JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS074
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		Review Date	10/18/2023
	Subject **Brilinta**	*Revision Date*	10/18/2023
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Brilinta

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I. POLICY

A. Brilinta® (ticagrelor) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Brilinta** may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing one of the following:
      a. **Diagnosis of acute coronary syndrome (ACS)** [Unstable angina, acute non-ST elevation myocardial infarction (NSTEMI), or acute ST elevation myocardial infarction (STEMI)]
         I. Additionally, if treatment includes percutaneous coronary intervention (PCI), documentation has been submitted showing:
            i. Patient has had trial and inadequate response or intolerance to prasugrel
               A. *Trial is not applicable if the patient has history of stroke, transient ischemic attack, or active bleeding, is 75 years of age or older
      b. **History of myocardial infarction (MI)** and the following:
         I. At least one of the following risk factors:
            i. Patient is 65 years of age or older
            ii. Diagnosis of diabetes requiring medication
            iii. History of a second MI in the past
            iv. Evidence of multivessel coronary artery disease (CAD)
            v. Creatinine clearance less than 60mL/min
         II. Documentation showing the following:
            i. Patient has had trial and inadequate response or intolerance to clopidogrel

A. *Trial is not applicable if the patient is unable to use clopidogrel due to being identified as a cytochrome P450 (CYP) 2C19 poor metabolizer [genetic testing results required]

c. **Diagnosis of CAD without MI or stroke**, and the following:
   I. Documentation of a history of PCI or coronary artery bypass graft (CABG)
   II. Documentation has been provided showing the following:
      i. Patient has had trial and inadequate response or intolerance to clopidogrel
         A. *Trial is not applicable if the patient is unable to use clopidogrel due to being identified as a cytochrome P450 (CYP) 2C19 poor metabolizer [genetic testing results required]

d. **Stroke Risk Reduction**, and the following:
   I. Documentation showing the patient has had one of the following:
      i. a mild-to-moderate acute noncardioembolic ischemic stroke, supported by a National Institutes of Health Stroke Scale (NIHSS) score of 5 or less
      ii. a high-risk Transient Ischemic Attack (TIA), defined as one of the following:
         A. an $ABCD^2$ stroke risk assessment score of 6 or greater
         B. an ipsilateral atherosclerotic stenosis of 50% or greater in the internal carotid or an intracranial artery
   II. Documentation has been provided showing the following:
      i. Patient has had trial and inadequate response or intolerance to clopidogrel
         A. *Trial is not applicable if the patient is unable to use clopidogrel due to being identified as a cytochrome P450 (CYP) 2C19 poor metabolizer [genetic testing results required]

3. Patient will be using Brilinta with a daily maintenance dose of aspirin 75mg to 100mg

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial authorization may be approved for up to 12 months of therapy.
B. Continuation of therapy may be approved in 12-month intervals with documentation showing continued patient tolerance and clinical benefit.

IV. EXCLUSIONS

A. Brilinta will not be approved for the following:
   1. Patients with clinically significant anemia
   2. Patients with peptic ulcer disease (PUD) with active bleeding, or other predisposition for increased bleeding risk
   3. Patients with a history of intracranial hemorrhage
   4. Concurrent use with another $P2Y_{12}$ platelet inhibitor
   5. Any indications or uses that are not FDA-approved, or guideline-supported
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Tantry US, Hennekens, CH, Zehnder JL et.al. Clopidogrel resistance and clopidogrel treatment failure. UpToDate. Waltham, MA 2019.
2. Johns Hopkins HealthCare Pharmacy Policy PHARM20, Step Therapy, Prior Authorization and Quantity Limits
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4. Effient [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; March 2019.
5. Brilinta [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2022.

6. Schüpke S, Neumann FJ, Menichelli M, et al. Ticagrelor or Prasugrel in Patients with Acute Coronary Syndromes. N Engl J Med. 2019 Oct 17;381(16):1524-1534.
7. Levine GN, Bates ER, Bittl JA, et al. 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients with Coronary Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery, 2012 ACC/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease, 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction, 2014 AHA/ACC Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes, and 2014 ACC/AHA Guideline on Perioperative Cardiovascular Evaluation and Management of Patients Undergoing Noncardiac Surgery. Circulation. 2016 Sep 6;134(10):e123-55.
8. Johnston SC, Amarenco P, Denison H, et al. Ticagrelor and aspirin or aspirin alone in acute ischemic stroke or TIA. N Engl J Med. 2020;383(3):207–217

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Removed background information/definitions; updated title to reflect brand name of both medications
06/19/2017	Clarified clinical criteria
07/27/2017	Updated Exclusions section regarding physician refills
10/31/2019	Clarified criteria based on updated Plavix prescribing information; add guidance regarding brand and generic forms of Effient
01/30/2020	Clarified policy and removed criteria for Effient and its generic
07/15/2020	Clarified clinical criteria, and added new criteria for new indication: MI and Stroke prevention in high risk CAD patients
10/18/2023	Updated clinical criteria based on FDA-approved indication expansion

Review/Revision Dates: 07/18/2012, 03/01/2014, 04/20/2016, 6/19/2017, 07/01/2018, 07/27/2017, 10/31/2019, 01/15/2020, 01/30/2020, 07/15/2020, 10/18/2023