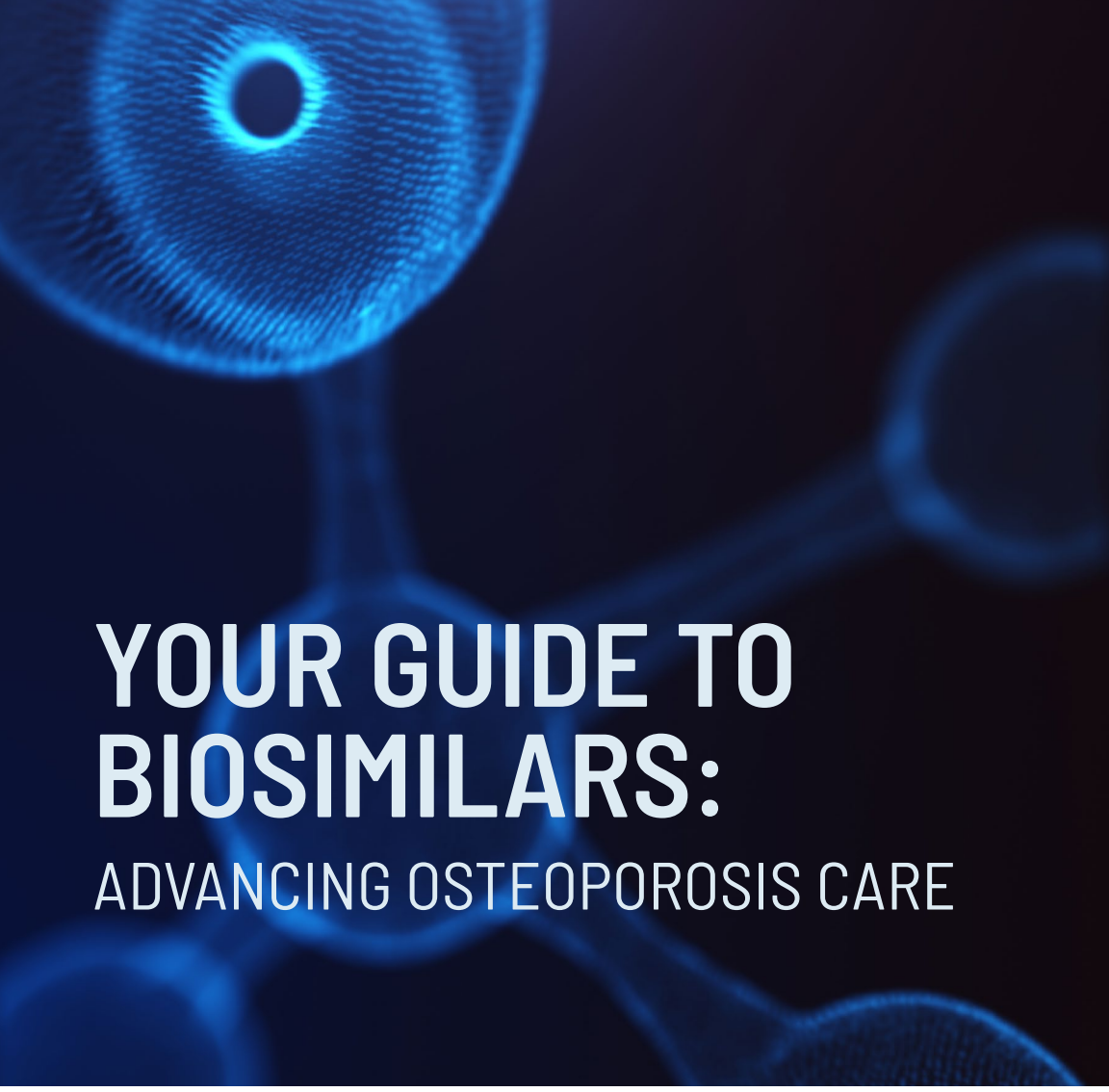

YOUR GUIDE TO BIOSIMILARS:

ADVANCING OSTEOPOROSIS CARE

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TABLE OF CONTENTS

4 INTRODUCTION TO BIOSIMILARS

5 UNDERSTANDING BIOLOGICS AND BIOSIMILARS

6 THE SCIENCE BEHIND BIOSIMILARS

6 FDA APPROVAL REQUIREMENTS

7 COST SAVINGS AND PATIENT ACCESS

8 FREQUENTLY ASKED QUESTIONS

INTRODUCTION TO BIOSIMILARS

This guide provides comprehensive information about biosimilars to support informed treatment decisions. Biosimilars are used for the treatment of many chronic and severe conditions, including osteoporosis.

