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Humira® & Biosimilars Forecast for 2023 and Beyond

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Introductions

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- Biosimilars for the blockbuster drug Humira® hit the market in 2023
- We will unpack the complexities surrounding biosimilars, how they may influence the pharmacy landscape and the important considerations for employers

Pharmacy Trends Challenging Employers

U.S. NET TOTAL RX SPEND

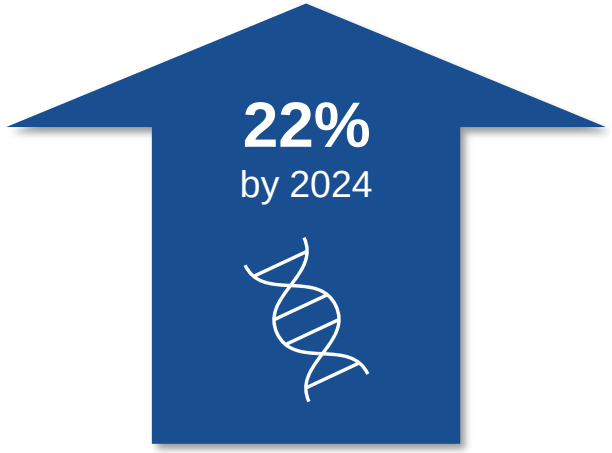
- Pharmacy costs continue to rise and remain a significant component of overall healthcare spend
- Total drug spend projected by 2025
  - » Growth is mostly expected from new brand launches in specialty and niche treatments
  - » Oncology spending will exceed $110B
  - » Immunology is expected to exceed $130B
  - » Losses in patent exclusivity are expected to result in lower brand spending of $128B
- Specialty drugs currently account for over 50% of an employer's pharmacy drug spend, expected to increase to 60% - 65% over the next few years

Source: https://pharmanewsintel.com/news/prescription-drug-spending-expected-to-reach-400b-in-2025

Specialty Drugs Driving the Narrative

SPECIALTY DRUG TRENDS

Specialty Growth Continues due to new drugs, expanding populations and price increases through **2025**



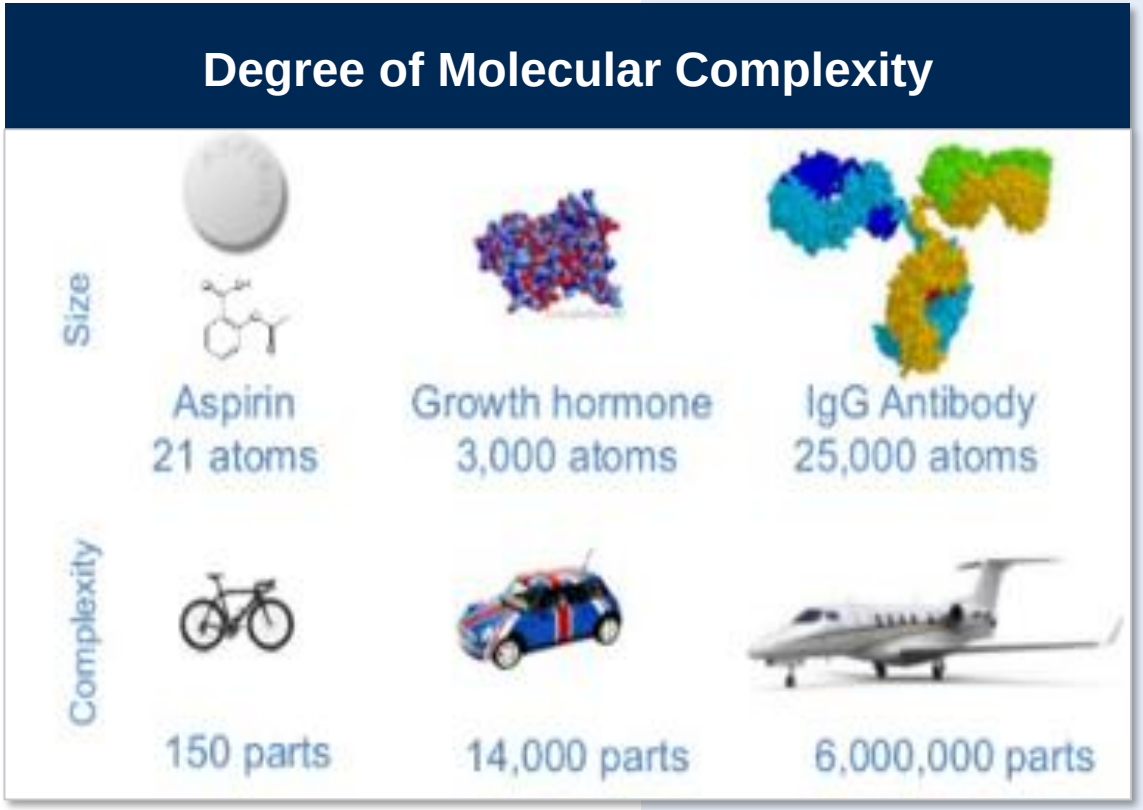
Gene Therapies Sales Up 25 new anticipated approvals by **2025**; hemophilia, sickle cell anemia, very high cost $$$$

