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VIA ELECTRONIC SUBMISSION

Louis Jacques, MD
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mail Stop S3-02-01
7500 Security Boulevard
Baltimore, MD 21244

Re: Evidentiary Characteristics for Coverage with Evidence Development

Dear Dr. Jacques:

Boston Scientific Corporation (Boston Scientific) appreciates the opportunity to provide comments in response to the questions that will be discussed at the upcoming meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC).[1]

As the world's largest company focused on the development, manufacturing, and marketing of less-invasive medicine, Boston Scientific supplies medical devices and technologies used by the following medical specialty areas, all of which provide CMS beneficiary care in the hospital inpatient setting:

- Cardiac Rhythm Management;
- Gastroenterology;
- Interventional Bronchoscopy;
- Interventional Cardiology;
- Interventional Radiology;
- Oncology;
- Neuromodulation;
- Urology; and
- Women's Health.

Boston Scientific is very interested in the CMS coverage with evidence development (CED) process as part of the national coverage determination (NCD) process. We are committed to working with CMS as the CED process is revised to ensure that beneficiaries have access to the most appropriate medical technology at the right time during their care delivery. We share CMS's belief that adequate evidence should be available to justify that a service or procedure is

[1]Centers for Medicare & Medicaid Services Public Solicitation, March 15, 2012; http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/downloads//id63.pdf

reasonable and necessary. We further believe that in order to effectively respond to the rapidly evolving health care system and medical device industry, the CED process should be flexible, transparent, collaborative and predictable.

We offer comments to specific questions CMS posed to interested stakeholders.

CMS Definitions

Binary Coverage Paradigm:
"Yes or No" final coverage decision without planned reconsideration of prespecified clinical outcomes.

Non-Binary Coverage Paradigm:*
Qualified coverage decision that may evolve as evidence base changes over time, with planned reconsideration based on the achievement of prespecified clinical outcomes.
*CED is an example of a non-binary coverage paradigm.

CMS Question 1

Are there significant, practical differences between binary and non-binary coverage paradigms? If the answer favors "Yes" please discuss the advantages and disadvantages of non-binary paradigms.

There are practical differences between binary and non-binary coverage paradigms. Binary coverage suggests that additional evidence would not impact current coverage decision nor would there be planned review of a coverage policy after generation of new clinical data.

Non-binary coverage paradigms would have an advantage over Binary coverage in that:

- There is opportunity to update coverage policies as new evidence is developed;
- Patients have quicker access for newer technologies if used to provide coverage;

In addition, challenges of a strictly non-binary coverage paradigm includes increased agency resources required to implement and manage, challenges in defining evidentiary thresholds for planned reconsiderations, and the possibility of limiting coverage if policy changes do not keep up with advancements in clinical evidence.

We suggest that in situations where there is a large body of positive evidence, it is prudent to consider using Binary coverage. However, in situations of uncertainty in a potential service or procedure benefit, we encourage CMS to use non-binary coverage to allow access to potentially life enhancing benefits, while collecting impactful data through the CED process.

CMS Question 2

Can an evidentiary threshold be defined to invoke CED?
If the answer favors "Yes" please discuss how this threshold should be identified.

If the answer favors "No" please discuss the impediments and recommend strategies to overcome them.

Defining an evidentiary threshold to invoke CED will be extremely challenging. We are not sure that it is possible to define an evidentiary threshold for medical procedures or services. We believe that such a threshold, if it could be identified, would vary widely depending upon the item or service being evaluated and the clinical needs of individual patients. Therefore, we do not believe that it is possible to determine one evidentiary threshold.

As CMS determines their forward steps in defining evidentiary thresholds, we encourage transparency and the involvement of impacted stakeholders. There should also be adequate time allowed for public comment.

CMS Question 3

How would an evidentiary threshold to invoke CED be influenced by the following?

a. **whether the item or service is a diagnostic v. a therapeutic technology;**
b. **the severity of the disease;**
c. **the safety profile of the technology;**
d. **the availability of acceptable alternatives for the same disease/condition**
e. **other factor(s)**
f. **a combination or tradeoff involving two or more of the above**

All of the above factors, plus others such as type of patients for example, would have a significant impact when evaluating an evidentiary threshold to invoke CED. For example, therapeutic devices may be required to generate data focusing on impact on disease outcome and safety; whereas a diagnostic technology may simply need to document specificity and sensitivity to support the reasonable and necessary criteria. We agree that a technologies safety profile should be weighted heavily.

However, the availability of alternative therapies/technologies may not have bearing on invoking CED, as it is critical to not limit a provider's choices when deciding upon the best treatment of their patients. We encourage CMS not to take a limited approach to CED, but to think more broadly as to how CED could be invoked most effectively (i.e., infrequently, in situations of uncertainty, taking into considerations such as device use, safety profile and available data).

CMS Question 4

How would an evidentiary threshold to invoke CED be influenced if the outstanding questions focused only on the generalizability of a strong but narrow evidence base to

i. **additional settings;**

ii. additional practitioners;

iii. broader clinical indications for related or unrelated diseases#?

 # An example of a related condition might include a different stage of the same cancer. An example of an unrelated condition might include the use of a cancer drug for a rheumatologic disease.

An evidentiary threshold with specific conditions would potentially further limit patient access and is a challenging area to generalize broadly. Each CMS beneficiary procedure and service under review would need to be assessed in context of the clinical condition treated, impact on patient access and provider recommendations prior to limiting coverage to specific settings, practitioners, etc. We suggest that for each situation in which special limitations are considered for a coverage determination should be discussed with the impacted stakeholder groups in a transparent manner. There should also be adequate time for public comment.

CMS Question 5

Can an evidentiary threshold be defined to trigger an evidentiary review to determine if CED should cease, continue or be modified?

If the answer favors "Yes" please discuss how this threshold should be identified.
If the answer favors "No" please discuss the impediments and recommend strategies to overcome them.
Please discuss whether the factors identified in Questions 3 and 4 are relevant to Question 5.

An evidentiary threshold could be defined in certain circumstances, although it would be very challenging. For instance, under conditions of CED, CMS could work with stakeholders to predefine criteria when a new review NCD would occur; i.e. following specified data capture or prespecified number of patients receiving treatment. However, one evidentiary threshold can't be used across all clinical or therapeutic areas. Any evidentiary threshold should take into account medical technology intended use, the technologies safety profile, and available data.

* *

In closing, Boston Scientific supports CMS efforts to be open and transparent in this process. We agree with the CMS goal to ensure that patients receive the optimal medical therapy to improve care and general health through the NCD-CED process.

We believe that CMS should make the recommended modifications to the CED process to make it more efficient for various stakeholders and to continue to allow patients access to life saving technologies.

We appreciate the opportunity to comment on this important topic, and your consideration of our overall perspectives. If you or your staff has questions, please do not hesitate to contact Michael

Ferguson, PhD (Director Health Economics, 508-652-5234; michael.ferguson@bsci.com) or Kristen Hedstrom, MPH (Director Healthcare Policy, 202-637-8021; kristen.hedstrom@bsci.com).

Sincerely,

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Boston Scientific Corporation