



BsUFA and the Rheumatology Perspective

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Financial Disclosure

I have no disclosures to report.

Biosimilars and Rheumatology



Rheumatology utilization of biologics



- Basic science
- Clinical research
- Clinical prescribers
- Monitor on-site medication administration

ACR Position on Biosimilars

- Safe and effective treatment must be available to patients at the lowest possible cost
- All approval decisions must be driven by science and consider:
 - Greater scrutiny on the size, complexity, and heterogeneity of biologics and biosimilars
 - Rigorous analysis of human clinical trials to ensure safety and effectiveness and bolster confidence



Importance of BsUFA

Cost and Access:

- Current cost of biologics is debilitating.
- Biosimilars provide greater access to life-changing medications due to their cost-effectiveness

BsUFA Fees

- ACR supports fees that are based on complexity of review.

BsUFA Performance Goals

- ACR strongly supports performance goals that will allow for prompt and thorough review of biosimilar submissions.





BsUFA

2023-2027

Assessment of BsUFA

- BsUFA funding has allowed for a greater number of biosimilars to be approved and available to our patients with 17 commercialized biosimilars on the market
- BsUFA has improved the FDA's capacity and manufacturing ability to bring safe, effective biosimilars to market to maximize access to treatment by lowering costs



Enhancements to the program



Labeling must provide clarity and transparency for patients and providers.

- It is imperative for labels to provide information about whether a treatment is a biosimilar, interchangeable, or both.
- Suffixes must be more meaningful/memorable to eliminate any confusion from the patient and provider.
- All labels and patient inserts should provide links to biosimilar's analytical and trial data.

A close-up photograph of a silver stethoscope resting on a teal-colored surface. The stethoscope's chest piece is prominent in the upper right, with its tubing extending towards the top left. The background is a solid, vibrant teal. Overlaid on this background is the text "Thank you!" written in a white, elegant cursive font. The text is positioned in the lower right quadrant, with the exclamation point being particularly large and expressive. The overall composition is clean and professional, likely intended for a medical or healthcare-related context.

Thank you!