AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 504
(A-24)

Introduced by: California

Subject: FDA Regulation of Biosimilars

Referred to: Reference Committee E

Whereas, biologics drugs account for 2% of pharmaceutical prescriptions by volume, but account for 37-43% of current U.S. pharmaceutical spending and 90% of net pharmaceutical spending growth over the past decade;[1-6] and

Whereas, biologic drugs, typically recombinant proteins or monoclonal antibodies, are significantly more expensive than small molecule drugs; prices average ~$10,000-$40,000 per patient per year, and can be as costly as $250,000 per patient per year;[1-6] and

Whereas, biosimilar medications are defined by the Food and Drug Administration (FDA) and European Medicines Agency (EMA) as "highly similar to and have no clinically meaningful differences in terms of safety, purity, and potency when compared to an originator biologic that is already approved;"[7] and

Whereas, under the 2010 Biologics and Price Competition Act, the FDA created a licensure pathway (called the 351(k) pathway) for approving biosimilars of originator biologics; the first biosimilar was approved by the FDA in 2015;[7] and

Whereas, the approval process is more stringent for a biosimilar in comparison with a generic small molecule, requiring approval through the Biologics License Application Pathway and post-marketing surveillance;[8] and

Whereas, in 2018, the FDA standardized requirements for approving "interchangeable biologics", defined as a biosimilar that meets additional requirements that allow it to be substituted for an originator biologic without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand name drugs, i.e., "pharmacy-level substitution;"[9] and

Whereas, existing regulations allow physicians to specify when a pharmacy-level substitution is not clinically appropriate, such as for reasons of allergies or concern for adverse reactions to inactive ingredients; and

Whereas, U.S. regulatory requirements to designate a biosimilar as 'interchangeable' are significantly more stringent than those in Europe; to demonstrate 'interchangeability' the FDA requires a Phase 3 switching non-inferiority trial, in which patients are repeatedly switched between the biosimilar and reference biologic agent, whereas the EMA considers biosimilars as 'interchangeable' without the need for additional crossover "switching" studies;[10-16] and

Whereas, long-term clinical studies of biosimilars in European countries have not demonstrated any notable difference in the efficacy or safety of biosimilar products relative to originators, which challenges the necessity for these switching studies;[15-16] and

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Whereas, the FDA requirements to achieving an "interchangeable" designation in the U.S. are another reason that uptake of biosimilars has been lower in the U.S. than in other Organization for Economic Cooperation and Development (OECD) countries;[10-25] and

Whereas, pharmaceutical companies have made huge investments in the U.S. to market biologics as superior to their biosimilar counterparts; which may explain why biosimilars only have an average market penetration rate of 20%, compared with 80% in Europe;[17-25] and

Whereas, a survey of 510 U.S. community oncologists illustrated significant knowledge gaps in the use of biosimilars and this translated into hesitancy in prescribing biosimilars;[26] and

Whereas, a recent American Society of Clinical Oncology (ASCO) policy statement recognized that "biosimilars and reference products can be considered equally efficacious for the purpose of inclusion in ASCO clinical practice guidelines," regardless of its FDA designation as "interchangeable", and supports removal of this distinction;[27,28] therefore be it

RESOLVED, that our American Medical Association recognize that, by definition, Biosimilar medications are clinically equivalent to their reference Biologic and therefore do not need a designation of "interchangeability;" (New HOD Policy); and be it further

RESOLVED, that our AMA support a rigorous approval process for Biosimilar medications and oppose the application of the redundant designation of "interchangeability" with the reference biologic drug (New HOD Policy); and it be further

RESOLVED, that AMA support the development of a model and a process for biologic and biosimilar medication prescribing that protects physician decision-making when a pharmacy-level substitution is not clinically appropriate (New HOD Policy); and be it further

RESOLVED, that our AMA support physician education on the clinical equivalence of Biosimilars, the FDA approval process and the post-market surveillance that is required. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

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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.
[Modified: CSAPH Rep. 4, A-14; Modified: CSAPH Rep. 1, 1-11; Reaffirmation A-11; Res. 220, A-09.]

H-125.976 Biosimilar Interchangeability Pathway

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 Product" with 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. [Res 523, A-18]

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D-125.989 Substitution of Biosimilar Medicines and Related Medical Products
Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution when physicians expressly authorize substitution of an interchangeable product; (3) limit the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA. [Modified: CSAPH Rep. 4, A-14, Modified: CSAPH Rep. 1, 1-11; Res. 918, I-08]

D-330.960 Cuts in Medicare Outpatient Infusion Services
1. Our AMA will actively support efforts to seek legislation to ensure that Medicare payments for drugs fully cover the physician's acquisition, inventory and carrying cost and that Medicare payments for drug administration and related services are adequate to ensure continued patient access to outpatient infusion services.
2. Our AMA will continue strong advocacy efforts working with relevant national medical specialty societies to ensure adequate physician payment for Part B drugs and patient access to biologic and pharmacologic agents. [Reaffirmation: I-18; Reaffirmed: CMS Rep. 10, A-16; Reaffirmation A-15; Reaffirmed and Modified: CMS Rep. 3, I-08; Res. 926, I-03]

D-330-.904 Opposition to the CMS Medicare Part B Drug Payment Model
1. Our AMA will request that the Centers for Medicare & Medicaid Services (CMS) withdraw the proposed Part B Drug Payment Model.
2. Our AMA will support and actively work to advance Congressional action to block the proposed Part B Drug Payment Model if CMS proceeds with the proposal.
3. Our AMA will advocate against policies that are likely to undermine access to the best course of treatment for individual patients and oppose demonstration programs that could lead to lower quality of care and do not contain mechanisms for safeguarding patients.
4. Our AMA will advocate for ensuring that CMS solicits and takes into consideration feedback from patients, physicians, advocates, or other stakeholders in a way that allows for meaningful input on any Medicare coverage or reimbursement policy that impacts patient access to medical therapies, including policies on coverage and reimbursement.
[Res. 241, A-16]

H-110.983 Medicare Part B Competitive Acquisition Program (CAP)
Our AMA will advocate that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:
(1) it must be genuinely voluntary and not penalize practices that choose not to participate;
(2) it should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs;
(3) it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate healthcare inflation rate;
(4) it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of CAP-acquired drugs at multiple office locations;
(5) it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;
(6) it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician;
(7) it should not allow vendors to restrict patient access using utilization management policies such as step therapy; and
(8) it should not force disruption of current systems which have evolved to ensure patient access to necessary medications.
[Reaffirmed: CMS Rep. 4, A-22; Reaffirmed: CMS Rep. 4, I-19; Res. 216, I-18]

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