A Time for Change: Biosimilars

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Disclosure

The following individuals report having no relevant conflicts of interest:

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Learning Objectives

1. Describe the factors affecting utilization and uptake of adalimumab biosimilar products
2. Assess market shifts and trends in the autoimmune anti-inflammatory landscape in 2023
3. Discuss the impact of payer influence on the utilization of biosimilars
4. Explain the correlation of genetic testing to biosimilar selection and utilization

Biosimilar Adalimumab

Biosimilars are based on the foundation that they are the same as the originator biologic in relation to safety and efficacy.

Education

- Providers, staff, patients on efficacy and safety of biosimilar
- Providers, staff education on adalimumab biosimilar products
- Patients will need education on new devices

Operational challenges

- Staffing
- Workload changes
- Education (providers, staff, patients)

Product attributes

What differentiates these eight biosimilar products

Pricing/rebates/bundling

- First product launch with 2 products: AMJEVITA (~5% lower WAC than HUMIRA) and then a non-branded version (~55% lower WAC than HUMIRA)
- Rebates and bundling is still unknown

Payor preference

Discussed later in this presentation

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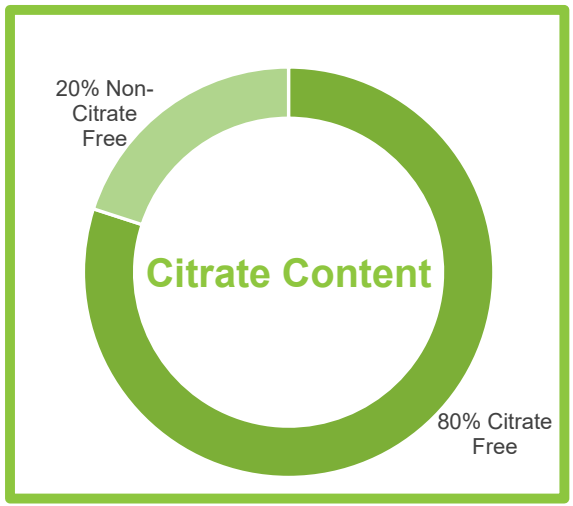
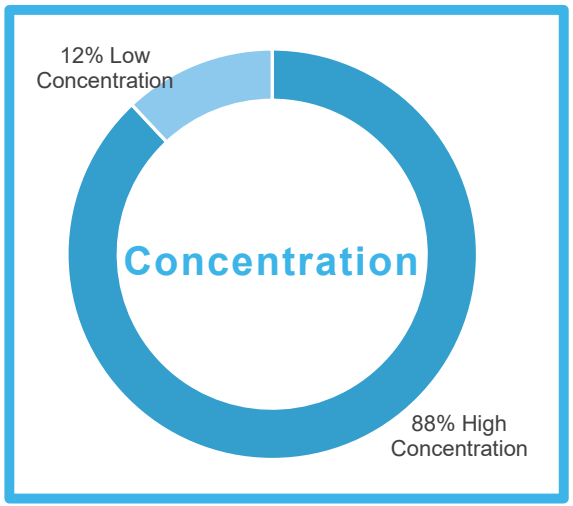
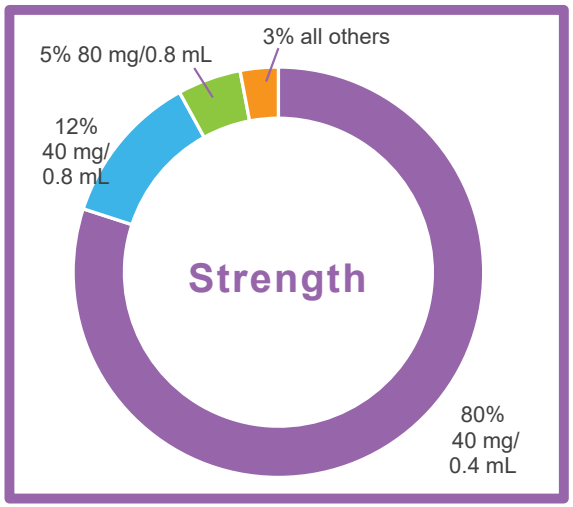
Market Share by HUMIRA Formulation







