AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 207
(A-24)

Introduced by: Medical Student Section

Subject: Biosimilar Use Rates and Prevention of Pharmacy Benefit Manager Abuse

Referred to: Reference Committee B

Whereas, biologics account for only 2% of prescriptions but 40% of US pharmaceutical spending and 90% of the net pharmaceutical spending growth over the past decade[1-6]; and

Whereas, biologics are often significantly more expensive than small-molecule drugs, costing on average $10,000 to $40,000 per patient annually with some prices up to $500,000[1-6]; and

Whereas, biosimilars exhibit no clinically meaningful differences in safety, purity, and potency compared to their corresponding “brand-name” (originator, or reference product) biologic[7]; and

Whereas, the US has only approved 50% of the biosimilars approved in other industrialized nations, with an average uptake rate of 20% compared to over 80%[8-16]; and

Whereas, average US price decreases due to biosimilar entry are only 15 to 40% compared to 70% in other industrialized nations[8-16]; and

Whereas, other industrialized nations improve biosimilar uptake through lucrative financial incentives for physicians to maintain robust reimbursement while saving on medication costs, including rewards for biosimilar usage targets and shared savings programs[17-23]; and

Whereas, “brand-name” biologics manufacturers have blocked biosimilar uptake in the US via long-term exclusivity agreements with pharmacy benefit managers (PBMs) for preferential coverage in insurance plans, such as Johnson & Johnson with Remicade (infliximab) and AbbVie with Humira (adalimumab)[24-25]; and

Whereas, biologics manufacturers’ efforts to prevent biosimilar coverage by insurers interfere with physician’s prescriptive authority, conflict with analogous AMA policy supporting physicians’ right to prescribe generic drugs, and maintain exorbitant pharmaceutical costs; and

Whereas, the Federal Trade Commission (FTC) and Department of Justice (DOJ) have the authority to investigate and block exclusive distribution clauses as antitrust violations, and AMA advocacy can help ensure that PBM exclusivity agreements are an antitrust priority[25-27]; therefore be it

RESOLVED, that our American Medical Association support economic incentives to increase physician use of less expensive biosimilars instead of their reference biologics (New HOD Policy); and be it further

RESOLVED, that our AMA encourage the Federal Trade Commission (FTC) and Department of Justice (DOJ) Antitrust Division to closely scrutinize long-term exclusive contracts signed

between biologics originators and PBMs to ensure they do not impede biosimilar development and uptake. (New HOD Policy)

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

Received: 4/5/2024

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RELEVANT AMA POLICY

H-125.980 Abbreviated Pathway for Biosimilar Approval
Our AMA supports FDA implementation of the Biologics Price Competition and Innovation Act of 2009 in a manner that 1) places appropriate emphasis on promoting patient access, protecting patient safety, and preserving market competition and innovation; 2) includes planning by the FDA and the allocation of sufficient resources to ensure that physicians understand the distinctions between biosimilar products that are considered highly similar, and those that are deemed interchangeable. Focused educational activities must precede and accompany the entry of biosimilars into the U.S. market, both for physicians and patients; and 3) includes compiling and maintaining an official compendium of biosimilar products, biologic reference products, and their related interchangeable biosimilars as they are developed and approved for marketing by the FDA.