

Request for permission for oral testimony at Idaho  
Medicaid's P&T Committee meeting on 04-20-2012

Submission # 3

As of April 10, 2012, this request has been:

- Approved
- Denied

## Gennrich, Jane - Medicaid

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**From:** Eide, Tamara J. - Medicaid  
**Sent:** Wednesday, March 28, 2012 3:06 PM  
**To:** Gennrich, Jane - Medicaid  
**Subject:** FW: INFORMATION REQUEST RESPONSE – BRILINTA MM REQUEST Inquiry 00009610  
**Attachments:** Medicaid Testimonial March 2012\_Idaho.docx; Dossier Cover Letter.docx

Tami Eide, Pharm.D., BCPS  
Medicaid Pharmacy Program Supervisor/Manager Idaho Department of Health and Welfare  
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-----Original Message-----

**From:** [no-reply@salesforce.com](mailto:no-reply@salesforce.com) [<mailto:no-reply@salesforce.com>] On Behalf Of AstraZeneca US Medical Information  
**Sent:** Tuesday, March 27, 2012 12:47 PM  
**To:** Eide, Tamara J. - Medicaid  
**Subject:** INFORMATION REQUEST RESPONSE – BRILINTA MM REQUEST Inquiry 00009610

The enclosed information is supplied to you as a professional courtesy in response to your request regarding BRILINTA. Documents cited as "Hard Copy" in the attached cover letter will follow via FEDEX.

If the attached file is pdf file, in order to view, you must have Adobe ® Acrobat Reader installed on your computer. If you do not have this software installed, you can download it at no cost from <http://www.adobe.com> or contact AstraZeneca LP at 877-212-6597 in order to receive this information via an alternative delivery method.

See attachment for response.

Should you have any questions or concerns regarding this information, please contact us at 877-212-6597.

Please do not respond to this e-mail. This is an automatically generated notice from a system mailbox, which is NOT monitored.

Thank you,

Medical Resources  
AstraZeneca LP

This information is being provided, as a professional courtesy, in response to your request. These materials may include information that is not found in the currently approved prescribing information for BRILINTA. The enclosed information is intended to provide pertinent data in response to your request and should in no way be construed as a recommendation for the use of this product in any manner other than as approved by the Food and Drug Administration and as described in the prescribing information for BRILINTA Prescribing information for BRILINTA may be obtained from [www.astrazeneca-us.com](http://www.astrazeneca-us.com) or by calling AstraZeneca Medical Affairs at 1-877-893-1510.

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### BRILINTA (ticagrelor) Medicaid Testimonial

- Hello, my name is Dr. Mandy Hosford with AstraZeneca. Thank you for the opportunity to present information on BRILINTA (ticagrelor).
- The information I will discuss is provided to support the recommendation for inclusion of BRILINTA on the preferred drug list in the Idaho Medicaid Program
- BRILINTA is indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) including unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI), or ST elevation myocardial infarction (STEMI), when given with maintenance doses of aspirin 100 mg or less.<sup>1</sup>
- BRILINTA has been shown to reduce the rate of a combined endpoint of cardiovascular (CV) death, myocardial infarction (MI), or stroke compared to clopidogrel, which was driven by CV death and MI with no difference in stroke.<sup>1</sup>
- In patients treated with PCI, BRILINTA also reduces the rate of stent thrombosis.<sup>1</sup>
- BRILINTA is contraindicated in patients with a history of intracranial hemorrhage, active pathological bleeding, or severe hepatic impairment.<sup>1</sup>
- BRILINTA is orally active and does not require hepatic metabolism to exert its pharmacologic action.<sup>2</sup> CYP3A4 is the major enzyme responsible for BRILINTA metabolism and the formation of its active metabolite. The systemic exposure of the active metabolite is approximately 30%-40% of the exposure of BRILINTA.<sup>1</sup>
- It is not known how either bleeding risk or thrombotic risk correlate with IPA, for either BRILINTA or clopidogrel. The onset of IPA was evaluated after a 180-mg loading dose of BRILINTA versus a 600-mg loading dose of clopidogrel. The IPA was higher in the BRILINTA group at all time points, and the maximum IPA effect of BRILINTA was reached at around 2 hours, and was maintained for at least 8 hours.<sup>1</sup>
- BRILINTA can be administered with unfractionated or low molecular weight heparin, GPIIb/IIIa inhibitors, proton pump inhibitors, beta-blockers, angiotensin converting enzyme inhibitors, and angiotensin receptor blockers.<sup>1</sup>
- The PLATO trial<sup>1,3</sup> compared BRILINTA to clopidogrel for the reduction of CV events in 18,624 patients with UA, NSTEMI, or STEMI.
- At 12 months, patients who received BRILINTA versus clopidogrel had a 16% relative risk reduction (1.9% ARR) in the primary endpoint of CV death, MI, or stroke compared to clopidogrel; this was driven by CV death (21% RRR) and MI (16% RRR), with no difference observed in stroke.<sup>1</sup>
- In the North American subgroup, BRILINTA was numerically inferior to clopidogrel. In PLATO, use of >100 mg of aspirin decreased the effectiveness of BRILINTA. After initial dosing, use aspirin 75-100 mg per day.<sup>1</sup>
- PLATO defined major bleeding rates were similar between the BRILINTA and clopidogrel groups.<sup>1</sup>
- BRILINTA was associated with a higher risk of non-CABG related bleeding.<sup>1</sup>
- The most commonly reported adverse reactions were bleeding and dyspnea.<sup>1</sup>