Data source: IQVIA Humira spend accessed Jan. 2023

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Adalimumab Autoject Device Attributes

Delivery device considerations:

- Adalimumab products are available as autoject pen, prefilled syringe, and vial
- Not all adalimumab biosimilars offer all delivery device options
- Autoject devices are not all the same
- Patient may need education on new device

Product	Steps	Push Button
HUMIRA	3 step	X
AMJEVITA	2 step	X
HADLIMA	2 step	
HULIO	2 step	X
HYRIMOZ	2 step	
ABRILADA	3 step	X
IDACIO	2 step	X

Interchangeability

What it is and what it isn't

An interchangeable product is a biosimilar that may be substituted for a reference product without the intervention of the prescribing health care provider, depending on state pharmacy laws

It does not mean that the interchangeable biosimilar is safer or more effective than other biosimilars

Interchangeability does have some benefits, but it is not imperative to the successful uptake in utilization of a biosimilar

Currently, one adalimumab biosimilar has the interchangeability designation, with many submitted or pending approval

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Patient Assistance

HUMIRA

- Copay cards
- Patient assistance
- Nursing assistance

Biosimilars

- Will need to offer similar programs as originator
- Unknown current offerings from originators

Considerations

- Time for patients to apply for copay card or patient assistance
- Patient qualifications may be different for originator products
- Avoid gaps in therapy due to prior authorization and patient assistance application process

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Attributes That Will Affect Utilization

Product	Manufacturer	Likely launch date	Attributes						
			Citrate Free	High Concentration (100mg/ml)	Autoject pen	Interchangeable	Available strength		Patient Assistance
Approved									
Amjevita (adalimumab-atto)	Amgen	1/31/2023	Yes	Phase III	Yes	Seeking	20 mg PFS LC 40 mg PFS LC	40 mg PEN LC	TBD
Hadlima (adalimumab-bwwd)	Organon	7/1/2023	Yes *	Yes	Yes	Submitted	40 mg PFS LC 40 mg PFS HC	40 mg PEN LC 40 mg PEN HC	TBD
Cyltezo (adalimumab-adbm)	Boehringer Ingleheim	7/1/2023	Yes	No	Pursuing	Yes	20 mg PFS LC 40 mg PFS LC		TBD
Hulio (adalimumab-fkjp)	Mylan	7/31/2023	Yes	No	Yes	No	20 mg PFS LC 40 mg PFS LC	40 mg PEN LC	TBD
Hyrimoz (adalimumab-adaz)	Novartis Sandoz	9/30/2023	Pending 3/23/2023 **	Pending 3/23/2023 **	Yes	No	10 mg PFS LC 40 mg PFS LC	40 mg PEN LC	TBD
Abrilada (adalimumab-afzb)	Pfizer	7/1/2023	Yes	No	Yes	Submitted	10 mg PFS LC 20 mg PFS LC 40 mg PFS LC	40 mg PEN LC	TBD
Yusimry (adalimumab-agyh	Coherus BioScience	7/1/2023	Yes	No	No	No		40 mg PEN LC	TBD
Idacio (adalimumab-aacf)	Fresenius	12/16/2022	Yes	No	Yes	No	40 mg PFS LC	40 mg PEN LC	TBD
Pending Approval									
CT-P17 (Yuflyma)[9]	Celltrion	Pending approval	Phase III	Phase III	Phase III	Seeking	TBD		TBD
AVT02[9]	Alvotech Teva	Pending approval	Phase III	Phase III	Phase III	Seeking	TBD		TBD

