November 18, 2015

Josh Morse, MPH
Program Director Health Technology Assessment Program
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Dear Mr. Morse

Thank you for the opportunity to comment on this draft report. We hope that we can work with the Health Technology Assessment Program (HTAP) to arrive at the optimal outcome for cardiovascular patients and taxpayers in Washington State. This report is the result of extensive research into the literature in this field.

The Society for Cardiovascular Angiography and Interventions is a 4,500-member professional organization representing invasive and interventional cardiologists in approximately 70 countries. SCAI's mission is to promote excellence in invasive/interventional cardiovascular medicine through physician education and representation, and advancement of quality standards to enhance patient care. SCAI's public education program, SecondsCount, offers comprehensive information about cardiovascular disease. For more information about SCAI and SecondsCount, visit www.SCAI.org or www.SecondsCount.org.

We remain concerned that the draft document, while representing an in-depth review of the literature, adds little to established guidelines and appropriate use criteria that already exist, and which are much more likely to be read and followed by cardiologists than this review. As an example, a recently published article examining the impact of AUC shows convincing evidence of the impact of such documents on the utilization of PCI nationally and in Washington State (1,2). We would also like to point out that there have been recent updates to two important guideline documents that can be found at: http://www.scai.org/Assets/10542bc9-c8be-48d1-aa84-c647137878b7/635810359561230000/scai-2015-10-21-primarypciupdate-pdf and http://www.scai.org/Assets/d428d716-f835-4a7d-a169-...
It is clear from the review that these and prior similar documents have already had an impact on the frequency of coronary stenting both nationally and more locally in the State of Washington (see our comments in the next paragraph).

In the draft document beginning on page 45 and continuing to page 47 are tables 1 to 5. There are several points to be made from these tables:

1. There is in general a decline in stenting overall, as noted in table 3, which is also reflected in national Medicare data as well.
2. The absolute number of patients receiving coronary stents is small compared to the population base covered by PEBB/UMP (0.03% in 2014)
3. The impact of the prior document on savings is interestingly absent from the tables and
4. The potential clinical and financial impact of this HTA draft document on the population served is therefore likely to be very small.

Specific responses to the Key Questions follows; starting with Key Question 1. It is not surprising that no mortality benefit was found comparing stenting to medical therapy since medical therapy is the cornerstone of treatment of chronic stable ischemic heart disease and the studies reviewed by and large serve as the foundation for the current guidelines and AUC. Revascularization, be it by surgery or stenting, would not be expected to impact hard endpoints like mortality with a chronic disease like coronary artery disease given long enough follow up. With respect to quality of life it is important to understand that studies looking at that endpoint typically use “as randomized methodology”, which while statistically valid, does not represent the way patients are treated with a chronic disease. In such studies, patients initially randomized to medical therapy but then cross over to revascularization because of worsened or uncontrolled symptoms are counted in the medical arm which “contaminates” follow up and potentially delivers and incorrect message, a message that in addition doesn’t reflect how patients are cared for long term with a chronic disease. As an example, the crossover rate in COURAGE was about 25% from the medical to revascularization arm.

With respect to the review of the literature regarding Key Question 2, while extensive, it adds little important new information. As this body of data is reviewed it is important to remember that most of it was designed to determine any safety signals between DES and BMS and to be used by the companies developing the devices for FDA approval. The safety issue was looked at because there was a concern in the past (due to poorly designed meta analyses) that there might be excessive stent thrombosis with DES vs. BMS. Subsequent studies have confirmed that is not the case. The studies were not powered to determine if one device was superior to another with regard to stent thrombosis/MI. They were also not designed to evaluate mortality with respect to one device being superior to another. Looking for superiority of one device vs. another from these studies can be predicted to show no difference. This is exactly what has been shown in the draft document. These limitation exist with many of the other RCTs that were designed to lead to FDA approval of newer DES stents and not to show that DES was superior to BMS. Superiority
of DES to BMS with respect to instant restenosis, in most cases, has been generally accepted by
the cardiology community based on the totality of the evidence that has been generated from
initial approval of the coronary stent in 1995 to date, not just since the prior HTA document in
2009. If one reviews the extensive evidence tables in the draft document it is clear that most of
the evidence is of low to moderate strength which speaks to the evidence and raises concerns
about the validity of any conclusions drawn from the review. As we stated in our 2009 HTA
response we, as interventional cardiologist, have no vested interest in which stent type (DES vs.
BMS) is chosen since physicians are not reimbursed based on the type of stent used. We are truly
the patient’s advocate when it comes to this aspect of their care.

We would also like to point out that evaluations such as this will likely become more difficult in
the future as the focus moves away from BMS vs. DES to studies looking at new platforms to
deliver anti restenotic drugs to the coronaries. A prime example of this are bioreabsorable
platforms that are on the near horizon for approval in the US. In addition, because of the
prohibitive cost associated with bringing these devices to market in the US, trials have not and
will not be designed as superiority studies but as non-inferiority trials. This will add additional
complexity to this type of literature review. It will also bring to question any attempt to draw
inferences using meta analyses of future datasets based on these trials.

We believe this review, while extensive, does not further inform the HTA process with respect to
the key questions and adds little to the previous document. It is our opinion that, absent data to
confirm otherwise, there will likely be little cost savings to the State from this exercise. We also
firmly believe that going forward, reviews such as this will add little to guidelines and other
documents produced by national organizations such as SCAI, ACC and the AHA. With all due
respect the proper use of these devices and where they fit within the armamentarium used to treat
coronary artery disease, a chronic disease with no cure, has been informed by the literature and
not by reviews such as this.

Sincerely,

[Signature]

James C. Blankenship, MD, MHCM, FSCAI
President