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TO: Part D Sponsors

FROM: Amy K. Larrick
Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Part D Requirements for Biosimilar Follow-On Biological Products

DATE: March 30, 2015

The Affordable Care Act amends section 351 of the Public Health Service Act (PHS Act) adding a subsection (k) to create an abbreviated licensure pathway for follow-on biological products that are demonstrated to be either “biosimilar” to or “interchangeable” with a Food and Drug Administration (FDA) licensed reference biological product.¹ This memorandum clarifies the application of Part D formulary review policies, low-income subsidy (LIS) and catastrophic cost sharing rules, and Coverage Gap Discount Program (Discount Program) requirements regarding “biosimilar” follow-on biological products covered under Medicare Part D. Additional guidance may be issued for “interchangeable” biological products at a later date.

Medicare Part D Formulary Review Policies

Biosimilars may provide Part D sponsors with new products that create formulary design options to help control costs while still ensuring beneficiaries have access to the medications they need. Our existing formulary review and formulary change policies provide Part D sponsors with the flexibility to promote the appropriate use of biosimilars through their formulary and drug utilization management strategies when designing their Part D benefits. CMS will evaluate formulary change requests involving biosimilars on an individual basis and will determine if they meet the requirements of our formulary review and approval process based on information in the FDA-approved label and statutory compendia. However, the reference and biosimilar products will not be considered as different drugs for the purposes of satisfying the two distinct drugs requirement for each of the submitted categories and classes, except as provided in 42 CFR § 423.120(b)(2)(ii).

Biosimilars may be added to plan formularies at any time as a formulary enhancement. Formulary changes involving the addition of the biosimilar and removal of the reference biological product will generally be considered a non-maintenance change. These formulary

¹ Follow-on biological products approved under subsection (k) will be listed in the FDA’s new *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm>. Part D sponsors are also encouraged to monitor the FDA’s website for new BLA approvals at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu>.

changes will be evaluated, as are all non-maintenance changes, on a case-by-case basis, and allowed if the formulary continues to meet the formulary review standards with the corresponding addition of the biosimilar. Because biosimilars are not interchangeable with the reference biological product, CMS expects that Part D sponsors' Pharmacy and Therapeutics (P&T) committees will review newly approved biosimilars in accordance with section 30.1.5 of Chapter 6 of the Medicare Prescription Drug Benefit Manual.

For the purposes of Part D transition supply and notice requirements, biosimilars and the reference biological product should be treated like different products. Part D enrollees taking the reference biological product should receive a transition supply when only a biosimilar is available on the formulary. Similarly, Part D enrollees taking the biosimilar should receive a transition supply when the reference biological product is the only formulary product.

Low Income Subsidy (LIS) and Catastrophic Cost Sharing

Section 1860D-14(a) of the Social Security Act specifies lower maximum copayments for LIS eligible individuals for generic drugs and preferred drugs that are multiple source drugs (as defined in §1927(k)(7)(A)(i) of the Social Security Act) than available for all other Part D drugs. Biosimilars do not meet the CMS definition of a generic drug in 42 CFR §423.4 or the §1927(k)(7) definition of a multiple source drug. Consequently, biosimilars are subject to the higher maximum copayments for LIS eligible individuals applicable to all other Part D drugs. In 2015, the maximum copayment would be either \$3.60 or \$6.60 depending upon the individual's subsidy level.

Similarly, lower minimum copayments specified in §1860D-2(b)(4) for non-LIS individuals in the catastrophic coverage portion under the standard Part D benefit for generic drugs and preferred drugs that are multiple source drugs would not apply to biosimilars. Nevertheless, CMS generally expects that non-LIS individuals will pay the 5% coinsurance for biosimilars in the catastrophic portion of the standard Part D benefit in accordance with §1860D-2(b)(4) requirements.

Applicability to the Medicare Part D Coverage Gap Discount Program

The Affordable Care act established the Discount Program by adding sections 1860D-43 and 1860D-14A of the Social Security Act. When defining "applicable drugs" that are discounted under the Discount Program, the statute specifically excludes follow-on biological products receiving FDA approval under subsection (k) of section 351 of the PHS Act. Consequently, biosimilars are non-applicable drugs for purposes of establishing coverage gap cost sharing under the basic Part D benefit, and are not discounted or otherwise subject to Discount Program requirements.

If you have any questions regarding this memorandum, please contact Stephanie Hammonds at Stephanie.Hammonds@cms.hhs.gov or (410) 786-1646.