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Biosimilars Coding & Reimbursement Significance under Medicare Part B

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On April 15, 2015, CMS issued a preliminary recommendation for a HCPCS code for Zarxio, the first biosimilar product ever to be approved by the FDA. CMS's recommendation provides the first indication of how the agency will establish HCPCS codes for biosimilars that are not interchangeable with the reference products they are based on, and also has significant implications for how such biosimilars will be reimbursed under Medicare Part B.

Background on Biosimilars

A similar biologic medicinal product, commonly referred to as a biosimilar, is a copy of an approved original biologic medicine whose data protection has expired. The relationship of biosimilars to the original biologic medicine is like the relationship of a generic to a brand name drug but not exactly the same as biosimilar, as the name implies, are similar to but not exact copies of the original product. Because biologicals are derived from living cells or organisms and consist of relatively large and often highly complex molecules, the biosimilar cannot be entirely identical to the original biologic, also referred to as the reference product. FDA approved the first biosimilar, Zarxio on March 6, 2015, a biosimilar of the biologic reference product, Neupogen, active ingredient filgrastim.¹ As part of the approval, FDA also gave Zarxio a temporary name, filgrastim-sndz, composed of the name of the biologic and a modifier identifying the manufacturer, Novartis (Sandoz).

When physician-administered biologics are provided in freestanding physician clinics and hospital outpatient departments, Medicare Part B payment amounts for drugs and biologics are tied to the Healthcare Common Procedure Coding System (HCPCS) codes assigned to them. In April 2015, as part of its annual review of HCPCS code applications, CMS announced its preliminary recommendation that Zarxio (filgrastim-sndz) be assigned HCPCS code Q5101 [Injection, Filgrastim, (G-CSF), Biosimilar, 1 microgram].² This preliminary code descriptor reveals CMS's approach to biosimilar coding, and its acknowledgement that this approach is subject to change. Below, we explain the main concepts of HCPCS coding, how it relates to Medicare Part B payment, and some implications.

Coding for Medicare Part B Reimbursement of Drugs and Biologics

The HCPCS is divided into two principal subsystems. Level I of the HCPCS is comprised of CPT (Current Procedural Terminology), a numeric coding system maintained by the American Medical Association (AMA). It is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, including drugs and biologicals.

Authority to maintain and distribute HCPCS Level II Codes lies with CMS.³ The HCPCS Work Group, an advisory body established by CMS and composed of representatives from CMS, the Pricing, Data Analysis and Coding Contractor for durable medical equipment, Medicaid, private payers, and the Veteran's Health Administration,

¹ FDA News Release. "FDA approves first biosimilar product Zarxio " March 6, 2015. Last accessed 4/28/15 at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm>

²CMS. Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals. May 7, 2015 12. Last accessed on 4/27/15 at <http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/May-7-2015-DrugAgenda.pdf>

³ 42 CFR Sec. 414.40 (a)

provides input to support the decision-making process.⁴ Annually, CMS receives HCPCS applications from manufacturers due in the first week of January. CMS's preliminary recommendations are published in April and are open for comment. There is opportunity for public discussion during meetings hosted by CMS and HCPCS Work Group usually in May. Final decisions are published in November and effective January of the next calendar year.

For drugs and biologics, one of three types of HCPCS codes may be assigned. Most drugs and biologics eventually receive a permanent "J code". Initially, but not always, CMS may assign a temporary, but specific "Q" code for the particular biologic⁵, as in the case of Zarxio. In these cases, CMS may lack the information it needs to assign a permanent code; but for programmatic needs, CMS establishes a temporary code to facilitate claims processing. In other cases, if a manufacturer has not yet applied for a HCPCS code or CMS has not yet assigned a specific HCPCS code for the particular drug or biologic, providers would report the drug or biologic using a J code designated for unclassified biologics or unclassified drugs. Since such a code is not specific to a particular drug, payers will request more information from providers before covering and paying for drugs reported with a miscellaneous HCPCS code.

There are several interesting observations about CMS's preliminary recommendation to assign Zarxio (filgrastim-sndz) the HCPCS code Q5101 [Injection, Filgrastim, (G-CSF), Biosimilar, 1 microgram].⁶ First, CMS assigned Zarxio (filgrastim-sndz) its own unique code and not the code of the reference product, Neupogen which is reported with J1442 [Injection, filgrastim (G-CSF), 1 microgram]. Generally, for brand and generic drugs, CMS assigns the same HCPCS code to all drug products listed as therapeutically equivalent in FDA's Orange Book. Therefore a brand-name drug and therapeutically equivalent generic versions of the drug would have the same HCPCS code.⁷

In September 2014, FDA established the Purple Book for biological products. Among other things, the book identifies whether a biological product licensed under section 351(k) of the Public Health Service Act has been determined by the FDA to be biosimilar ("B")⁸ to or interchangeable ("I")⁹ with a reference biological product (an already-licensed FDA biological product).¹⁰ CMS's assignment of a unique HCPCS codes for Zarxio suggests that CMS does not consider biosimilars with the Purple Book designation of "B" as therapeutically equivalent.