Biosimilars represent a significant advancement in health care, offering patients and health care systems more treatment options while potentially reducing costs and improving access to critical therapies.

KEY MESSAGE

BIOSIMILARS ARE DESIGNED TO WORK THE SAME WAY IN THE BODY AS THE ORIGINATOR BIOLOGIC PRODUCT, WITH THE SAME TREATMENT RISKS AND BENEFITS.

UNDERSTANDING BIOLOGICS AND BIOSIMILARS

WHAT ARE BIOLOGIC MEDICINES?

Medicines can generally be classified as small molecules or large molecules. Small molecules are made up of chemical structures and are made with a chemical process.

Biologics are large, complex molecules. Large molecules are bigger in size and are made from living organisms such as bacteria and yeast. This makes biologic medicines much more difficult—and much costlier—to produce.

KEY CHARACTERISTICS OF BIOLOGICS:

- Large molecular size
- Made up of complex protein structures
- Manufactured using sugars, proteins, living cells, tissues, or a combination of these
- Require specialized handling
- Usually administered via injection or infusion

WHAT ARE BIOSIMILAR MEDICINES?

A biosimilar is a biologic product that is highly similar to an existing reference product (the originator biologic) that has been approved by the US Food and Drug Administration (FDA). The name “biosimilar” reflects this similarity. Biosimilars are designed to work the same way in the body as the originator biologic product, with no clinically meaningful differences in terms of safety, purity, and potency (safety and effectiveness).

A biosimilar has the same dosage as the originator biologic, and it’s taken the same way. A biosimilar and its originator biologic have the same treatment risks and benefits.

THE SCIENCE BEHIND BIOSIMILARS

UNDERSTANDING THE DIFFERENCE: BIOSIMILARS AND GENERIC MEDICINES
While some may view biosimilars as "generic biologics," there are important distinctions.

GENERIC MEDICINES	BIOSIMILARS
Generally made from chemicals	Generally made from living sources
Have a simpler process to copy	Require a specialized process to produce
Identical active ingredients	Very similar, but not identical, to originator biologics
Usually less expensive than brand-name drugs	Usually less expensive than originator biologics

FDA APPROVAL REQUIREMENTS

The FDA requires a biosimilar to be rigorously tested to demonstrate that it is similar to the originator biologic in several ways:

- A biosimilar must be shown to have no clinically meaningful differences in terms of safety, purity, and potency (safety and effectiveness) compared to the originator biologic.
- A biosimilar must show it's designed to work in the body in the same way as the originator biologic.
- A biosimilar is developed in a way that helps ensure that it is similar in structure to the originator biologic.

COST SAVINGS AND PATIENT ACCESS

THE ECONOMIC IMPACT OF BIOSIMILARS
Biosimilars are transforming health care economics by creating competitive markets for biologics and delivering substantial savings.

2024 US National Health Care System Savings:

- $467 billion saved from generics and biosimilars combined in 2024
- $20.2 billion saved from biosimilars alone in 2024
- $56.2 billion in total biosimilar savings since 2015 (first biosimilar)

WAYS COSTS ARE REDUCED

Price Competition:

- Biosimilars introduce competition into the marketplace.
- When biosimilars enter the market, their sale prices are on average 40% cheaper than brand biologics.
- Competition forces reference biologics to reduce prices by an average of 23% after 3 years.
- When more options enter the market, this helps make treatments more affordable for patients.

Insurance and Co-pay Benefits:

- 92% of generic prescriptions had co-pays under $20 in 2023.
- Average co-pay for generic prescriptions was $6.16 vs $56.12 for name brands in 2023.
- Medicare saved $142 billion from generics in 2024.

Expanded Patient Access:

- Due to lower prices, patients have collectively received 460 million more days of patient therapy than if no biosimilar was available since 2015.
- Lower costs allow more patients to receive treatment.

PATIENT-LEVEL COST SAVINGS BY CONDITION FOR GENERICS AND BIOSIMILARS (2024)

CONDITION	SAVINGS
Heart Disease	$122.2 billion
Mental Illness	$76.8 billion
Diabetes	$61.6 billion
Cancer	$26.6 billion

Source: IQVIA and Association for Accessible Medicines (AAM) 2025 Savings Report.

FREQUENTLY ASKED QUESTIONS

Q: Are biosimilars as safe and effective as the originator biologics?

A: Yes. Biosimilars must show no clinically meaningful differences in safety, purity, and potency compared to the reference products. They undergo rigorous testing and FDA review.

Q: Why do we need biosimilars if we already have the originator biologics?

A: Biosimilars offer several benefits. They create competitive pricing, reducing health care costs; they expand patient access to biologic treatments; they provide additional treatment options for patients; and they generate health care system savings that can be reinvested.

