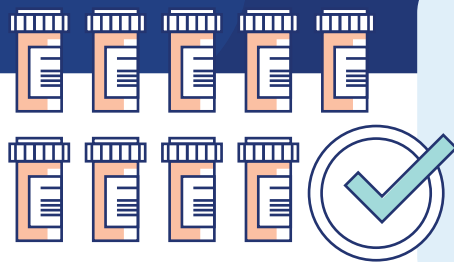


WHAT ARE BIOSIMILARS?



Biosimilars, which are highly similar alternatives to approved reference biologics, are now available in the United States with 12 biosimilars FDA-approved and 3 biosimilars on the market. Biosimilars are held to the same standards as the reference biologic medicine.

WHAT IS HAPPENING WITH THEM, AND WHY SHOULD WE CARE?

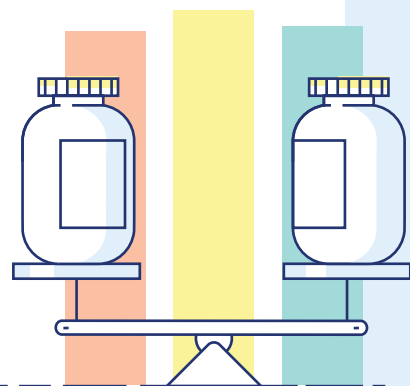
MEDICARE PART B

New Coding and Payment Policies Promote Competition

Beginning CY 2018, CMS will provide each biosimilar its own J-code, consistent with the treatment of new biologics. **The new coding and payment policy provides for a competitive and sustainable biosimilar marketplace.**



2018



MEDICARE PART D

Coverage Gap Policy Change Improves Access to Biosimilars

BI supports 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.** Before the BBA, 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. As a result of the BBA, manufacturers of biosimilars will now pay the same rebate and be on par with the branded innovator drug.

STATE SUBSTITUTION

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.