Second, CMS chose not to use FDA's temporary naming convention, filgrastim-sndz, but rather to include the name of the active ingredient only, filgrastim. Traditionally, CMS has established HCPCS code descriptors which are neutral to manufacturers.

Third, CMS chose to use the term, "biosimilar", in the code descriptor. This is a unique to biologics (i.e., CMS does not use the term "generic" in the code descriptor for non-biologics).

Fourth, by assigning a "Q" code, which as explained above is a temporary code assignment, CMS indicates that this initial coding assignment and descriptor is subject to change. Among other things, CMS may be waiting for FDA guidance on considerations in demonstrating interchangeability to a reference product; labeling for biosimilar biological products; and policies on appropriate naming convention for biosimilar and interchangeable products.

⁴ CMS. 2015 Guidelines for Participation in Public Meetings for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS). Last accessed 4/17/15 at <http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/ParticipationGuidelines.pdf>

⁵ CMS. Healthcare Common Procedure Coding System Level II Coding Procedures. Rev. September 6, 2012. Last accessed on 4/27/15 at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelIIICodingProcedures7-2011.pdf>

⁶ CMS. Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals. May 7, 2015. Last accessed on 4/27/15 at <http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/May-7-2015-DrugAgenda.pdf>

⁷ Senate Report 111-089. Section 3139. Present Law. Last accessed 4/28/15 at http://thomas.loc.gov/cgi-bin/cpquery/?&sid=cp111mY39a&r_n=sr089.111&&sel=TOC_761929&

⁸ Christl, Leah. "Overview of the Regulatory Pathway and FDA's Guidance for the Development and Approval of Biosimilar Products in the U.S." FDA. January 7, 2015. [A biologic product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.]

⁹ Ibid. [The biosimilar can be expected to produce the same clinical result as the reference product in any given patient; and for a product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the product and its reference product is not greater than the risk of using the reference product without such alternation or switch.]

¹⁰ FDA. Purple Book. Last accessed 4/28/15 at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm>

With the Q code assignment, CMS has moved expeditiously to assign a specific temporary code and make it operational July 1, 2015 ahead of the usual January 1, 2016 effective date for new codes and retroactive to Zarxio's FDA-approval date.¹¹

Finally, as with most HCPCS code descriptors, the unit of measure follows CMS's preference for billing units tied to the ingredient, rather than the standard billing units established by the National Council for Prescription Drug Programs, Inc. (NCPDP). Although CMS does not publish specific policies on selection of billing units, it tends to select units tied to amount of the ingredient.

Looking ahead, as CMS updates its "HCPCS Decision Tree For External Requests to Add or Revise Codes"¹² for biosimilars, several branches need to be fleshed out. Will FDA's designation of a biosimilar as biosimilar or interchangeable determine assignment of a unique code? Will CMS link HCPCS code assignments to FDA's potential range of interchangeable rankings (e.g., highly similar, finger-print-like similarity)? Will CMS assign the same HCPCS code only to those biosimilars which are interchangeable for all of the patient indications included in the label of the reference product? Will CMS change the HCPCS code assignment for a biosimilar when it changes its FDA designation from biosimilar to interchangeable, that is, potentially reassigning the biosimilar to the HCPCS code of the reference product?

Reimbursement Incentives

For drugs and biologics, a single HCPCS code may apply to multiple National Drug Codes (NDCs) where each NDC captures different labelers, strengths, dosages, and packaging. For example, the HCPCS code for the biologic, epoetin alfa, is J0885 [Epoetin Alfa (for non-esrd use),1000 units] and it applies to Amgen's Epogen (represented by six NDCs) and Janssen's Procrit (represented by eight NDCs).¹³ Regardless of the NDC, the billing units for the HCPCS code is the same, namely 1000 units of the ingredient, as indicated in the HCPCS code descriptor.

