

April 24, 2007

As announced earlier this year, after a careful examination of Section 1847A of the Social Security Act, as established in the MMA of 2003, CMS has been working to ensure that accurate and separate payment is made for single source drugs and biologicals as required by this section of the Act. 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 will utilize a multi-step process. CMS will consider:

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

Therefore, if 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) was first sold in the United States after October 1, 2003, as appropriate a unique HCPCS code will be assigned to facilitate separate payment.