Q: How much can patients save with biosimilars?

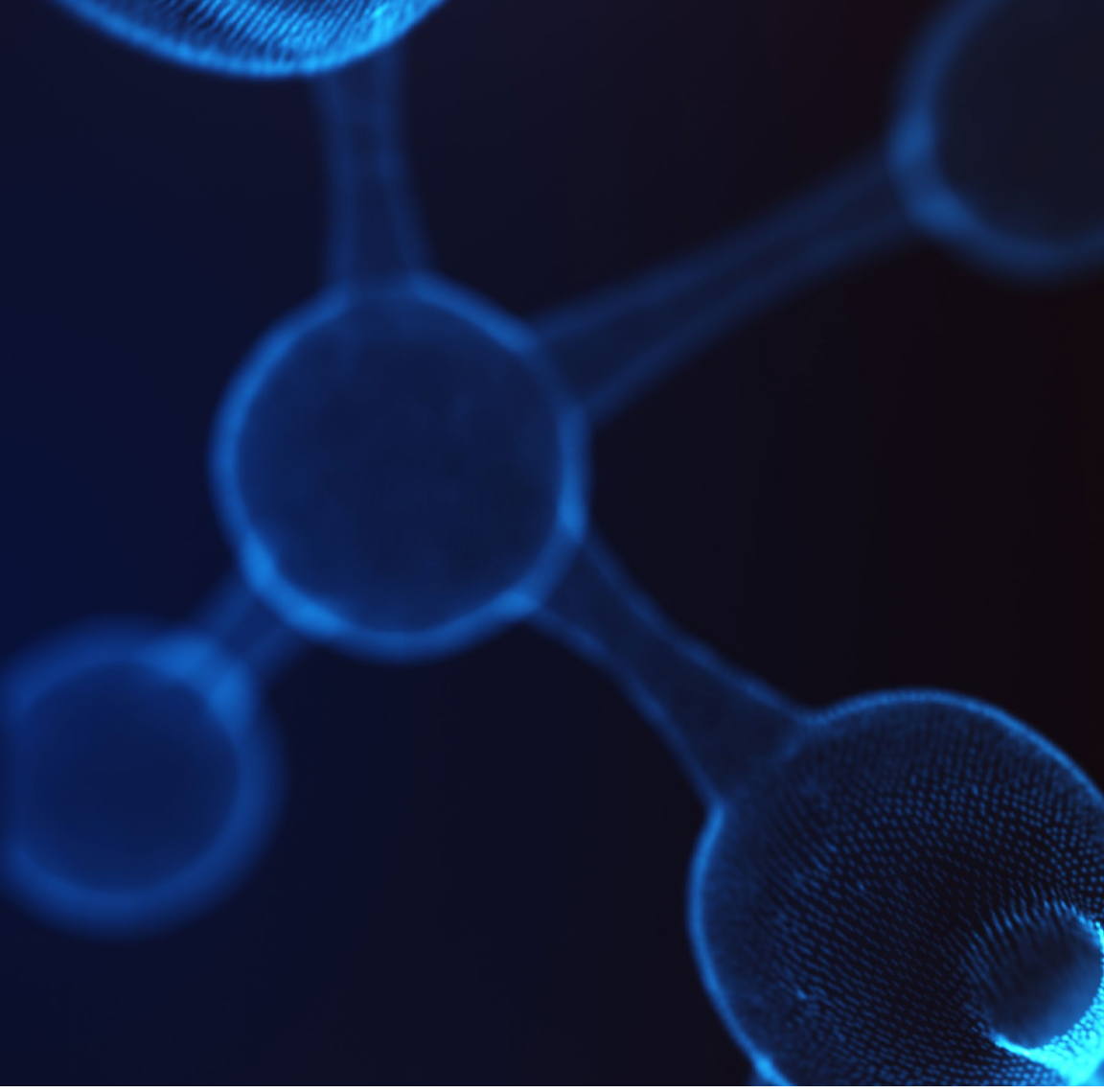
A: Savings vary as cost and coverage are dependent on the terms and conditions of individual insurance benefits, including any applicable deductible, co-insurance, or co-payment. However, in 2024, the average sale price of biosimilars was approximately 40% less than brand biologics.

Q: Can biosimilars be automatically substituted at the pharmacy?

A: This depends on whether the biosimilar has received "interchangeable" designation from the FDA and whether state laws permit substitution at the pharmacy level. Not all biosimilars are designated as interchangeable.

Q: How long have biosimilars been used?

A: The first biosimilar was approved in Europe in 2006. In the US, biosimilars have been used since 2015, with almost 3.3 billion days of patient therapy.



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