



Position Statement: Biosimilars

Boehringer Ingelheim (BI) supports government policies that allow for beneficiary choice and optimal access to biosimilars while ensuring a competitive and sustainable marketplace. Specifically, we support:

- Centers for Medicare and Medicaid Services (CMS) 2018 Medicare Part B policy that will no longer group newly approved biosimilar biological products with the same reference product into a common HCPCS billing code
- CMS 2018 Medicare Part B policy that provides pass-through status to biosimilars to encourage utilization
- Recent change to the Part D “Coverage Gap” policy that now includes biosimilars in the Coverage Gap Discount Program (CGDP)
- Development of state substitution policies that allow automatic substitution of interchangeable biosimilars by pharmacists.

Background:

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation. Boehringer Ingelheim is one of the world’s top 20 pharmaceutical companies. Headquartered in Ingelheim, Germany, the company operates globally with approximately 50,000 employees. Since its founding in 1885, the company has remained family-owned and today creates value through innovation for three business areas including human pharmaceuticals, animal health and biopharmaceutical contract manufacturing. Boehringer Ingelheim is committed to improving lives and providing valuable services and support to patients and their families.

Biologic medicines have changed the world of healthcare by revolutionizing the treatment of many debilitating and life-threatening diseases. Biosimilars, which are highly similar alternatives to the approved reference biologic, are now available in the United States with 9 biosimilars FDA-approved and 3 biosimilars on the market. Biosimilars are held to the same standards of quality, safety, and efficacy as the complex reference biologic.

Medicare Part B: New Coding and Payment Policies Promote Competition

Consistent with Boehringer Ingelheim’s biosimilar principles, we support CMS’ 2018 Medicare Part B policy that will no longer group newly approved biosimilar biological products with the same reference product into a common HCPCS billing code, as was previously required for 2016 and 2017. Beginning CY 2018, CMS will provide each biosimilar its own J-code, consistent with the treatment of new biologics. We believe the new coding and payment policy provides for a competitive and sustainable biosimilar marketplace.

In addition to the revision of the coding policy, in the same regulatory release, CMS provided temporary “pass-through” status to all biosimilars beginning in CY 2018. Pass-through is a temporary status under the



Outpatient Prospective Payment System (OPPS) which sets payment at ASP + 6% for the duration of pass-through. This policy is particularly notable since CMS changed payment for drugs acquired via 340B to be paid at ASP – 22.5% beginning in CY 2018. We believe the application of pass-through to biosimilars is consistent with CMS’ coding and payment policies for all new biologics.

Medicare Part D: Coverage Gap Policy Change Improves Access to Biosimilars

We support the recent legislative change included in the Balanced Budget Act of 2018 (BBA) to allow biosimilars to be “applicable drugs” for the purposes of the Coverage Gap Discount Program effective January 1, 2019. Prior to passage of this bill, biosimilars were considered “non-applicable drugs” within the CGDP which meant even at a lower price point, a biosimilar was more expensive to both the patient and a health plan during the “Coverage Gap”. As a result of the BBA, manufacturers of biosimilars will now pay the same rebate and be on par with the branded innovator drug. Boehringer Ingelheim is committed to proactively pursuing policies to improve the patient, provider and payer experience with biosimilars.

State Substitution

As biosimilars represent a new type of product, concepts related to pharmacy-level substitution need to be addressed at the state level, where pharmacy practice laws reside. BI supports the development of state substitution policies that allow automatic substitution of interchangeable biosimilars by pharmacists. A majority of states have updated their laws to reflect this approach and BI continues to encourage remaining states to do the same.

Patient Impact:

We believe biosimilars represent an opportunity to drive savings across the health system and improve access for patients. Boehringer Ingelheim is committed to proactively pursuing policies to improve the patient, provider, and payer experience with biosimilars.