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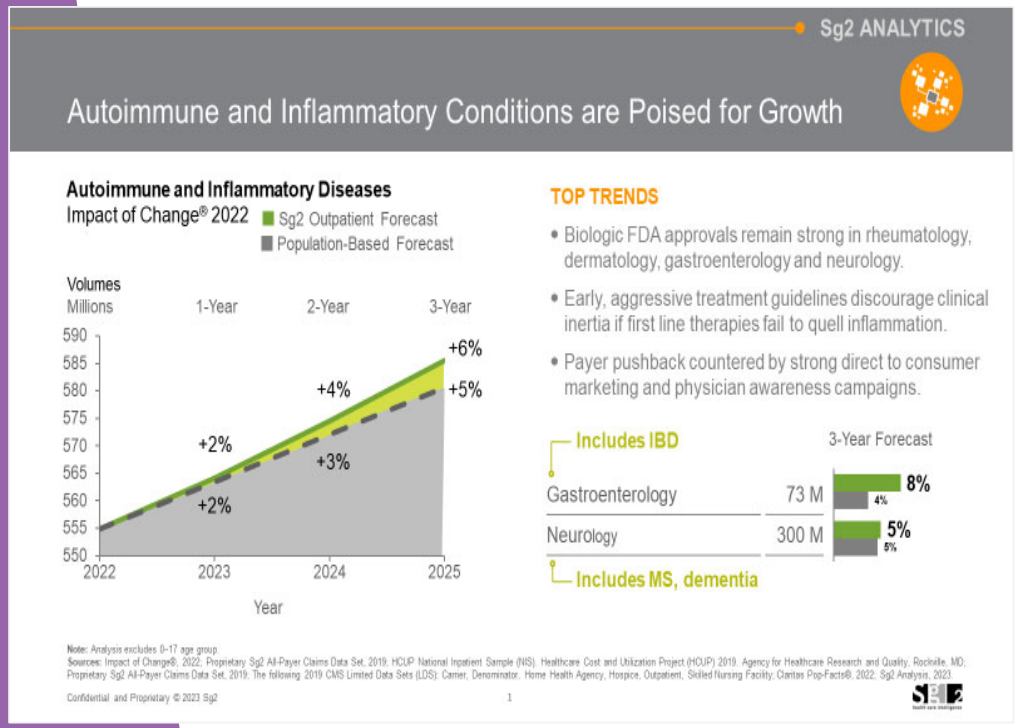
Autoimmune and Chronic Inflammatory Conditions

Growth in utilization of outpatient services

Gastroenterology largest 3-year forecast for growth

Growth in FDA approvals for medications in these service lines:

- Dermatology
- Gastroenterology
- Rheumatology
- Neurology



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Payor Influence on Utilization of Biosimilars

- The Biosimilar Trend
- Key Market Considerations
- What Drives Payor's Decisions

