

As announced in late 2006, after carefully examining Section 1847A of the Social Security Act, as added by the Medicare Modernization Act of 2003, CMS has been working further to ensure that more accurate and, as appropriate, separate payment is made for single source drugs and biologicals under Section 1847A. As part of this effort, we have also reviewed how we have operationalized the terms "single source drug," "multiple source drug," and "biological product" in the context of payment under section 1847A. For the purposes of identifying "single source drugs" and "biological products" subject to payment under section 1847A, generally CMS (and its contractors) will utilize a multi-step process. We will consider:

- The FDA approval,
- Therapeutic equivalents as determined by the FDA, and
- The date of first sale in the United States.

For a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book) first sold in the United States after October 1, 2003, the payment limit under Section 1847A for that biological product or single source drug will be based on the pricing information for products produced or distributed under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may also be operationalized through use of existing specific HCPCS codes or "not otherwise classified" HCPCS codes. Examples of how we are operationalizing this approach using unique HCPCS codes include: (1) the Q codes for EuflexxaTM, Orthovisc®, and Synvisc® effective January 1, 2007, and (2) the series of Q codes for immune globulin and the new Q code for Reclast® effective July 1, 2007.

Section 1847A requires single source drugs or biologicals that were within the same billing and payment code as of October 1, 2003, be treated as multiple source drugs, so the payment under Section 1847A for these drugs and biologicals is based on the volume weighted average of the pricing information for all of the products within the billing and payment code. We are working to ensure that payments accurately reflect this "grandfathering" provision. Examples of how we are operationalizing this provision include: (1) Q4083 for Hyalgan and Supartz effective January 1, 2007, and (2) Q4094 for albuterol and levalbuterol and Q4093 for concentrated forms of albuterol and levalbuterol effective July 1, 2007.

In addition, appropriate modifications of the NDC to HCPCS crosswalk used to calculate the payment limits for purposes of Section 1847A will be made to ensure that payment will be based on the pricing information for all products produced or distributed under an FDA approval for the drug or biological. One result is the same payment limit for J0885 (injection, epoetin alfa, (for non-ESRD use)) and J0886 (injection, epoetin alfa, (for ESRD on dialysis)).

We will continue to work to identify and implement payment and coding changes as necessary to ensure more accurate payments under Section 1847A. So that we can implement any further necessary changes during 2007, we will continue to use our internal process for modifying the HCPCS code set and for adjusting the NDC to HCPCS crosswalk.

A full list of the July 2007 quarterly updates to the HCPCS is available at http://www.cms.hhs.gov/HCPCSReleaseCodeSets/02_HCPCS_Quarterly_Update.asp#TopOfPage

Pricing information for Part B drugs and biologicals for the third quarter of 2007 (July 1 – September 30) will be posted on or after June 15th at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2007aspfiles.asp#TopOfPage

The announcement for the Q codes for EuflexxaTM, Orthovisc®, and Synvisc® effective January 1, 2007 and Q4083 for Hyalgan and Supartz also effective January 1, 2007, was posted on December 22, 2006 and is available at <http://www.cms.hhs.gov/Transmittals/downloads/R1152CP.pdf>