ALSTON&BIRD

WWW.ALSTON.COM

Health Care ADVISORY ■

APRIL 6, 2015

Biosimilar Reimbursement Pathways: CMS Guidance and Outstanding Issues

On March 6, 2015, the U.S. Food and Drug Administration (FDA) approved the first biosimilar in the United States. The Centers for Medicare & Medicaid Services (CMS) recently issued three guidances regarding reimbursement for biosimilars under Medicare Parts B and D, as well as under Medicaid. These guidances address questions that have arisen regarding reimbursement policies that CMS will implement for biosimilars. However, a number of issues remain outstanding and will need to be addressed by CMS in future guidances or regulations.

Medicare Part B

Medicare Part B generally covers drugs and biologicals that are not usually self-administered, including those that are administered in a physician's office or hospital outpatient department. On March 31, 2015, CMS issued a "Medicare Learning Network (MLN) Matters" (SE1509) that addresses frequently raised questions regarding biosimilar reimbursement under Medicare Part B. CMS clarifies, among other things, that the agency will incorporate biosimilars that are approved under the abbreviated biological approval pathway into the average sales price (ASP) payment methodology. Initially, Medicare will pay 106 percent of the product's wholesale acquisition cost (WAC). Once ASP information is available for the biosimilar product, Medicare will pay an amount equal to ASP for the product plus 6 percent of the reference product, as required by the Affordable Care Act (ACA).

CMS anticipates including the newly approved biosimilar in the next quarterly Healthcare Common Procedure Coding System (HCPCS) tape release, appearing in the claims processing system on July 1, 2015. Reimbursement for the biosimilar will be effective retroactively to the FDA approval date. CMS will create a separate code to distinguish the biosimilar from the reference product and is "considering policy options for coding of additional biosimilars."

The "MLN Matters" notes that CMS will release further guidance on coding and incorporation of biosimilars into the ASP payment methodology in the future.

Medicare Part D

Medicare Part D generally covers self-administered drugs from every therapeutic category of prescription drugs, with formularies varying to a certain extent by plan. On March 30, 2015, CMS issued to Part D sponsors a memorandum on coverage of biosimilars under Part D that clarifies the application of formulary review policies, low-income subsidy (LIS) and catastrophic cost sharing rules, and Coverage Gap Discount Program requirements for biosimilars. The memo also notes that follow-on biological products approved by the FDA under Section 351(k) of the Public Health

Service Act will be listed in a new *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*.

Regarding formulary review, CMS clarifies that reference and biosimilar products generally will not be considered different drugs for purposes of satisfying the two distinct drugs requirement for each of the categories and classes submitted by a Part D sponsor.[1] CMS also provides that biosimilars may be added to Part D plan formularies at any time as a formulary enhancement. The addition of a biosimilar (or the removal of the reference biological product) will be considered a non-maintenance change, to be evaluated on a case-by-case basis. For purposes of the Part D transition supply and notice requirements, CMS states that biosimilars and the reference biological product should be treated as different products.

For the purposes of LIS and catastrophic cost sharing rules, CMS clarifies that biosimilars do not meet the CMS definition of either a generic drug or a multiple source drug. Biosimilars are therefore subject to the higher maximum copayments for LIS eligible individuals applicable to all other Part D drugs. In 2015, the maximum copayments for LIS individuals were set at either $3.60 or $6.60, depending upon an individual's subsidy level. At the same time, CMS clarifies that the lower minimum copayments applicable to non-LIS eligible individuals in catastrophic coverage under the standard Part D benefit would not apply to biosimilars. Nevertheless, CMS "generally expects" that individuals who are not eligible for LIS will pay the 5 percent coinsurance for biosimilars in the catastrophic portion of the standard Part D benefit.

CMS also clarifies that biosimilars are non-applicable drugs for purposes of establishing coverage gap cost sharing under the basic Part D benefit. Biosimilars are therefore not discounted in the coverage gap or otherwise subject to Discount Program requirements.

Medicaid

Reimbursement for drugs and biologicals under Medicaid—and the rebates established under this program—have far-reaching impacts for manufacturers, as they may not charge any 340B entity a price greater than that derived under the Medicaid rebate formula. On March 30, 2015, CMS issued guidance on biosimilars and the Medicaid Drug Rebate (MDR) Program.[2] Through this guidance, CMS clarifies that biosimilars fall within the definition of "single source drugs" for purposes of the MDR program. As a result, biosimilars will be subject to a 23.1 percent rebate (based on average manufacturer price (AMP)) and potentially subject to a penalty for any increases in AMP over inflation.