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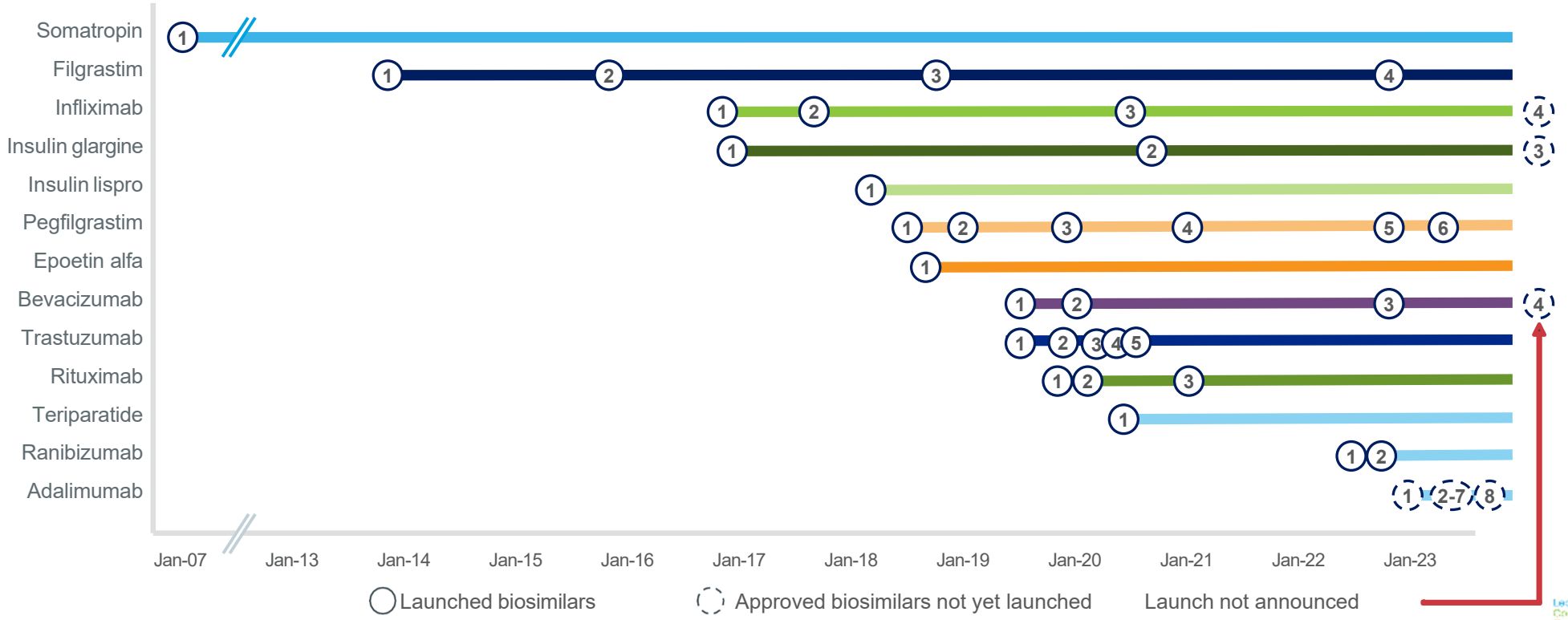
Since 2007, 30 biosimilars have launched in the U.S., with 10 more approved and set to launch by the end of 2023

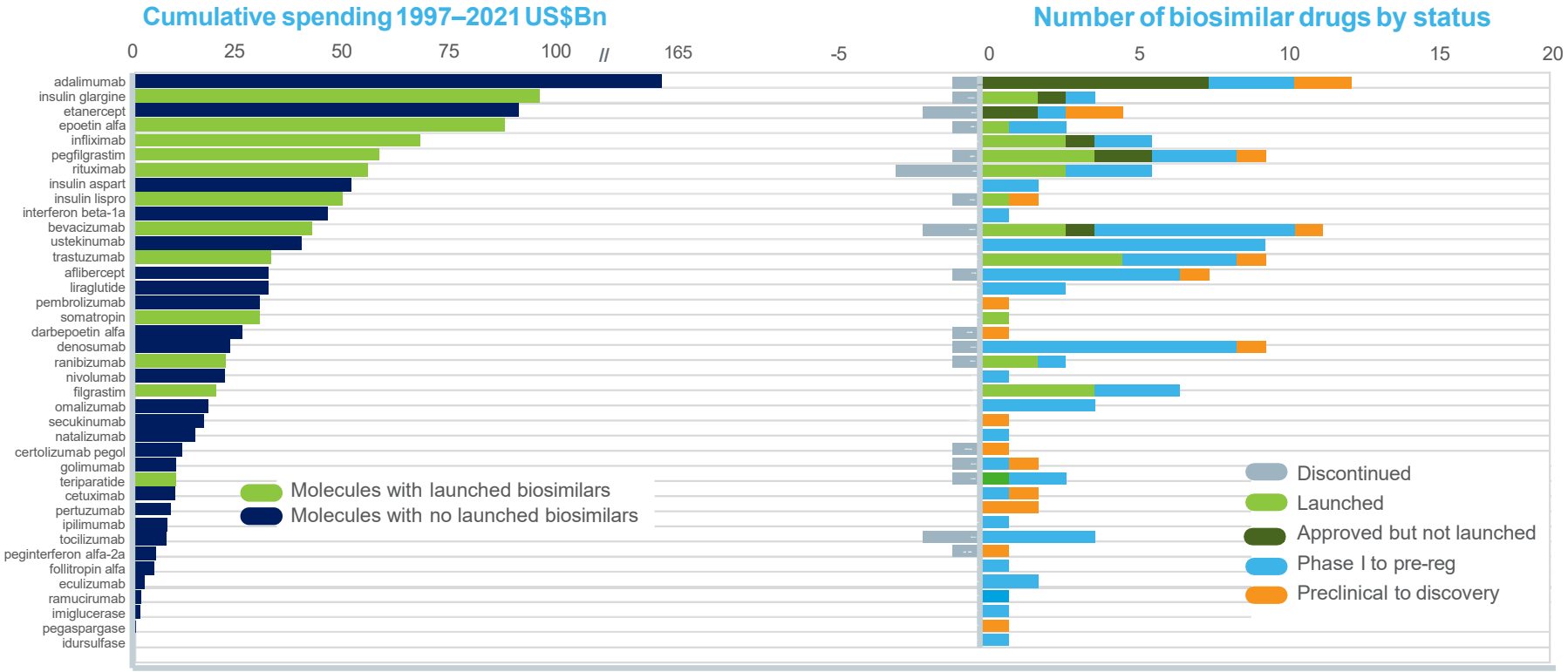
Biosimilars approved and launched in the U.S.