Biosimilars Projected Healthcare Savings Over Next Five Years from generic-like specialty drugs making their way into the market; Humira® options are launching in 2023

HTTPS://WWW.PCMANET.ORG/PCMA-CARDSTACK/WHAT-IS-A-SPECIALTY-DRUG/
HTTPS://PHARMANEWSINTEL.COM/NEWS/PRESCRIPTION-DRUG-SPENDING-EXPECTED-TO-REACH-400B-IN-2025

Biosimilars – What Are They?

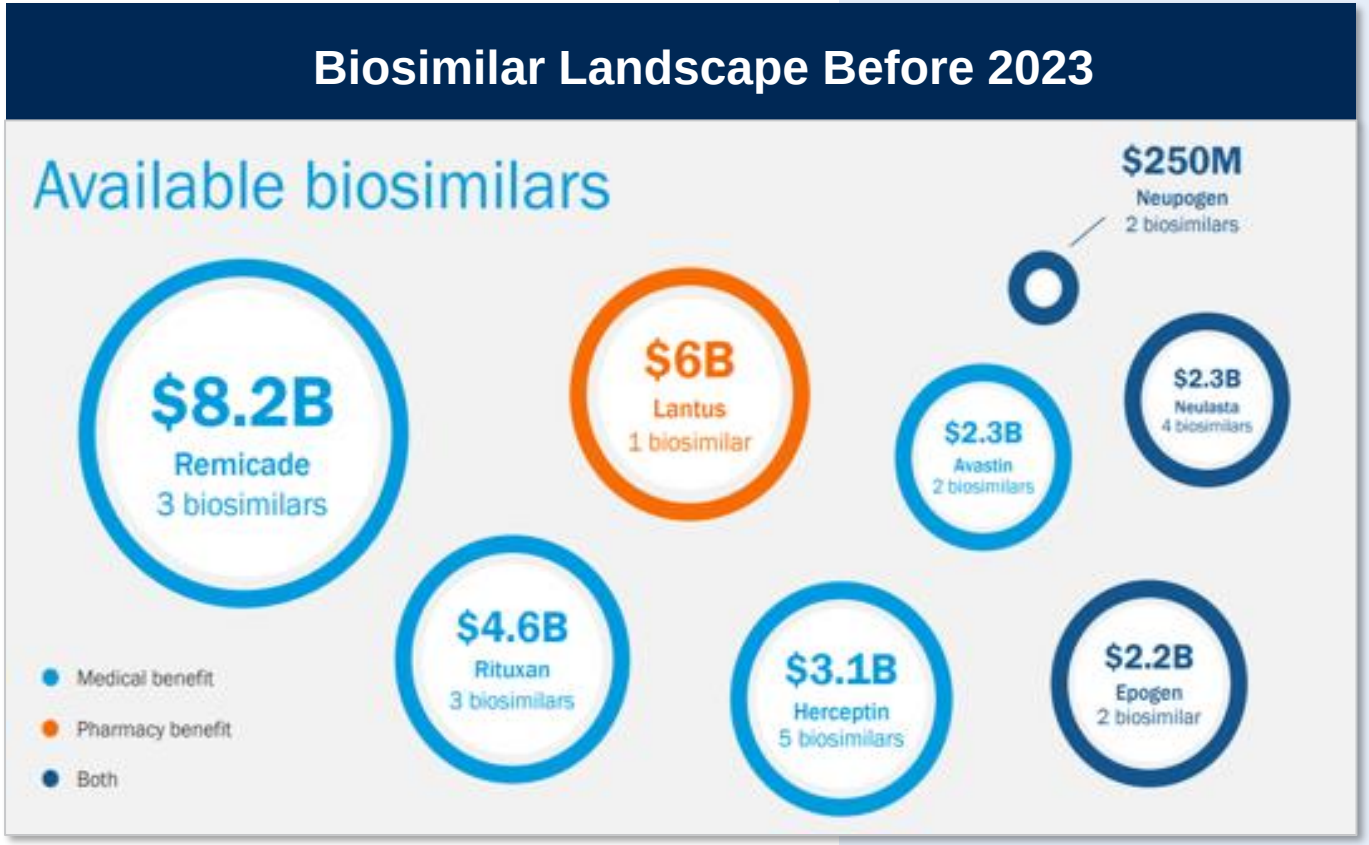
- Biosimilars are generally large, complex molecules derived from living organisms such as yeast, bacteria or plant/animal cells
  - » Biosimilars are specialty drugs, also known as a biologic
- Biosimilars have no clinically meaningful differences from their branded biologic regarding their safety, purity and potency
- Biosimilars are highly similar or ‘generic-like’ to their branded biologic; however, differing characteristics may exist with:
  - » Interchangeability
  - » Indications, dosage forms or formulations
  - » Other components, e.g., allergy free