CMS specifically suggests that cost savings may be achieved by states by applying traditional drug utilization and cost management tools to biosimilars, as well as through supplemental rebate agreements between states and manufacturers. CMS also notes that prescribers may not be able to "simply write the proprietary name of a reference biological product and expect the pharmacist to substitute it with the biosimilar biological product," as may be the case today with certain brand name and generic chemical compounds. Finally, to ensure "safe and efficacious use" of biosimilars, CMS encourages states to use drug utilization review programs and pharmacy and therapeutics (P&T) committees to inform physicians and pharmacists about appropriate prescribing and dispensing of biologics, including biosimilars.

---

1 Except as provided in 42 C.F.R. 423.120(b)(2)(ii), which provides that a Part D plan must include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, that only two drugs are available in that category or class of Part D drugs and that one drug is clinically superior to the other drug in that category or class of Part D drugs.

2 CMS issued separate guidances to drug manufacturers and state technical contacts, which are substantively identical.

Key Outstanding Reimbursement Issues

Beyond the issue areas on which CMS has already noted additional guidance is forthcoming, there are several key issues around biosimilar reimbursement which have not yet been addressed by CMS, all of which may be ripe for additional action from Congress.

- ***Interchangeability.*** CMS's memo to Part D sponsors specifically notes that additional guidance for "interchangeable" biological products may be issued at a later date. Neither CMS nor the FDA has provided final guidance or regulations on interchangeability.
- ***Medicare Part B.*** The "MLN Matters" guidance does not address how biosimilars will be reimbursed in all Part B settings. The guidance is notably silent on reimbursement policies for drugs provided in hospital outpatient departments, including the availability of a transitional add-on payment. Additional guidance from CMS may be forthcoming; the annual hospital outpatient regulations may serve as one vehicle for CMS to address these remaining issues. The next hospital outpatient proposed rule is anticipated in July.
- ***Medicare Part A.*** The administration and procurement costs of drugs and biologicals for use in certain provider settings, such as a hospital inpatient department, may subject the drug or biologic to payment under Medicare Part A. In general, Part A pays for such drugs or biological products as part of an overall prospective payment, akin to a "bundled payment." CMS has not yet addressed how these payment systems will be updated to account for biosimilars, and additional guidance may be forthcoming. Research suggests that "it may be challenging to adjust [prospective] payment rates to reflect lower biologic prices,"[3] potentially impacting provider incentives to use certain biological products.
- ***Bundled Payments and Demonstration Projects.*** As CMS continues to implement an array of payment reform demonstration projects (largely through the Center for Medicare and Medicaid Innovation (CMMI)), guidance on how payments for biosimilars will be made under these programs will be necessary.

These and other issues will impact the acceptance of biosimilars by providers and patients alike, dictating the clinical success of biosimilars as well as their ability to drive down overall health care spending. We continue to closely monitor how CMS is regulating and how Congress is legislating on these new products.

Written by **Timothy Trysla** *and* **Danielle White**.

---

[3] Mulcahy, Andrew W., Zachary Predmore, and Soeren Mattke, "The Cost Savings Potential of Biosimilar Drugs in the United States," *RAND Perspectives*, Nov. 3, 2014.

If you would like to receive future ***Health Care Advisories*** electronically, please forward your contact information to **healthcare.advisory@alston.com.** Be sure to put "**subscribe**" in the subject line.

If you have any questions, or would like additional information, please contact any of the following:

