VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Effient®(Prasugrel)

Effective Date: 1/31/12
Date Developed: 12/20/11 by Albert Reeves MD
Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19
(Archived 1/22/19)

Effient (Prasugrel) is an Antiplatelet Agent; Antiplatelet Agent, Thienopyridine

Pre-Authorization Criteria: treatment to reduce the rate of thrombotic cardiovascular events (e.g. stent thrombosis) in patients who are to be managed with percutaneous coronary intervention (PCI) for unstable angina, non-ST-segment elevation MI (NSTEMI), or ST-elevation MI (STEMI).

Dosing: Adult

Acute coronary syndrome managed with PCI: Oral: Loading dose: 60 mg administered promptly (as soon as coronary anatomy is known or before if risk for bleeding is low and need for CABG considered unlikely) and no later than 1 hour after PCI; Maintenance dose: 10 mg once daily (in combination with aspirin 81-325 mg/day). **Note:** In patients weighing <60 kg, the manufacturer suggests to consider decreasing maintenance dose to 5 mg once daily; however, prospective clinical trial data does not exist to support this recommendation and may place some patients at risk of thrombotic complications (eg, stent thrombosis); consider use of full dose while monitoring closely for bleeding complications or administration of an alternative agent (eg, clopidogrel).

Duration of prasugrel (in combination with aspirin) after stent placement:
Premature interruption of therapy may result in stent thrombosis with subsequent fatal and nonfatal MI. With STEMI, prasugrel for at least 12 months regardless of stent type (ie, either bare metal or drug eluting stent) is recommended (Kushner, 2009). With UA/NSTEMI, at least 12 months of prasugrel regardless of stent type is recommended and for up to 15 months unless the risk of bleeding outweighs the benefits (Wright, 2011). In either setting, a duration >15 months may be considered in patients with DES placement (Kushner, 2009; Wright 2011).

Dosing: Geriatric

Refer to adult dosing. Patients ≥75 years: Use not recommended; may be considered in high-risk situations (eg, patients with diabetes or history of MI).

Dosage Forms: U.S.

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Tablet, extended release, oral: Effient®: 5 mg, 10 mg

Administration

Administer without regard to meals.

WARNINGS / PRECAUTIONS

Concerns related to adverse effects:

Bleeding: **[U.S. Boxed Warning]: May cause significant or fatal bleeding.** Use is contraindicated in patients with active pathological bleeding or history of TIA or stroke. Additional risk factors for bleeding include age ≥75 years, propensity to bleed (eg, recent trauma or surgery, recent or recurrent GI bleeding, active PUD, severe hepatic impairment), body weight <60 kg, CABG or other surgical procedure, concomitant use of medications that increase risk of bleeding (eg, warfarin, NSAIDs). Bleeding should be suspected if patient becomes hypotensive after undergoing

recent coronary angiography, PCI, CABG, or other surgical procedure even if overt signs of bleeding do not exist; if possible, do not discontinue prasugrel. Management of bleeding episodes includes the use of PRBCs and platelet transfusion.

Thrombotic thrombocytopenic purpura (TTP): Cases of thrombotic thrombocytopenic purpura (usually occurring within the first 2 weeks of therapy), resulting in some fatalities, have been reported with other thienopyridines; urgent plasmapheresis is required.

Disease-related concerns:

Hepatic impairment: No dosage adjustment is necessary in patients with mild-to-moderate hepatic impairment; use with caution in patients with severe hepatic impairment (patients not studied and may be at higher risk of bleeding).

Renal impairment: No dosage adjustment is necessary; use with caution in patients with end-stage renal disease (experience is limited).

DRUG Interactions

(For additional information: Launch Lexi-Interact™ Drug Interactions Program)

Anticoagulants: Antiplatelet Agents may enhance the anticoagulant effect of Anticoagulants. *Risk C: Monitor therapy*

Antiplatelet Agents: May enhance the anticoagulant effect of other Antiplatelet Agents. *Risk C: Monitor therapy*

Collagenase (Systemic): Antiplatelet Agents may enhance the adverse/toxic effect of Collagenase (Systemic). Specifically, the risk of injection site bruising and/or bleeding may be increased. *Risk C: Monitor therapy*

CYP3A4 Inhibitors (Strong): May decrease serum concentrations of the active metabolite(s) of Prasugrel. *Risk C: Monitor therapy*

Dasatinib: May enhance the anticoagulant effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Drotrecogin Alfa: Antiplatelet Agents may enhance the adverse/toxic effect of Drotrecogin Alfa. Bleeding may occur. Management: When possible, avoid use of drotrecogin within 7 days of use of any IIb/IIIa antagonists, higher dose aspirin (more than 650 mg/day), or use of other antiplatelet agents. *Risk D: Consider therapy modification*

Glucosamine: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Herbs (Anticoagulant/Antiplatelet Properties) (eg, Alfalfa, Anise, Bilberry): May enhance the adverse/toxic effect of Antiplatelet Agents. Bleeding may occur. *Risk D: Consider therapy modification*

Ibritumomab: Antiplatelet Agents may enhance the adverse/toxic effect of Ibritumomab. Both agents may contribute to impaired platelet function and an increased risk of bleeding. *Risk C: Monitor therapy*

Nonsteroidal Anti-Inflammatory Agents: May enhance the adverse/toxic effect of Antiplatelet Agents. An increased risk of bleeding may occur. Nonsteroidal Anti-Inflammatory Agents may diminish the cardioprotective effect of Antiplatelet Agents. This interaction is likely specific to aspirin, and not to other antiplatelet agents. *Risk C: Monitor therapy*

Omega-3-Acid Ethyl Esters: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Pentosan Polysulfate Sodium: May enhance the adverse/toxic effect of Antiplatelet Agents. Specifically, the risk of bleeding may be increased by concurrent use of these agents. *Risk C: Monitor therapy*

Pentoxifylline: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Prostacyclin Analogues: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Ranitidine: May decrease serum concentrations of the active metabolite(s) of Prasugrel. *Risk C: Monitor therapy*

Rifampin: May diminish the antiplatelet effect of Prasugrel. *Risk C: Monitor therapy*

Rivaroxaban: Antiplatelet Agents may enhance the anticoagulant effect of Rivaroxaban. Management: Avoid concurrent use of clopidogrel with rivaroxaban unless the anticipated benefits outweigh the risks of bleeding. Avoid concurrent use of rivaroxaban with other antiplatelet agents whenever possible. *Risk D: Consider therapy modification*

Salicylates: Antiplatelet Agents may enhance the adverse/toxic effect of Salicylates. Increased risk of bleeding may result. *Risk C: Monitor therapy*

Thrombolytic Agents: Antiplatelet Agents may enhance the anticoagulant effect of Thrombolytic Agents. *Risk C: Monitor therapy*

Tocilizumab: May decrease the serum concentration of CYP3A4 Substrates. *Risk C: Monitor therapy*

Tositumomab and Iodine I 131 Tositumomab: Antiplatelet Agents may enhance the adverse/toxic effect of Tositumomab and Iodine I 131 Tositumomab.

Specifically, the risk of bleeding-related adverse events may be increased. *Risk C: Monitor therapy*

Vitamin E: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

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Revision History:
Date Reviewed/No Updates: 1/16/13 by A. Reeves MD
Date Approved by P&T Committee: 1/31/12; 1/29/13
Date Reviewed/No Updates: 1/28/14 by C. Sanders MD
Date Approved by P&T Committee: 1/28/14
Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
Date Approved by P&T Committee: 1/27/15
Date Reviewed/Updated: 3/10/15 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/26/16
Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/24/17
Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/23/18
Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review

1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check ESI