POSTTEST

Managing Costs and Advancements in Biosimilars

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Sample of Online Posttest

Choose the best answer for each of the following:

1. Current marketing approval for biologics is regulated by:

A. The FDA, under the Public Health Service Act
B. The FDA, under the Federal Food, Drug, and Cosmetic Act
C. The NIH, under the Federal Food, Drug, and Cosmetic Act
D. The NIH, under the Drug Price Competition and Patent Term Restoration Act

2. With respect to reference-biologics, biosimilars:

A. Have identical primary structure (amino acid [AA] sequence) and clinically equivalent efficacy and safety.
B. Differ in primary structure (AA sequence) but are identical in clinical efficacy and safety.
C. Are not required to undergo a transition study to test interchangeability for FDA approval.
D. Have a higher risk of adverse effects due to differences in manufacturing processes.

3. A patient with rheumatoid arthritis is being treated with infliximab. It is determined that CT-P13, a biosimilar of infliximab, would have a lower out-of-pocket expense for the patient. Which of the following is most true?

A. If the patient were to experience an adverse effect, the incident could be reported through the US MedWatch program and collected as part of postmarketing surveillance.
B. Pharmacy-level substitution is regulated at the federal level.
C. Due to inherent differences in immunogenicity to the reference-biologic, the prescribing physician is required to clinically assess the patient before authorizing a switch to the biosimilar.
D. Biosimilars are not required to be assessed for interchangeability with the reference-biologic and have a serious risk for spikes in immunogenicity.

4. Predicting the impact of biosimilars on the US market is necessary for adapting the healthcare system to properly incorporate these medicines for patient benefit. Budget impact analysis (BIA) is a commonly used modeling method to predict economic changes in a healthcare system. Which of the following is most true regarding the use of BIAs in predicting the impact of biosimilars on the US market?

A. BIAs may be most effective paired with cost-effectiveness analyses.
B. Unlike the BIAs used in predicting biosimilar adoption in the European Union, those analyzing the US market are standardized and frequently published.
C. EU healthcare systems are very similar to those of the United States. Thus, BIAs of the EU member states can easily be extrapolated to predict the impact on the US market.
D. Cost savings generated by adoption of biosimilars can be achieved through direct competition with reference-biologics without modification of existing laws.

5. Incorporation of biosimilars into the US healthcare system will require a targeted approach to multiple barriers to adoption. Which of the following solutions may provide the largest impact on biosimilar use as discussed in the supplement?

A. A consensus of information, similar to that done in the European Union, provided jointly by manufacturers of reference-biologics and biosimilars along with increased transparency of FDA approval decisions
B. Modification of Medicare Part D and the 340B Drug Pricing Program to incentivize competition between biosimilars and reference-biologics
C. Adopting marketing approval requirements for biosimilars that are identical to those required for reference-biologics
D. Allowing pharmacy-level substitution of reference-biologics for a biosimilar through federal legislation

6. **More than 1200 specialty clinics (including oncology clinics) where biologics and biosimilars are often administered have closed or consolidated due to economic pressures in the past decade. With the reduction in the number of clinics, which of the following best describes a patient access barrier to biologics and biosimilars?**
   A. Increase in transportation time and costs
   B. Increase in prices of biologics
   C. Increase in treatment options
   D. Increase in provider options

7. **In 2018, the Centers for Medicare & Medicaid Services updated its policy on Healthcare Common Procedure Coding System (HCPCS) codes for biosimilars in which of the following ways?**
   A. Assigned the same HCPCS codes to biosimilars and reference-biologic products
   B. Assigned the same HCPCS codes to biosimilars of a single reference-biologic product
   C. Assigned unique HCPCS codes to biosimilars and reference-biologic products
   D. Assigned the same HCPCS codes to biosimilars of the same manufacturer

8. **HC is a 53-year-old woman undergoing myelotoxic chemotherapy treatment for stage III breast cancer. HC has been receiving pegfilgrastim once per chemotherapy cycle for the prophylaxis of neutropenia. At her most recent chemotherapy treatment, HC was administered pegfilgrastim with an on-body injector (Onpro). The on-body injector system for pegfilgrastim is an example of which of the following?**
   A. Use of interchangeability to expand market presence
   B. Use of substitution to expand market presence
   C. Use of new formulation to expand market presence
   D. Use of new delivery technologies to expand market presence

9. **Biologic products are manufactured using living cells and recombinant DNA technology. One consequence of the complex manufacturing process is that slight batch-to-batch variations in the final biologic product are common. Some scholars have maintained that the variations effectively amount to which of the following?**
   A. A biosimilar
   B. An interchangeable biologic
   C. A substitution biologic
   D. A biobetter

10. **Physician acceptance is one of the factors in the market uptake of biosimilars. Which of the following best describes the major driver in physician acceptance of biosimilars?**
   A. Consulting fees to promote biosimilars
   B. Education on biosimilars
   C. Providing free samples of biosimilars
   D. Providing patient coupons for biosimilars