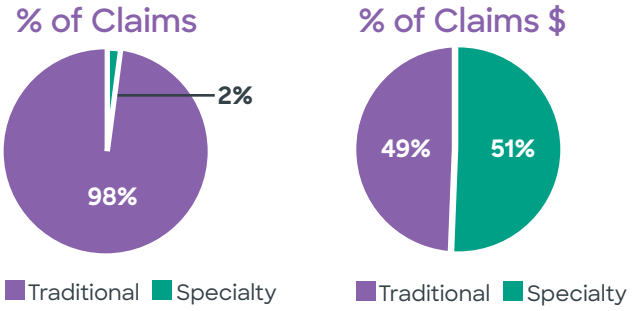
Biosimilars help lower drug costs

While specialty drug claims (including biologics) represent less than 2% of overall prescriptions, they account for more than 50% of total prescription medication spend.[1]



Biosimilar drugs could lower prices for therapies for cancer and rheumatoid arthritis, with savings estimated to be $38.4 billion (5.9%) of projected total U.S. spending on biologics from 2021 to 2025.[2]

A biosimilar is a biological product similar to with no clinically meaningful differences from an FDA-approved product.[3] It also has no meaningful differences in safety, purity or potency.[4]

A reference product is the brand biologic that was the first-to-market for a unique compound. It is also known as the original biologic.

Interchangeability

Traditional Drugs (non-biologic)	Biologic Drugs
Small molecules that can be copied exactly. They usually have generics available after the patent protection has expired.	Large molecules with complex mechanisms of action. An exact copy of the drug is not possible, so interchangeable status requires additional studies and approval by the FDA.
These drugs can usually be substituted by the pharmacist filling the prescription. Approval of the generic by the FDA allows substitution.	In Texas, an interchangeable drug may be substituted by the pharmacist filling the prescription.

What can prescribers do?

- **Patients new to therapy:** Choose a biosimilar drug.
- **Patients on current therapy with a reference product:** Consider changing therapy to a biosimilar drug.
- **Educate patients:** Biosimilars are as safe and effective as the original product. Biosimilars may cost less than the original biologic.
- **Biosimilar selection:** Choose the biosimilar product that is preferred on the patient's formulary

Note: Some pharmaceutical companies have identical products with different names. One has a brand name (costs more) while the other is unbranded (costs less).

Illustrative Example:

Type	Branded	Unbranded
Manufacturer	ABC Co.	ABC Co.
Package Label Name	Extendamab	Biosimilar-mnop
Generic Name	Biosimilar-mnop	Biosimilar-mnop

Are interchangeable biosimilars safer or more effective than other biosimilars?

No. Per the FDA both biosimilars and interchangeable biosimilars are as safe and effective as the original biologic they were compared to, and they can both be used in its place.[5]

A recently published meta-analysis by the FDA supports that there were no differences in multiple factors between a reference product and a switched product.[6]

In the oncology therapeutic area, the American Society of Clinical Oncology (ASCO) has stated "distinction between interchangeability designation and biosimilars is unnecessary, burdensome, and creates barriers to high value care".[7]

The FDA is currently deemphasizing the interchangeable requirement.[8]

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1) Specialty drug prices giving you sticker shock? | Optum Rx. 2) Biosimilar Drugs Could Generate $38.4 Billion in Savings over Five Years. 3) Biological Product Definitions, fda.gov. 4) Review and Approval | FDA. 5) Safety outcomes when switching between biosimilars and reference biologics: A systematic review and meta-analysis | PLOS ONE) 6) Ibid. 7) Review and Approval | FDA. 8) BioRationality: FDA Publishes Results of First Meta-Analysis to Conclude All Biosimilars Are Interchangeable (centerforbiosimilars.com)