September 10, 2013

Via Electronic Mail
Foaud Atouf, Ph.D.
Director, Biologics & Biotechnology
U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852

Re: USP review of non-implantable biologicals for monograph inclusion

Dear Dr. Atouf:

AdvaMed is writing this letter to seek clarification on the process for including non-implantable biologicals in U.S. Pharmacopeia (USP) monographs.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

A number of AdvaMed member companies manufacture non-implantable biologicals and frequently utilize the transitional pass-through process, under Medicare’s hospital outpatient prospective payment system, to obtain this status for their products. Transitional pass-through status is granted for a minimum of two and a maximum of three years to new technologies with significant costs.

The transitional pass-through application requirements, established by CMS, require a copy of the USP monograph if a product has not received FDA approval as a biological. The USP process for updating monographs to incorporate newly approved/added technologies is infrequent (occurring only a few times each year) and does not follow a standardized schedule. Therefore, the USP has historically issued what are known as letters of inclusion. These letters indicate that a product has been approved for inclusion in an existing monograph and will be added to that monograph’s title during its next publication.

The CMS deadlines for submitting a completed transitional pass-through application are very strict. If a manufacturer misses the quarterly application deadline they must wait a minimum of seven months before their code can be granted transitional pass-through status. The lack of a
timeline for issuing revised monographs or inclusion letters makes it difficult for manufacturers to plan to submit transitional pass-through applications in compliance with CMS deadlines. Delays in getting the necessary documentation required to submit a transitional pass-through application could result in delays in receiving these critical payments.

Manufacturers should not experience undue delays with regard to their ability to file a transitional pass-through status application. In an effort to ensure that applicants are able to take full advantage of the opportunity to receive transitional pass-through payments for their technologies, AdvaMed recommends that the USP consider expediting and/or establishing timelines for reviewing and making decisions regarding inclusion of non-implantable biological products in existing monographs.

Please feel free to contact DeChane Dorsey (ddorsey@advamed.org or 202-434-7218) with any questions. We appreciate your consideration of this request and look forward to your response.

Sincerely,

[Signature]

Richard James Price
Senior Vice President
Payment and Health Care Delivery Policy