Harvard Medical School

Division of Pharmacoepidemiology and Pharmacoeconomics

BRIGHAM AND WOMEN'S HOSPITAL

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Andrew Slavitt, M.B.A.
Acting Administrator
Centers for Medicare and Medicaid Services

Dear Acting Administrator Slavitt:

We are researchers in one of the nation's largest programs studying the benefits and risks of medications, with particular reference to older patients. We write to point out an important potential problem with the proposed rule by CMS to blend reimbursement for follow-on biologics of the same reference product:[1] namely the challenges it would pose for conducting post-approval adverse event and effectiveness research necessary to inform the safe and effective use of this nascent category of follow-on biologics.

A program of blended reimbursement would result in the use of non-unique Healthcare Common Procedure Coding System "J codes" for follow-on biologics of the same reference product. However, as with national drug codes (NDCs) for small-molecule drugs, J codes also function as the principal means through which pharmacoepidemiologists—including those working for or with the government[2]—conduct post-approval research on the effects of biologics in typical patient care. Medicare claims data have become one of the most important resources for information on the adverse effects and benefits caused by medications in large, typical populations. Because of its loss of specificity, the proposed rule would hinder pharmacovigilance by precluding all product-specific surveillance.[3]

Such monitoring is needed because follow-on biologics are a new class of drugs. They can offer patients lower-cost treatment alternatives that can help stem rising prescription drug costs, increase medication adherence, and improve health outcomes. Still, physicians and patients may be hesitant about using follow-on biologics initially because biologics are structurally more complex than small-molecule drugs and because each product is created by a slightly different manufacturing process. Post-approval studies harnessing product-specific J codes are needed to conduct rapid, efficient claims-based pharmacovigilance to demonstrate the safety and effectiveness of specific follow-on biologics in relation to their reference product and to each other in order to dispel these fears. Such research could also identify which follow-on biologics perform better than others and under what circumstances—a particularly important question if a given follow-on biologic does not have the same indications as its reference product. Such data would be valuable to the FDA as it refines its approval requirements.

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[1] Centers for Medicare and Medicaid Services, 80 Fed Reg. 41,686 (proposed July 15, 2015) (to be codified at 42 C.F.R. pts. 405, 410, 411, 414, 425, 495).

[2] Chrischilles EA, et al. Mini-Sentinel assessment protocol: thromboembolic events after immunoglobulin administration v.2.0. April 22, 2014 (http://www.mini-sentinel.org/work_products/Assessments/Mini-Sentinel_Thromboembolic-Events-After-Immunoglobulin-Administration-Protocol.pdf).

[3] Sarpatwari A, Avorn J, Kesselheim AS. Progress and hurdles for follow-on biologics. N Engl J Med 2015;372(25):2380-2.

Providing separate J codes for each follow-on biologic product is also consistent with the statutory language of the Social Security Act. Section 1847A(b)(8) of the SSA specifies that payment for "a biosimilar biological product" (singular) shall constitute the average sales price of NDCs assigned to "such product" (singular) plus six percent of the average sales price of the reference product.[4] A plain reading of this provision supports a product-specific, as opposed to group-specific, payment mechanism for follow-on biologics.

Although the proposed rule could achieve savings, we believe that robust, product-specific, post-approval safety and effectiveness data will foster greater public confidence in FDA-approved follow-on biologics, which will help promote market competition. We respectfully encourage CMS to reconsider its proposed rule in regard to this issue.

Sincerely,

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[4] 42 U.S.C. § 1395w-3a(b)(8).