Source: IQVIA Institute, Dec 2022.
Biosimilars in the United States 2023-2027 – Competition, Savings and Sustainability. Report by the IQVIA Institute for Human Data Science.

Biosimilars approved or in clinical development in the U.S. for 20 additional molecules

Cumulative molecule spending and approved, launched, and pipeline biosimilar products for the molecule



Source: IQVIA MIDAS, Dec 2021; IQVIA Pipeline Intelligence, IQVIA Institute, Dec 2022.

Biosimilars in the United States 2023-2027 – Competition, Savings and Sustainability. Report by the IQVIA Institute for Human Data Science.

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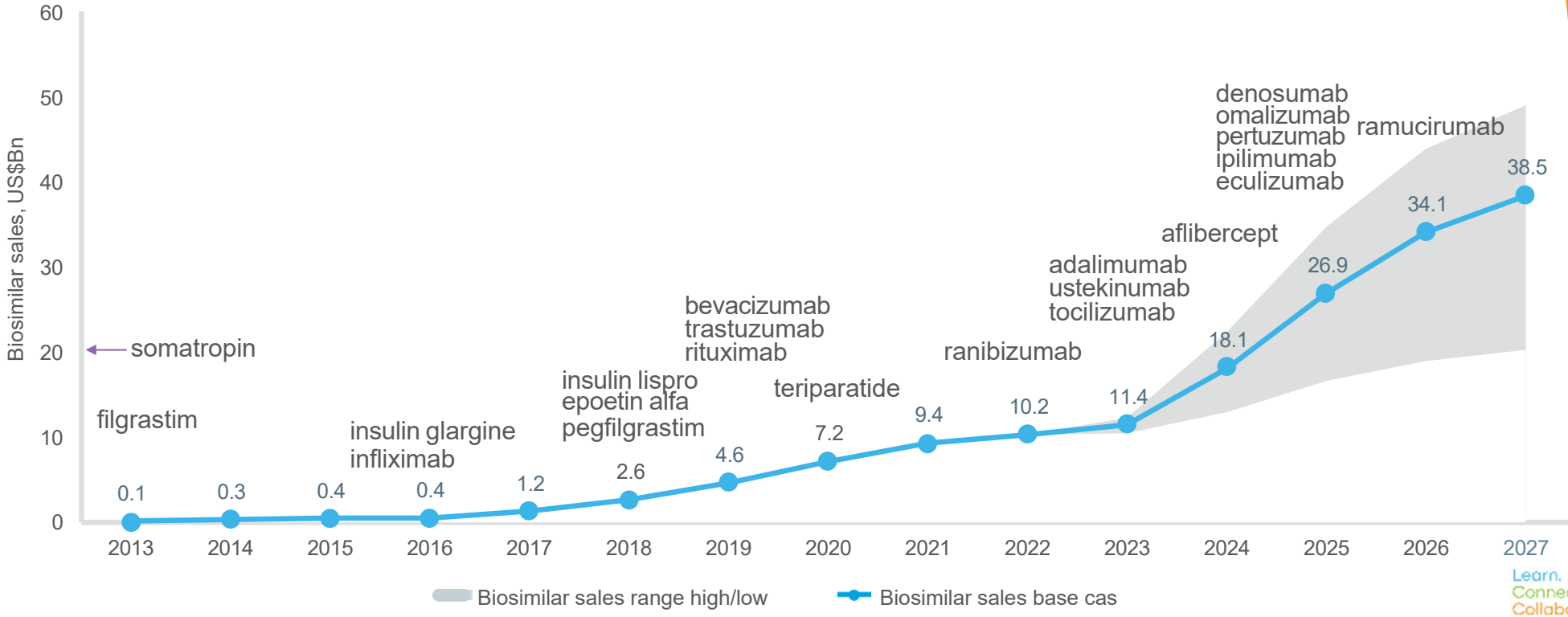
Expected launches and uptake are likely to increase overall spending on biosimilars significantly, to $20–49 billion in 2027

