National Quality Forum

Measure Pre-Meeting Comment Report for Cardiovascular Project

Comments received as of Feb 18, 2014

Topic	Commenter	Comment
# 0964-Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients	Submitted by Dr. Kathy Gans-Brangs, PhD	From AstraZeneca: We recommend adding ticagrelor to the list of P2Y12 agents. BRILINTA is an FDA approved P2Y12 platelet inhibitor indicated to reduce the rate of thrombotic cardiovascular (CV) events in patients with acute coronary syndrome (ACS), when given with maintenance doses of aspirin less than 100 mg. In patients treated with percutaneous coronary intervention (PCI), it also reduces the rate of stent thrombosis. Supporting Information : The safety and efficacy of BRILINTA was evaluated in PLATO, a multicenter, randomized, double-blind study comparing ticagrelor to clopidogrel in 18,624 patients with ACS.1,2 At 12 months, the rate of CV death/MI/stroke was 9.8% for ticagrelor vs 11.7% for clopidogrel resulting in a relative risk reduction of 16% ($p<0.001$). The difference between treatments was driven by CV death and MI with no difference in stroke. The relative risk reduction of CV death was 21% and MI was 16% for ticagrelor vs clopidogrel ($p=0.0013$ and $p=0.0045$, respectively).1,2 In PLATO, 11,289 (60.6%) patients either had a previous stent implanted (n=1404) or underwent stent implantation during the study (n=9885).7There was a lower risk of stent thrombosis with ticagrelor (1.3% for adjudicated “definite”) than w/ clopidogrel (1.9%) (hazard ratio [HR], 0.67; 95% CI, 0.50-0.91; $p=0.009$).1,2,3Results were similar for drug-eluting stents and bare metal stents.3 The reduction in definite stent thrombosis with ticagrelor was numerically greater for late [> 30 days: HR 0.48, (CI 0.24 – 0.96)], and subacute [24 h – 30 days: HR 0.60, (CI 0.39 – 0.93)] vs. acute stent thrombosis [< 24 h: HR 0.94 (CI 0.43 – 2.05)]. 1. BRILINTA Prescribing Information. 2. Wallentin L et al for the PLATO Investigators. Ticagrelor versus clopidogrel in patients with acute coronary syndromes. NEJM 2009;361:1045-1057. 3. Steg PG et al. Stent thrombosis with ticagrelor versus clopidogrel in patients with acute coronary syndromes: an analysis from the prospective, randomized PLATO trial. Circ. 2013;128:1055-1065.

		Please refer to the BRILINTA Prescribing Information for Boxed Warnings related to increased risk of bleeding and reduced effectiveness with maintenance doses of ASA greater than 100 mg per day.
# 0964-Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients	Submitted by Dr. Kathy Gans-Brangs, PhD	From AstraZeneca: REQUEST FOR HARMONIZATION OF SIMILAR MEASURES -- We believe that revisions like the one NQF is currently undertaking present an opportunity to conduct a more thorough harmonization of all measures in a particular class. So, for example, we would recommend that all measures mentioned as competing by the developers in Section 5a, Harmonization, of the response forms be reviewed by the Expert Panel at the same time. A comprehensive review of a set of competing measures related to specific treatments (e.g., PCI and CAD) would allow for continuity and consistency that results in a stronger suite of measures that do not read as if they have been cobbled together over time. COMPETATIVE MEASURE ISSUE, REQUEST FOR CONSISTENCY IN SPECIFICITY -- In reviewing the measures for this pre-comment period, we recognize an inconsistency that dates the measures before they are re-endorsed; NQF sometimes endorses measures which list specific agents and other times stay at the class level. Sometimes, inconsistency exists within a single measure as seen with Measure #0964: Therapy with P2Y12, ASA, statin at discharge. Three agents, described as P2Y12 inhibitors, are called out by name, but statins are not, and P2Y12 inhibitor(s) approved by FDA after data collection are not mentioned. Further, measure #0964 is not current in its list of approved P2Y12 agents and is inconsistent with measures including #2379 that list 3 different agents as P2Y12 inhibitors. Further, Measure #2379 notes that “obsolete drug products are excluded from NDCs with an inactive date more than 3 years prior to the beginning of the measurement period or look-back period, if applicable” (section 5.6, page 8/18). Not including agents at the class level can lead to provider confusion as noted in public comments submitted to NQF on measures # 0067, 0068 and 0230 during its Cardiovascular Endorsement Maintenance 2010 comment period. We do support NQF in using the approach that it feels is best, but specificity does require continuous updating to capture products that are approved by the FDA.

# 2379- Adherence to Antiplatelet Therapy after Stent Implantation	Submitted by Dr. Kathy Gans-Brangs, PhD	From AstraZeneca: REQUEST FOR HARMONIZATION OF SIMILAR MEASURES -- We believe that revisions like the one NQF is currently undertaking present an opportunity to conduct a more thorough harmonization of all measures in a particular class. So, for example, we would recommend that all measures mentioned as competing by the developers in Section 5a, Harmonization, of the response forms be reviewed by the Expert Panel at the same time. A comprehensive review of a set of competing measures related to specific treatments (e.g., PCI and CAD) would allow for continuity and consistency that results in a stronger suite of measures that do not read as if they have been cobbled together over time. COMPETATIVE MEASURE ISSUE, REQUEST FOR CONSISTENCY IN SPECIFICITY -- In reviewing the measures for this pre-comment period, we recognize an inconsistency that dates the measures before they are re-endorsed; NQF sometimes endorses measures which list specific agents and other times stay at the class level. Sometimes, inconsistency exists within a single measure as seen with Measure #0964: Therapy with P2Y12, ASA, statin at discharge. Three agents, described as P2Y12 inhibitors, are called out by name, but statins are not, and P2Y12 inhibitor(s) approved by FDA after data collection are not mentioned. Further, measure #0964 is not current in its list of approved P2Y12 agents and is inconsistent with measures including #2379 that list 3 different agents as P2Y12 inhibitors. Further, Measure #2379 notes that "obsolete drug products are excluded from NDCs with an inactive date more than 3 years prior to the beginning of the measurement period or look-back period, if applicable" (section 5.6, page 8/18). Not including agents at the class level can lead to provider confusion as noted in public comments submitted to NQF on measures # 0067, 0068 and 0230 during its Cardiovascular Endorsement Maintenance 2010 comment period. We do support NQF in using the approach that it feels is best, but specificity does require continuous updating to capture products that are approved by the FDA.