or NSTEMI
  - or
  - Patients with STEMI when managed with primary or delayed PCI
- Must be < 75 years of age unless they are high risk patients (diabetes or prior MI).
- Patient must not have active pathological bleeding
- Patient must not have a history of mini-strokes (transient ischemic attacks) or stroke.
- Patient must weigh more than 60kg.

**Caution:**

- CABG- related bleeding: Risk increases in patients receiving Effient who undergo CABG.
- Discontinuation of Effient: Premature discontinuation increases risk of stent thrombosis, MI and death.
- Must stop use 7 days prior to surgery.
- In patients  $\geq$  75 years of age, Effient is generally not recommended because of the increased risk of fatal and intracranial bleeding and uncertain benefits, except in high risk patients (diabetes or prior MI), where its effect appears to be greater and its use may be considered.
- Suspect bleeding in any patient who is hypotensive and has recently undergone coronary angiography, percutaneous coronary intervention (PCI), CABG, or other

- surgical procedures in the setting of Effient.
- Additional risk factors for bleeding include:
  - Body weight < 60kg
  - Propensity to bleed
  - Concomitant use of medications that increase the risk of bleeding

**Contraindication:**

- Active pathological bleeding
- Prior transient ischemic attack or stroke

**Not approved if:**

- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of Effient.

**Special considerations:**

- For every 1000 patients, there are 23 fewer heart attacks and 6 more causes of major bleeding with Effient compared to clopidogrel.
- In the major clinical trial upon which approval was based, life threatening bleeding occurred in 1.3% of patients, fatal bleeding occurred in 0.3% of patients, and major or minor bleeding occurred in 4.5% of patients. These events were all non-CABG-related bleeding.

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

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

Adopted: 12/09/09

Revised: 03/10/10