Biosimilar historical sales 2013–2022 and outlook scenarios 2023–2027, US$billion



Source: IQVIA MIDAS, Jun 2022; IQVIA Institute, Nov2022.

Biosimilars in the United States 2023-2027 – Competition, Savings and Sustainability. Report by the IQVIA Institute for Human Data Science.

IQVIA

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What Do We Believe?

Payors are interested in…

1. Price
2. Price
3. Price
4. REBATE
5. Price
6. Price
7. An even better price!

What Payors Actually Believe

How do payors see the market?

Biosimilars of HUMIRA are DIFFERENT

Different products

- Latex free
- Citrate free
- Low concentrate
- High concentrate
- Interchangeabiliy
- Non-interchangeability
- Significant patient experience (Europe)

Interchangeability—Why?

- Uniquely U.S. characteristic
- Not an issue for patients in Europe
- No negative consequences

Interchangeability—Questions

- How will individual state boards address this question?
- Will this make it easier to substitute vs. not?
- What will be the burden on the MD office, etc., in changing products?
- What will be the acceptance by the patients if they need to be engaged in the process?

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How Payors Think (???)

What drives payor's decisions (traditionally)

What is the unmet need?

- Is there a lack of FDA-approved therapies?
- What is the clinical differentiation among available therapies?
- Are there outcomes/event-driven data?
- What is the safety/tolerability?

How does it compare to the current "gold standard" (i.e., standard of care) regarding:

- Efficacy
- Safety
- Net cost

What is the potential for misuse/inappropriate use?

- Does this create a cost risk for the payor?

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Issues

What makes this unique vs. other biosimilar experiences?

1. **The sheer size of this potential impact**

2. **The fact that there are (approaching) 10 potential biosimilar products**
   - What can the industry/market support?
   - Note: Acorn recently went out of business, as its generic model was not sustainable.

3. **How different manufacturers are approaching the issue**

   Amgen: 2 products, 2 list prices

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Keys to Success

What will potentially drive biosimilar success?

Product Availability

With many choices in the market, who can assure the market that they can provide a consistent supply?

Product Quality

Who can assure the market that the quality and consistency of the product can meet the reference product?

Product Demand

- Generics are traditionally not promoted at the provider level
- How will the provider acceptance be driven
  (*Note how Optum/United and CVS are buying providers)*

Product Price

Risk: AbbVie is projecting limited losses

- Maintaining 90% of market access
- Maintaining 60–65% of volume

Questions

1. How will the market look in 2023 (immediately following biosimilar introduction)?
2. How will the market look in 2024 and beyond?

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Genetic Testing Correlation to Biosimilar Selection and Utilization

- What are cost drivers?
- Would there be a measurable ROI?
- Will payors support?
- Will providers support?