- There are boxed warnings for BRILINTA around an increased risk of bleeding and for use with maintenance doses of aspirin less than 100 mg per day.<sup>1</sup>
- Please refer to the BRILINTA Prescribing Information for complete product information, including Boxed Warnings and Warnings and Precautions.

In summary:

- BRILINTA is indicated to reduce the rate of thrombotic CV events in patients with ACS including UA, NSTEMI, or STEMI, when given with maintenance doses of aspirin 75-100 mg per day.<sup>1</sup>
- BRILINTA has been shown to reduce the rate of a combined endpoint of CV death, MI, or stroke compared to clopidogrel, which was driven by CV death and MI with no difference in stroke.<sup>1</sup>
- In patients treated with PCI, BRILINTA also reduces the rate of stent thrombosis.<sup>1</sup>
- AstraZeneca requests that BRILINTA be included on the preferred drug list for the Idaho Medicaid Program.
- Thank you and I will be happy to answer any questions you may have.

Reference(s):

<sup>1</sup>BRILINTA Prescribing Information

<sup>2</sup>Husted S, Emanuelsson H, Heptinstall S, et al. Pharmacodynamics, pharmacokinetics, and safety of the oral reversible P2Y<sub>12</sub> antagonist AZD6140 with aspirin in patients with atherosclerosis: a double-blind comparison to clopidogrel with aspirin. *Eur Heart J*. 2006;27:1038-47.

<sup>3</sup>Wallentin L, Becker RC, Budaj A, et al for the PLATO Investigators. Ticagrelor versus clopidogrel in patients with acute coronary syndromes. *N Engl J Med*. 2009;361(11):1045-1057.

March 27, 2012

Tamara Eide, Pharm.D.  
Idaho State Medicaid P&T  
3232 Elder Street  
Boise, Idaho 83705

Dear Dr. Eide:

Your Senior Regional Scientific Manager, Mandy Hosford, has forwarded your request regarding BRILINTA® (ticagrelor) Tablets. The following information is being provided, as a professional courtesy, in response to your request:

#### **BRILINTA Testimonial**

These materials may include information that is not found in the currently approved prescribing information for BRILINTA. The enclosed information is intended to provide pertinent data in response to your request and should in no way be construed as a recommendation for the use of this product in any manner other than as approved by the Food and Drug Administration and as described in the prescribing information for BRILINTA. The prescribing information for this product contains a boxed warning(s). Please consult the warning section of the prescribing information for further details and other important safety information. Prescription drugs used in a manner other than their approved indication may not be eligible for reimbursement by any third-party payors, including Medicaid, Medicare, or similar federal or state programs. Prescribing information for BRILINTA may be obtained from [www.astrazeneca-us.com](http://www.astrazeneca-us.com) or by calling the Information Center at AstraZeneca at 1-800-236-9933.

Thank you for your interest in BRILINTA. If we may be of further assistance to you, please contact AstraZeneca at 1-877-893-1510.

Tel 877 893 1510  
Fax 302 885-1400  
[www.astrazeneca-us.com](http://www.astrazeneca-us.com)

Medical Resources FOC/CE1 706, 1800 Concord Pike, PO Box 15437, Wilmington, DE 19850-5437

AstraZeneca 

Sincerely,

*Debra A. Perlswieg, Pharm.D.*  
Senior Medical Information Manager

00009610