AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

Position Statement

Use of Emerging Biologic Therapies

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The increasing use of biologics to try to improve outcomes for orthopedic patients presents new questions of safety and effectiveness for those products. As we note in the statement "Innovation and New Technologies in Orthopaedic Surgery," surgeons must be aware of the scientific basis for the different treatment options available to their patients, including the benefits and risks. Biologic therapies vary widely with regards to the requirements for evidence of safety and effectiveness needed for clearance by regulatory bodies, including the US Food and Drug Administration (FDA). Not all biologic products require extensive FDA regulation, and in some cases, the FDA has primarily focused on safety concerns and has ceded responsibility for determining the efficacy of these products to the clinician.

The American Academy of Orthopaedic Surgeons (AAOS) believes that surgeons should be cognizant of the risks, benefits, regulatory status and labeled indications of the products they use.

For all products, but particularly those which the FDA does not critically evaluate effectiveness data, clinicians bear a greater responsibility to independently weigh that evidence. This responsibility also extends to off-label use of FDA-regulated products, and cases where the devices used to create or deliver the biologic product, rather than the product itself, are what has been approved by the FDA. It also applies to cases where a manufacturer believes they are exempt from certain FDA regulations without formal review of exemption, such as the so-called 361 exemption for human cell and tissue products. In all of these examples, the clinicians using these biologic products need to be particularly careful to weigh the available evidence and conduct shared decision-making with the patient in the informed consent process.

The AAOS Standards of Professionalism state "An orthopaedic surgeon, or his or her qualified designee, shall present pertinent medical facts and recommendations to, and obtain informed consent from, the patient or the person responsible for the patient." The mandatory standard obligates surgeons to disclose any products that may be used during the episode of care and engage in frank discussion regarding the risks and benefits of biologics when they are part of that episode of care.

For any product, but in particular for biologic products where information on efficacy may be limited, orthopaedic surgeons and their organizations/facilities should support and participate in orthopaedic randomized controlled trials, registries and other data collection systems. Through voluntary reporting of key patient and orthopaedic treatment information to local, state and national repositories, patient outcomes will be improved. Documentation and reporting are critical to establishing the body of evidence needed to demonstrate the safety and effectiveness of emerging biologics.

AAOS champions the interests of patients by improving treatment options through education and research and by fostering a culture of safety and evidence based treatment.

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