Biosimilars and Genetic Testing

How does suboptimal care affect cost?

Up to **40%** of RA patients on TNF therapy have an inadequate clinical response to treatment.[1]

Up to **46%** of initial responders on anti-TNFs lose response in the first year after shifting to high-cost agents.[2]

Cost drivers:

1. **Inappropriate drug use:** Amount of drug used in the treatment or adjunct therapy use
2. **Office and ED visits:** Number of IBD office and/or emergency department visits
3. **IBD-related surgeries:** Medical procedures related to IBD
4. **Procedures:** Invasive nonsurgical procedures (such as endoscopy or imaging-guided)
5. **Hospitalization:** IBD-related hospitalizations

1) Treatment options in patients with rheumatoid arthritis failing initial TNF inhibitor therapy: a critical review Andrea Rubbert-Roth and Axel Finckh, April 6, 2009,with ACR 20
2) Roda G. Loss of Response to Anti-TNFs: Definition, Epidemiology, and Management. Clin Transl Gastroenterol. 2016;7(1):e135.

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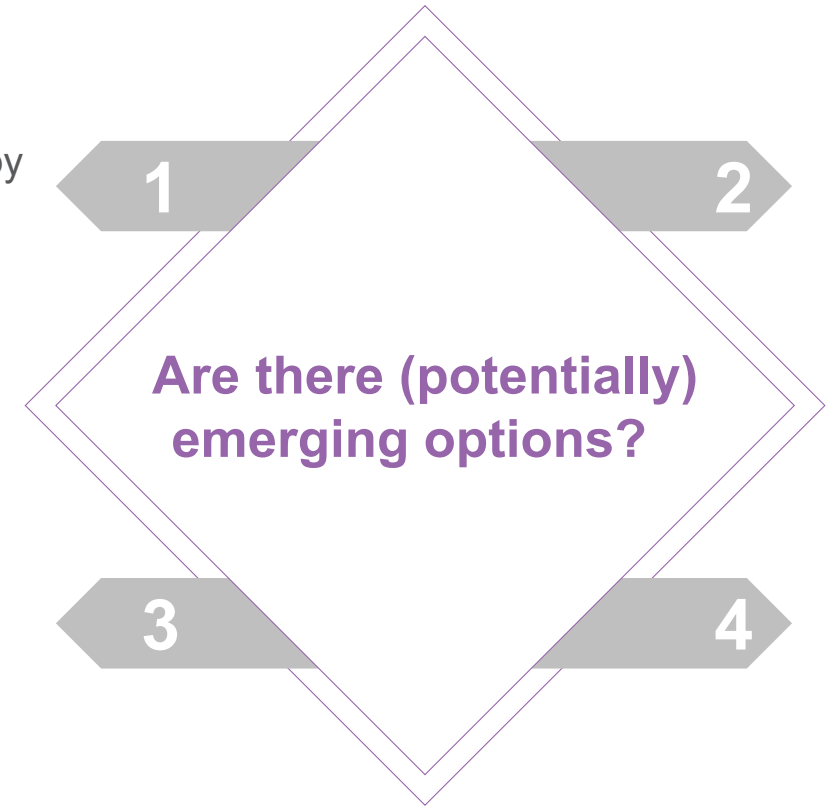
Biosimilars and Genetic Testing (continued)



Would utilizing genetic testing in advance of therapy enable better clinical decision making?

How can a health care system (IDN) potentially develop, determine, and implement?

Would this result in decreased health care costs?

Would payors support (reimburse) this model?

