

Prior Authorization DRUG Guidelines

PLAVIX® (clopidogrel)

Effective Date: 10/27/05

Date Developed: 9/9/05 by C. Wilhelmy MD

Last Approval Date: 1/26/16, 1/24/17, 1/22/19, 2/18/20, 2/2/21, 2/1/22,
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Clopidogrel is an antiplatelet agent. It blocks the ADP receptors, which prevents fibrinogen binding at that site and thereby reduce the possibility of platelet adhesion and aggregation due to inactivation of the GPIIb/IIIa receptor complex. It thereby reduces atherosclerotic events (myocardial infarction, stroke, vascular deaths) in patients with atherosclerosis documented by recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease. Platelets blocked by clopidogrel are affected for the remainder of their lifespan (~7 to 10 days).

Pre-Authorization Criteria

Acute coronary syndrome:

ST-segment elevation myocardial infarction: To reduce the rate of myocardial infarction (MI) and stroke in conjunction with aspirin in patients who are to be managed medically.

Non-ST-segment elevation acute coronary syndromes (unstable angina/non-ST-elevation MI): To decrease the rate of MI and stroke in conjunction with aspirin in patients who are to be managed medically or with coronary revascularization.

Recent myocardial infarction, Recent ischemic stroke, or established peripheral atherosclerotic disease: To reduce the rate of MI and stroke in patients with a history of recent MI, recent stroke, or established peripheral atherosclerotic disease.

Off-Label Use:

Symptomatic carotid artery atherosclerosis; Carotid artery stenting; Coronary artery bypass graft surgery; Percutaneous coronary intervention for stable ischemic heart disease; Stable ischemic heart disease; Thromboprophylaxis (Transcatheter aortic valve replacement; Transcatheter mitral valve repair with MitraClip device)

DOSING: ADULTS

Recent MI, recent stroke, or established arterial disease: Oral: 75 mg once daily.

Acute coronary syndrome:

Unstable angina, non-ST-segment elevation myocardial infarction (UA/NSTEMI):

Initial: 300 or 600 mg loading dose, followed by 75 mg once daily for at least 1 month and ideally up to 12 months (in combination with aspirin 75-162 mg once daily indefinitely) (Wright, 2011)

ST-segment elevation myocardial infarction (STEMI): 75 mg once daily (in combination with aspirin 162-325 mg initially followed by 81-162 mg/day).

Note:-

NOTE:—If using fibrinolytic therapy for reperfusion: initiate therapy with a 300 mg loading dose

NOTE:—If using percutaneous coronary intervention for reperfusion (alternative agent) (off-label use): initiate therapy with a 600 mg loading dose

Prevention of coronary artery bypass graft closure (saphenous vein): Aspirin-allergic patients (unlabeled use) [*Chest* guidelines, 2008]: Loading dose: 300 mg administered 6 hours following procedure; maintenance: 75 mg/day

Duration of therapy: Clopidogrel plus aspirin (dual antiplatelet therapy [DAPT]) should be continued for ≥ 12 months unless bleeding is a concern. If there have been no major bleeding complications after 12 months, continuation of DAPT may be considered.

MONITORING PARAMETERS — Signs of bleeding; hemoglobin and hematocrit periodically.

DRUG INTERACTIONS — Substrate (minor) of CYP1A2, 3A4; Inhibits CYP2C8/9 (weak). ,

PATIENT EDUCATION — Report any unusual or prolonged bleeding or fever; inform your prescriber before starting any new medications, changing your diet, or undergoing any

procedures that may be associated with a risk of bleeding.

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1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/1/18	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – excluded from the Formulary effective 1/1/18
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			For Exception Review Use Only Annual Review
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
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8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated preauthorization criteria, duration of therapy and references. Formatting changes
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Added "Platelets blocked by clopidogrel are affected for the remainder of their lifespan (~7 to 10 days)" in the description. Updated patient education and references sections.