AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 245
(A-23)

Introduced by: Association for Clinical Oncology

Subject: Biosimilar/Interchangeable Terminology

Referred to: Reference Committee B

Whereas, Biosimilars are a type of biologic medication that is safe and effective for treating many illnesses; and

Whereas, A biosimilar and its original biologic have no clinically meaningful differences in terms of quality, safety, and efficacy; and

Whereas, Biosimilars and biologics have the same treatment risks and benefits[1]; and

Whereas, Biosimilars may be available at a lower cost than the original biologic reference product and studies show that savings improve when biosimilars are used in place of reference biologics during the treatment of cancer malignancies, resulting in savings to the Medicare program and decreased out-of-pocket costs for patients; and

Whereas, An interchangeable product is not superior in quality to a biosimilar and would have to meet the same regulatory requirements as a biosimilar; and

Whereas, Interchangeability is simply a legislative term that has created confusion about the inherent lack of clinically meaningful difference among biosimilars; and

Whereas, If a biosimilar is equivalent in structure, function, safety, and efficacy to the reference product, by definition the two are interchangeable; and

Whereas, Despite the Food and Drug Administration's (FDA) efforts to provide clarity on the meaning of "interchangeable" (a new legislative term), including the release of guidance on interchangeability, confusion and misinformation remain; and

Whereas, By creating a divide between a biosimilar and an interchangeable biosimilar for regulatory purposes at the pharmacy level, the United States further exacerbates clinician and patient education and access barriers[2]; therefore be it

RESOLVED, That our American Medical Association repeal policy H-125.976, *Biosimilar Interchangeability Pathway* (Rescind HOD Policy); and be it further

RESOLVED, That our AMA advocate for state and federal laws and regulations that support patient and physician choice of biosimilars and remove the "interchangeable" designation from the FDA's regulatory framework. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 5/10/23

REFERENCES
1. Food and Drug Administration. Biosimilar Basics for Patients. (2023). https://www.fda.gov/drugs/biosimilars/biosimilar-basics-patients
2. Gladys Rodriguez et. al, ASCO Policy Statement on Biosimilar and Interchangeable Products in Oncology. *JCO Oncology Practice*. April 07, 2023. https://ascopubs.org/doi/pdf/10.1200/OP.22.00783?role=tab

RELEVANT AMA POLICY

Biosimilar Interchangeability Pathway H-125.976
Our AMA will: (1) strongly support the pathway for demonstrating biosimilar interchangeability that was proposed in draft guidance by the FDA in 2017, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times impacts the safety or efficacy of the drug; and (2) issue a request to the FDA that the agency finalize the biosimilars interchangeability pathway outlined in its draft guidance Considerations in Demonstrating Interchangeability With a Reference Productwith all due haste, so as to allow development and designation of interchangeable biosimilars to proceed, allowing transition to an era of less expensive biologics that provide safe, effective, and accessible treatment options for patients.
Citation: Res. 523, A-18;