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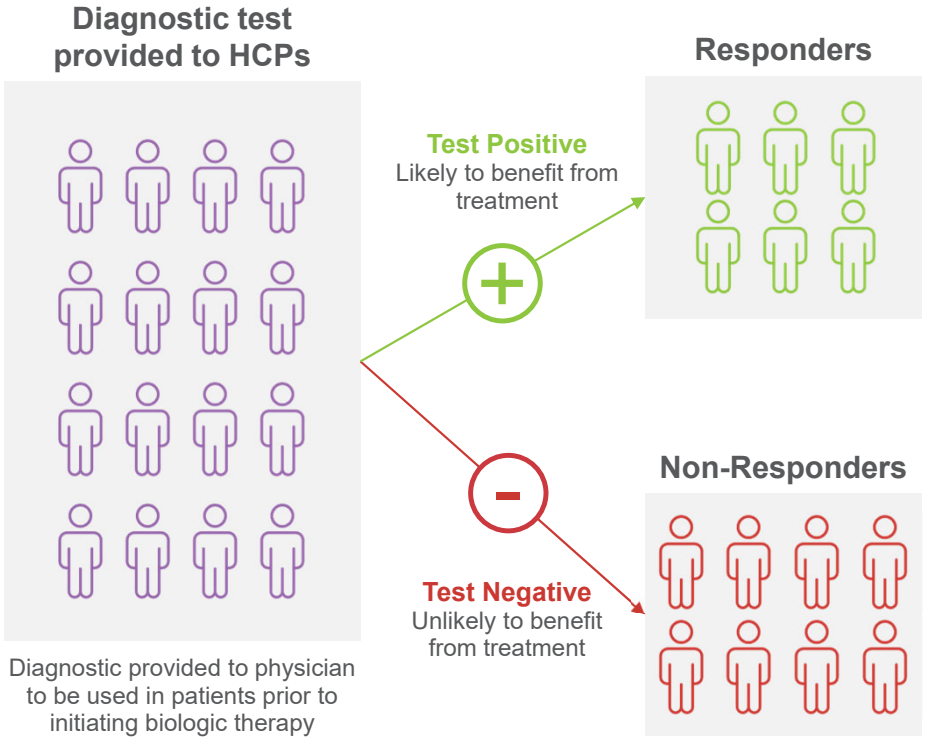
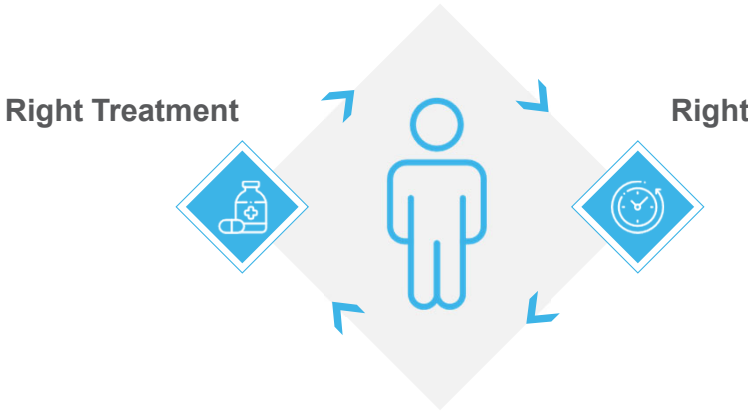
Genetic Testing + Biosimilar = Savings!

Diagnostic test provided by whom?



Diagnostic provided to physician to be used in patients prior to initiating biologic therapy

Individualized biologic predictability for existing patients



Intended for both induction and maintenance of biologics

Predictive algorithms that combine patient covariates with blood-based biomarkers predicting patient variable PK parameters

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Diagnostic testing + biosimilars offer improved clinical decision making and health care system cost savings

Product Acceptance

Diagnostic program viewed favorably by clinical community

> I have been waiting for the science in this area to develop for a while—if there are advances in diagnostic technology, **that would be of huge interest to the field.**
>
> —Rheumatologist, Member of the ACR

> **Exciting. Interesting.** May speed decision making, not waste time on TNF if I have a patient that fits this category.
>
> —Rheumatologist

> Excellent, strong, great test. Could convince insurance companies it's worth it. We could wait 6 months playing around with a medication that does not work, it's costly. **Doing one test will really help us.**
>
> —Gastroenterologist

94%

of physician responders preferred to prescribe the adalimumab biosimilar with the exclusive partnership with a diagnostics company.

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Questions

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