For physician-administered biosimilars such as Zarxio, statute sets the Medicare Part B reimbursement at ASP plus six percent of the reference biologic when provided in freestanding physician clinics.¹⁴ Statute does not, however, specify how physician-administered biosimilars are to be reimbursed when provided in hospital outpatient departments.¹⁵

This ASP-based payment amount is the weighted average of the manufacturer's ASP for all National Drug Codes (NDCs) assigned to the HCPCS code, the billing and payment code. More specifically, it is the manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume discounts, prompt pay discounts, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program.¹⁶ The Medicare database of ASPs is the basis for many private payers in setting drug reimbursement, although some private payers pay higher or lower percentages than Medicare's ASP plus six percent.¹⁷ Until information on the manufacturer's ASP is available for the biosimilar, CMS pays 106 percent of the wholesale acquisition cost (WAC) of the product.¹⁸

At this time, there is only one biosimilar assigned to the HCPCS code, Q5101 [Injection, Filgrastim, (G-CSF), Biosimilar, 1 microgram]. If CMS continues to assign each biosimilar with FDA designation "B" biosimilar (i.e. not

¹¹ CMS. Medlearn Matters. NewsFlash. "FDA Approval of First Biosimilar Product" March 31, 2015. SE1509.

¹² CMS. "HCPCS Decision Tree For External Requests to Add or Revise Codes." October 2006. Last accessed on 5/8/15 at http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS_Decision_Tree_and_Definitions.pdf

¹³ CMS. ASP NDC-HCPCS Crosswalk for Medicare Part B Drug: Effective April 1, 2015-June 30, 2015.

¹⁴ <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2015ASPFiles.html>

¹⁵ Social Security Act 1847A(b)(8); 1847A(c)(F), Biologics Price Competition Act

¹⁶ Social Security Act 1833(t)(14)

¹⁷ Social Security Act. Section 1847A(c).

¹⁸ Office of the Assistant for Planning and Evaluation. "ASPE Issue Brief: Medicare Part B Reimbursement of Prescription Drugs." June 2014.

¹⁹ CMS. Medlearn Matters. NewsFlash. "FDA Approval of First Biosimilar Product" March 31, 2015. SE1509.

interchangeable) a unique HCPCS code, then ASP-based payment will essentially be product-specific. If CMS assigns biosimilars with the FDA designation “I” or interchangeable to the same HCPCS code as the reference product, then the ASP will be a weighted average of the manufacturer’s ASP for each interchangeable product. In recent guidance, CMS indicated it will create a separate code to distinguish the biosimilar from the reference biological, but is considering other policy options for coding of additional biosimilars.¹⁹

If a biosimilar product does not have the same HCPCS billing code as the reference biologic, then there is no change to the ASP-based payment of the reference biologic. Because the payment amount for the biosimilar as established under the ACA includes six percent of the reference product instead of the biosimilar there is a modest incentive to use the biosimilar; modest under this scenario, because the payment amount for the reference product is unaffected.

If the biosimilar biologic product shares the same HCPCS billing code with the reference biologic, then the ASP-based payment creates more incentive to use the biosimilar and reduces the incentive to use the reference biologic. The presumably lower sales price of the biosimilar product will be factored into the weighted ASP paid by a physician for either product. This would increase the margin on the lower-priced biosimilar product for the physician and decrease the margin on the reference product for the physician. Assuming an increase in utilization, the payment incentive to use the biosimilar will attenuate over time as the biosimilar weighs more heavily in the ASP.

Conclusion

CMS’s preliminary recommendation for the HCPCS code assigned to Zarxio gives an indication of how it will set reimbursement for biosimilars which are not interchangeable. It would allow CMS to assign each subsequent biosimilar of the same reference product to the same HCPCS code and not necessarily create a unique HCPCS codes for each biosimilar. However, by assigning a temporary “Q” code, CMS suggests that its approach is subject to change.

CMS has already taken important steps to make its HCPCS coding decisions more transparent. Continued transparency will be particularly important as CMS revisits its “HCPCS Decision Tree For External Requests to Add or Revise Codes” to address coding for biosimilars. The resulting implications for payment and coverage are significant. Will lack of granularity in HCPCS coding, especially when multiple NDCs are assigned to a single HCPCS code, push payers to shift biosimilars from medical to pharmacy benefit as a way to strengthen utilization management strategies? For payers who want to strengthen utilization management for drugs handled under the medical benefit, will HCPCS coding be adequately detailed to support these efforts to ensure the right biosimilars are used for the appropriate patient indications? Depending on CMS’s approach, private payers may or may not choose to follow CMS’s lead. Private payers may choose to use CMS’s assigned HCPCS codes or may choose to develop their own HCPCS codes, i.e. “S” codes are temporary national HCPCS codes established by private payers that are not recognized by Medicare.

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¹⁹ CMS. Medlearn Matters. NewsFlash. “FDA Approval of First Biosimilar Product” March 31, 2015. SE1509

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