POSTTEST

Improving Provider and Patient Acceptance of Biosimilars in Treating Cancer: Clinical, Manufacturing, and Cost Considerations

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Sample of Online Posttest

Choose the best answer for each of the following:

1. The biosimilar class of drugs was created through the Biologics Price Competition and Innovation Act in part to spur innovation, stimulate competition, and promote cost reductions in the realm of biological products. Which of the following best describes a biosimilar in relation to the reference biological product?

A. In comparison to the biologic reference product, a biosimilar is partly similar and does not differ in a clinically meaningful way with respect to safety, purity, and potency.
B. In comparison to the biologic reference product, a biosimilar is mostly similar and may differ slightly with respect to safety, purity, and potency.
C. In comparison to the biologic reference product, a biosimilar is highly similar and does not differ in a clinically meaningful way with respect to safety, purity, and potency.
D. A biosimilar is identical to the reference product in the same way that a small-molecule generic drug is identical to its brand name counterpart.

2. Biosimilars are typically approved through 351(k) approval pathways. This streamlined approval mechanism places a heavy emphasis on which types of drug development studies?

A. Physicochemical, structural, and functional characterization of the products
B. Physiological, preclinical, and formulation characterization of the products
C. Physicochemical, identical, and similar characterization of the products
D. Physiological, identical, and interchangeable characterization of the products

3. Biosimilars can be approved for therapeutic indications held by the reference product without directly studying those indications in comparative clinical trials. Approval of those indications is predicated on the totality of evidence required by the FDA for regulatory approval based on sound regulatory and scientific principles. Gaining approval for such indications is referred to as _____.

A. Extrapolation
B. Interchangeability
C. Justification
D. Biosimilarity

4. In contrast to the small-molecule drugs where generic products and brand name products share an identically named active ingredient, a biosimilar cannot carry the same name as the reference biologic product. Specific naming is needed for a variety of reasons, including differentiation of products in the marketplace and in formularies, accuracy in pharmacovigilance, and processing of insurance claims. Which of the following best describes the naming convention specified by the FDA for biologics and biosimilars?

A. A root, nonproprietary name of the active ingredient plus a suffix that identifies the manufacturer
B. A root, nonproprietary name of the active ingredient plus a 4-letter suffix that is devoid of meaning
C. A root, proprietary name of the active ingredient unique to each manufacturer plus a random, 4-letter suffix
D. A root, nonproprietary name of the active ingredient plus a 4-letter suffix determined by the manufacturer

5. To promote reduced costs of biologic products, the 351(k) biosimilar approval was designed to require fewer of which of the following studies?

A. Biocompatibility studies
B. Interchangeability studies
C. Switching studies
D. Clinical studies

6. Interchangeability:

A. Enables the substitution of a biosimilar for a biologic at the point of purchase
B. Ensures that there are no hypersensitivity reactions to a biosimilar
C. Requires demonstrating similar efficacy and safety to the biologic drug with no greater risk in switching than in remaining on the reference drug
D. Affords a 5-year exclusivity for the manufacturer

7. Which of the following represents a barrier to the uptake and adoption of biosimilars in oncology clinical practice?

A. Centers for Medicare & Medicaid Services reimbursement formula
B. Preferred status on pharmacy benefit management formularies
C. Concern of immunogenicity
D. Interchangeability designation

8. In addition to being reimbursed 100% of the average sales price (ASP) of the biosimilar, providers under Medicare Part B receive:

A. 3.5% of the reference drug's ASP
B. 5% of the reference drug's ASP
C. 6% of the reference drug's ASP
D. 7.5% of the reference drug's ASP

9. A biobetter is:

A. A biosimilar that has received interchangeability status
B. A biosimilar that is identical to the reference biologic
C. A biologic that has been reformulated in some manner
D. A biologic that has received interchangeability status

10. All of the following support lower development costs for the biosimilar except:

A. Higher FDA fees
B. Phase 4 analytical studies and marketing
C. Totality of the evidence approach
D. Extrapolation