Robert A. Bauman
202.239.3366
bob.bauman@alston.com

Joshua L. Becker
404.881.4732
josh.becker@alston.com

Saul Ben-Meyer
212.210.9545
saul.ben-meyer@alston.com

Donna P. Bergeson
404.881.7278
donna.bergeson@alston.com

Kristine McAlister Brown
404.881.7584
kristy.brown@alston.com

Michael L. Brown
404.881.7589
mike.brown@alston.com

Cathy L. Burgess
202.239.3648
cathy.burgess@alston.com

Angela T. Burnette
404.881.7665
angie.burnette@alston.com

Jennifer L. Butler
202.239.3326
jennifer.butler@alston.com

Mark Timothy Calloway
704.444.1089
mark.calloway@alston.com

Craig Carpenito
212.210.9582
craig.carpenito@alston.com

Stacy C. Clark
404.881.7897
stacy.clark@alston.com

Patrick C. DiCarlo
404.881.4512
pat.dicarlo@alston.com

Hon. Robert J. Dole
202.654.4848
bob.dole@alston.com

Theodore B. Eichelberger
404.881.4385
ted.eichelberger@alston.com

Dan Elling
202.239.3530
dan.elling@alston.com

Sarah Ernst
404.881.4940
sarah.ernst@alston.com

Larry Gage
202.239.3614
larry.gage@alston.com

Ashley Gillihan
404.881.7390
ashley.gillihan@alston.com

David R. Godofsky, F.S.A.
202.239.3392
david.godofsky@alston.com

Katherine E. Hertel
213.576.2600
kate.hertel@alston.com

John R. Hickman
404.881.7885
john.hickman@alston.com

H. Douglas Hinson
404.881.7590
doug.hinson@alston.com

Sean C. Hyatt
404.881.4410
sean.hyatt@alston.com

Bill Jordan
404.881.7850
bill.jordan@alston.com

Ted Kang
202.239.3728
edward.kang@alston.com

Peter M. Kazon
202.239.3334
peter.kazon@alston.com

David Keating
404.881.7355
david.keating@alston.com

Johann Lee
202.239.3574
johann.lee@alston.com

Blake Calvin MacKay
404.881.4982
blake.mackay@alston.com

Emily W. Mao
202.239.3374
emily.mao@alston.com

Dawnmarie R. Matlock
404.881.4253
dawnmarie.matlock@alston.com

Wade Miller
404.881.4971
wade.miller@alston.com

Steven C. Mindy
202.239.3816
steven.mindy@alston.com

William (Mitch) R. Mitchelson, Jr.
404.881.7661
mitch.mitchelson@alston.com

Michael H. Park
202.239.3630
michael.park@alston.com

Craig R. Pett
404.881.7469
craig.pett@alston.com

Hon. Earl Pomeroy
202.239.3835
earl.pomeroy@alston.com

Steven L. Pottle
404.881.7554
steve.pottle@alston.com

T.C. Spencer Pryor
404.881.7978
spence.pryor@alston.com

J. Mark Ray
404.881.7739
mark.ray@alston.com

Mark H. Rayder
202.239.3562
mark.rayder@alston.com

Jonathan G. Rose
202.239.3693
jonathan.rose@alston.com

Colin Roskey
202.239.3436
colin.roskey@alston.com

Sam Rutherford
404.881.4454
sam.rutherford@alston.com

Karen M. Sanzaro
202.239.3719
karen.sanzaro@alston.com

Marc J. Scheineson
202.239.3465
marc.scheineson@alston.com

Thomas G. Schendt
202.239.3330
thomas.schendt@alston.com

Thomas A. Scully
202.239.3459
thomas.scully@alston.com

Donald E. Segal
202.239.3449
donald.segal@alston.com

John B. Shannon
404.881.7466
john.shannon@alston.com

Dominique Shelton
213.576.1170
dominique.shelton@alston.com

Robert G. Siggins
202.239.3836
bob.siggins@alston.com

Carolyn Smith
202.239.3566
carolyn.smith@alston.com

Paula M. Stannard
202.239.3626
paula.stannard@alston.com

Michael L. Stevens
404.881.7970
mike.stevens@alston.com

Brian Stimson
404.881.4972
brian.stimson@alston.com

Robert D. Stone
404.881.7270
rob.stone@alston.com

Daniel G. Taylor
404.881.7567
dan.taylor@alston.com

Julie K. Tibbets
202.239.3444
julie.tibbets@alston.com

Timothy P. Trysla
202.239.3420
tim.trysla@alston.com

Kenneth G. Weigel
202.239.3431
ken.weigel@alston.com

Kerry T. Wenzel
404.881.4983
kerry.wenzel@alston.com

Danielle F. White
202.239.3073
danielle.white@alston.com

Michelle A. Williams
404.881.7594
michelle.williams@alston.com

Marilyn K. Yager
202.239.3341
marilyn.yager@alston.com

ALSTON&BIRD

WWW.ALSTON.COM