

Policies Repository



Policy Title Prasugrel (Effient™)

Policy Number FS.CLIN.16

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Prasugrel (Effient™) is a P2Y12 platelet inhibitor indicated for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are to be managed with PCI as follows:

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

The use of prasugrel (Effient™) requires prior authorization (ie, clinical pharmacy and/or Medical Director review) to determine medical necessity.

Policy Description

Prasugrel (Effient™) is a member of the thienopyridine class of irreversible inhibitors of the adenosine diphosphate (ADP) receptor on platelet cell membranes (P2Y12). The blockade of P2Y12 inhibits platelet aggregation by blocking activation of the glycoprotein IIb/IIIa pathway.

The results of the TRITON-TIMI 38 study showed that prasugrel taken with aspirin reduced risk of combined endpoint of cardiovascular death, non-fatal MI or non-fatal stroke by 19% more than clopidogrel (Plavix®) taken with aspirin; however, there was also an increase in bleeding and concerns of related deaths in the treatment arm and more cancers discovered in the prasugrel group compared to clopidogrel in the TRITON study. The risk of bleeding was highest in prasugrel-treated patients who were either 75 years of age or older, weighed less than 132 pounds (60 kg), or who had a prior history of transient ischemic attacks (TIA) or stroke.

Policy Guideline Inclusion

Prasugrel (Effient™) is approved when the following inclusion criterion is met:

- Documentation of a diagnosis of acute coronary syndrome (ACS) in patients who are to be managed with Percutaneous Coronary Intervention (PCI)

Policy Guideline Exclusion

Prasugrel (Effient™) is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of acute coronary syndrome (ACS)
- No documentation that patient is to be managed with Percutaneous Coronary Intervention (PCI)

Policy List of Applicable Drugs

Brand Name	Generic Name
Effient	prasugrel

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

Prasugrel (Effient™). Micromedex Healthcare. Greenwood Village, CO: Thomson MICROMEDEX. Accessed December 30, 2010

Montalescot G, Wiviott SD, Braunwald E, et al: Prasugrel compared with clopidogrel in patients undergoing percutaneous coronary intervention for ST-elevation myocardial infarction (TRITON-TIMI 38): double-blind, randomised controlled trial. Lancet 2009; 373 (9665):723-731.

Wiviott SD, Braunwald E, McCabe CH, et al: Intensive oral antiplatelet therapy for reduction of ischaemic events including stent thrombosis in patients with acute coronary syndromes treated with percutaneous coronary intervention and stenting in the TRITON-TIMI 38 trial: a subanalysis of a randomised trial. Lancet 2008; 371 (9621):1353-1363.

Effient [package insert]. Indianapolis, IN: Eli Lilly & Co; December 2010.

Prasugrel (Effient™) In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed December 30, 2010.

Policy Link to Related Policies

Printed

01/04/2011 10:23:06

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