Source: The Chemistry of Monoclonal Antibodies (slideshare.net)

Biosimilars – Why Do They Matter?

- As with other new drug options entering the market, competition is initiated
- Biosimilars bring competition; however, their unique differences have presented a challenge to date
  - » The intricacies within this space has been challenging, including cost and utilization expectancy
  - » The number of biosimilars that have launched has been narrow
- Since 2007, 30 biosimilars have launched in the U.S. with modest impact



Source:
Biosimilar Approvals | Center for Biosimilars®
IPD Analytics. Market & Financial Insights. April 2022
Evernorth Internal Research
IQVIA Institute, Dec 2022

Biosimilars – Humira® Launches in 2023

- Humira® has been a top-selling drug for many years topping $20B in annual sales most recently, and now faces multiple biosimilar candidates to market
- This is a time of unprecedented competition for one product, making way for a new era of biosimilars
- The complexities around biosimilars combined with the timing of the candidate launches will guide the considerations influencing stakeholders
- As such, 2023 may offer limited savings, with more growth projected in 2024 and beyond

Biosimilars – Humira® Launches in 2023

HUMIRA BIOSIMILAR LAUNCH OUTLOOK

85% of Humira's utilization today resides within the high dose (100mg), Citrate-Free product

Biosimilar Name	Manufacturer	Concentration	Citrate-Free	Interchangeable	Anticipated Launch
Amjevita	Amgen	Low	Yes	No	Jan - 2023
Cyltezo	B/I	Low	Yes	Yes	Jul - 2023
Hyrimoz	Sandoz	Low	No	No	Jul - 2023
Hadlima	Samsung Bio/Org	Low	No	Seeking	Jul - 2023
Hadlima HC	Samsung Bio/Org	High	Yes	Seeking	Jul - 2023
Hulio	Mylan/Bio/Viatris	Low	Yes	No	Jul - 2023
Abrilada	Pfizer	Low	Yes	Seeking	Jul - 2023
Yusimry	Coherys/BioS	Low	Yes	No	Jul - 2023

Source: IPD Analytics, February 2023

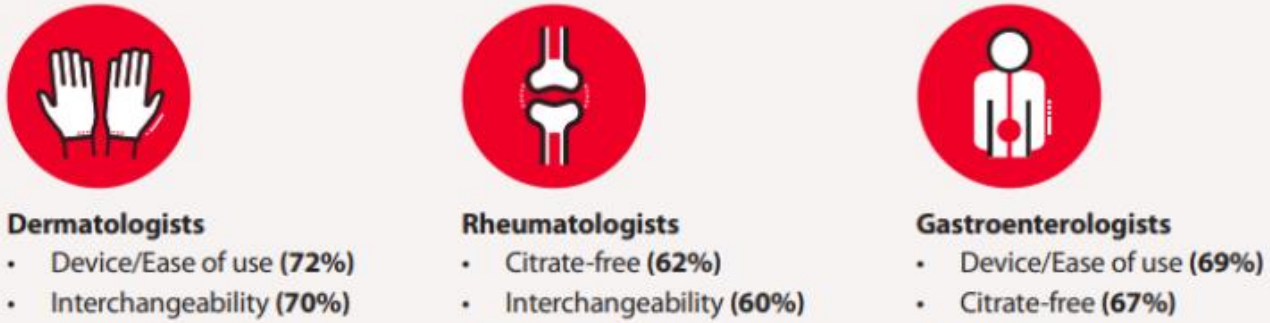
Humira®/Biosimilars – Impact Drivers

PHYSICIAN IMPACT

- Physician acceptance has improved over the past several years, but hesitancy still exists
- Differing characteristics within the biosimilar may determine its likelihood of being prescribed
  - » On average, > 60% of providers across all therapeutic areas will only feel comfortable prescribing a Humira biosimilar if it has an interchangeability designation
- Formulary placement may require a physician to make a switch depending on options available
- Newly diagnosed patients vs. those currently well managed may be more clinically acceptable for physicians to prescribe a biosimilar when applicable

Source: Drug Channels: Drug Channels News Roundup, February 2022: Mark Cuban vs. PBMs, MDs on Humira Biosimilars, States vs. PBMs, 340B Transparency, and Health Insurer Humor (?)

