



HCPCS Level II Coding for 505(b)(2)-Approved Drugs or Biologicals – Frequently Asked Questions

To better align with the program instruction, the Centers for Medicare and Medicaid Services (CMS) is working further to ensure that more accurate and, as appropriate, separate payment is made for single source drugs and biologicals under section 1847A of the Social Security Act (hereafter, the Act). Below are some frequently asked questions related to the single source drug coding efforts.

1. Why is CMS taking this coding action at this time?

Based on the statutory definition of “single source drug or biological” in section 1847A(c)(6) of the Act, CMS made several code changes, including product-specific codes to identify certain drugs approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or Biologics License Application (BLA) submitted under section 351 of the Public Health Service Act (PHS Act). These products meet the definition of single source drug or biological because they are approved under section 505(b)(2) NDAs are not rated as therapeutically equivalent by the FDA in the Orange Book¹ to any other drug or are licensed under a BLA, but were not within the same billing and payment code as of October 1, 2003 (see section 1847A(c)(6)(C)(ii) of the Act). Therefore, CMS identified a programmatic need for each product to have a unique billing and payment code, in order to conform with the general approach used for the assignment of products paid under section 1847A of the Act to HCPCS Level II codes.

2. What does this mean for providers?

Providers should review the Average Sales Price (ASP) Drug Pricing Files and especially the NDC-HCPCS Crosswalks² to help determine the most appropriate HCPCS Level II code to use when submitting claims. The ASP files and crosswalks are updated on a quarterly basis and are available at this CMS website:

<https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice>.

¹ The FDA’s Orange Book, officially entitled, *Approved Drug Products With Therapeutic Equivalence Evaluations*, identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>.

² The ASP crosswalks are maintained by CMS on a quarterly basis to support ASP-based Medicare Part B payments only.

3. What does this coding action mean for manufacturers?

Manufacturers should continue to report their ASP data to CMS as usual at this CMS website: <https://portal.cms.gov/portal/>.

4. What codes is CMS establishing?

CMS conducted a review to identify (1) products approved under a section 505(b)(2) NDA that are not rated as therapeutically equivalent to their reference listed drug in the FDA Orange Book and were not within the same billing and payment code as another drug or biological as of October 1, 2003; and (2) products approved under a BLA that were not within the same billing and payment code as another drug or biological as of October 1, 2003. Also, this effort will help reduce use of the not otherwise classified (NOC) codes, for example J3490 and J3590. Thus far, we established or revised at least 40 HCPCS Level II codes to separately identify these products and products that have been “not otherwise classified”, effective January 1, 2023. CMS intends to continue this review in subsequent HCPCS code application quarterly cycles under application number HCP220517FAENJ. The current and prior quarterly coding decision summaries are available at this CMS website: <https://www.cms.gov/medicare/coding/medhcpcsgeninfo/prior-years-cms-hcpcs-levelii-coding-decisions-narrative-summary>.

5. Where can I find more information?

For questions or more information regarding the HCPCS Quarterly Updates, visit this CMS website: <https://www.cms.gov/medicare/coding/medhcpcsgeninfo>, or send an email to hcpcs@cms.hhs.gov.

For questions or more information regarding the NDC-HCPCS Crosswalks, visit this CMS website: <https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice>, or send an email to sec303aspdata@cms.hhs.gov.