Product characteristics most commonly cited as 'very important' when it comes to utilizing a Humira biosimilar:



Humira®/Biosimilars – Impact Drivers

PBM Impact

- PBM positioning will be key for all manufacturers, including Abbvie's Humira
- Pharma will 'pay' for preferred formulary status as they push their products to gain utilization and market share
- So far in 2023, Humira remains in its preferred formulary status with most PBMs; Amjevita has launched with PBMs determining varied positions, including co-preferred, non-preferred option or not covered
- By July 2023, most of the biosimilar candidates are expected to launch; Cyltezo currently most similar to Humira will potentially push manufactures to further leverage pricing

Specialty Cost Management Program Impact

- Pharma is becoming less predictable when sharing pharma dollars now that the Humira market is in flux

Specialty Cost Management Program Impact

MANUFACTURER ASSISTANCE

Programs available to help maximize the financial assistance offered by drug manufacturers.

Prescription drug manufacturers provide coupons/copay assistance/free drug programs to patients who take their expensive drugs.

Third-Party Administer Programs designed to **capture the available dollars from drug manufacturers** to help reduce employee ***and*** employer costs.

Available for many specialty branded and biosimilar products.

Specialty Cost Management Program Impact

Manufacturer Copay Assistance Program

- No rebate impact
- No formulary change
- No pharmacy mandated
- Savings up to 25% of specialty spend

Patient Assistance Program
(Free Drug Program)

- Drugs ineligible for rebate
- Exclude drugs from formulary without removing access
- Dispensing pharmacy determined by program
- Savings up to 100% drug cost with patient eligibility

Specialty Cost Management Program Impact

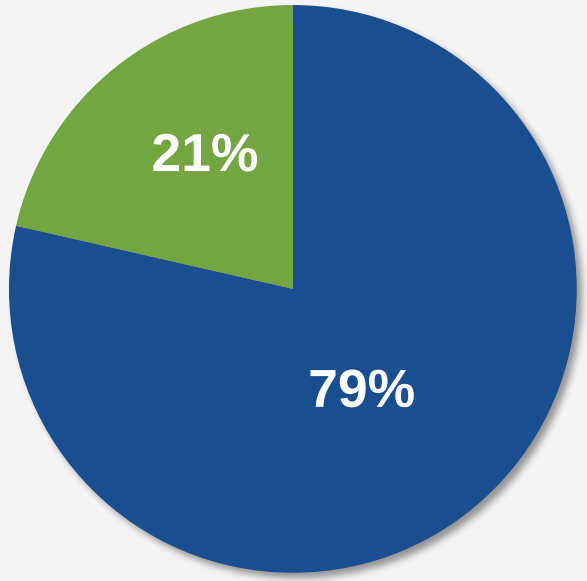
MANUFACTURER PUSHBACK, NOT WITHDRAWAL

Result of Anticipated Competition

The release of lower cost biosimilars impact currently available assistance programs

- ☑ Restricting eligibility requirements
- ☑ Decreased available assistance dollars
- ☑ Unpredictable program terms and conditions

Decreased Savings by 25% Annually



Humira® Average Percent Savings Per Claim

- 2022
- 2023

Next Steps for Employers

Important conversations to help navigate the ‘new’ biosimilar landscape.

Formulary Modifications

- Formulary Tier changes
- Potential product exclusions
- Additional utilization management
- Plan design variations
- Member disruption

Contract Considerations

- Contract revisions to capture changes in pricing driven by the availability of biosimilars
- Leveraging discounts and rebates separately for biosimilars vs. specialty drugs to drive true lowest net cost and transparency

Clinical Adaptations

- Understanding provider acceptance, regardless of interchangeability
- Variable indications and other clinical affects may impact utilization
- Member and clinician communications may be considered

Specialty Program Shifts

- Potential decrease in pharma dollars for manufacturer copay assistance and patient assistance programs
- Biosimilar manufacturers may begin offering assistance that may offset potential losses

THANK YOU!

Please reach out to your Brown & Brown contact with additional questions.
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