

Biosimilars: Comparable Efficacy, Continued Disease Control



When clinically appropriate, consider prescribing a preferred biosimilar for patients starting **new** therapy and evaluate transition options for patients receiving Humira® (adalimumab) or Stelara® (ustekinumab).

FDA-approved biosimilars have no clinically meaningful differences from their reference products in safety, purity, or potency. Clinical and real-world evidence also supports continued disease control after transitioning from the reference biologic.

Clinical Evidence

Adalimumab (Humira)

- In a 2025 prospective study, 90.4% of patients with inflammatory bowel disease maintained clinical remission 12 months after switching from reference adalimumab to a biosimilar.[1]
- In a study of 256 patients with inflammatory bowel disease who transitioned to adalimumab SB5, clinical remission, inflammatory biomarkers, and adalimumab trough concentrations did not differ significantly through 52 weeks.[2]

Ustekinumab (Stelara)

- In a 2026 study of clinically stable patients with Crohn's disease, six-month clinical success was 92.2% after switching to an ustekinumab biosimilar versus 92.7% among patients who continued reference ustekinumab, meeting the study's noninferiority criterion.[3]
- A separate real-world study found no significant difference in clinical remission or inflammatory biomarkers following transition from reference ustekinumab to a biosimilar.[4]

Texas Medicaid Coverage and Transition Support

For Superior HealthPlan Medicaid members, existing Humira and Stelara prior authorizations are being updated to allow the listed biosimilars to adjudicate through the current authorization end date. A new prescription for the selected biosimilar is still required but will not require a new PA.

Additional biosimilars may appear as preferred on the Texas Medicaid PDL but may not currently adjudicate as preferred.

Interchangeability notes: FDA interchangeability is product specific. Pharmacy substitution remains subject to the FDA designation, Texas law, patient choice, prescriber instructions, and indication/product requirements. When possible, prescribing the preferred biosimilar by name can reduce pharmacy follow-up.

Cost impact: The 2026 U.S. Generic & Biosimilar Medicines Savings Report estimated the US savings at \$25.4 billion in U.S. during 2025 and \$81.6 billion cumulatively since 2015.[6]

The tables below reflect preferred biosimilars currently verified for successful pharmacy claims adjudication:

Preferred Adalimumab Products Verified for Claims Processing

Product	Formulation	Strength	NDC
Hyrimoz	Auto-injector	40 mg/0.4 mL	61314047320
Hyrimoz	Prefilled syringe	10 mg/0.1 mL	61314050964
Hyrimoz	Prefilled syringe	20 mg/0.2 mL	61314047664
Hyrimoz	Prefilled syringe	40 mg/0.4 mL	61314047364
Hyrimoz / adalimumab-adaz	Auto-injector	80 mg/0.8 mL	61314032520
Hyrimoz Crohn's/UC Starter	Auto-injector starter kit	80 mg/0.8 mL	61314045436
Hyrimoz Psoriasis/Uveitis Starter	Auto-injector starter kit	80 mg/0.8 mL + 40 mg/0.4 mL	61314051736
Hyrimoz Pediatric Crohn's Starter, ≥40 kg	Prefilled syringe starter kit	80 mg/0.8 mL	61314045468
Cyltezo	Auto-injector kit	40 mg/0.8 mL	00597037597
Cyltezo	Prefilled syringe kit	10 mg/0.2 mL	00597040089
Cyltezo	Prefilled syringe kit	20 mg/0.4 mL	00597040580
Cyltezo	Prefilled syringe kit	40 mg/0.8 mL	00597037082
Hadlima PushTouch	Auto-injector	40 mg/0.4 mL	78206018701
Hadlima PushTouch	Auto-injector	40 mg/0.8 mL	78206018401
Hadlima	Prefilled syringe	40 mg/0.4 mL	78206018601
Hadlima	Prefilled syringe	40 mg/0.8 mL	78206018301
Simlandi	Auto-injector kit, 2 pens	40 mg/0.4 mL	51759040202
Simlandi	Auto-injector kit, 1 pen	40 mg/0.4 mL	51759040217

Preferred ustekinumab products verified for claims processing – *Stelara is Non-preferred

Product	Formulation	Strength	NDC
Pyzchiva	Prefilled syringe	45 mg/0.5 mL	61314065101
Pyzchiva	Single-dose vial	45 mg/0.5 mL	61314065194
Pyzchiva	Prefilled syringe	90 mg/1 mL	61314065201
Selarsdi	Prefilled syringe	45 mg/0.5 mL	51759050532
Selarsdi	Prefilled syringe	90 mg/1 mL	51759060732
Starjemza	Prefilled syringe	45 mg/0.5 mL	00143916801
Starjemza	Single-dose vial	45 mg/0.5mL	00143916901
Starjemza	Prefilled syringe	90 mg/1 mL	00143917001

Additional Information

To confirm current Texas Medicaid formulary status before prescribing please review the [Biosimilar Alternatives for Commonly Prescribed Biologics \(PDF\)](#).

References

- [1] D'Abbundo G, Nachury M, Wartski A, et al. Switch acceptance and persistence of adalimumab biosimilars in IBD patients: a prospective observational study. *Ther Adv Gastroenterol*. 2025;18:1-14. doi:10.1177/17562848251332025.
- [2] Derikx LAAP, Dolby HW, Plevris N, et al. Effectiveness and safety of adalimumab biosimilar SB5 in inflammatory bowel disease. *J Crohns Colitis*. 2021;15(12):2011-2021. doi:10.1093/ecco-jcc/jjab100.
- [3] Ribaldone DG, Tribocco E, Scaldaferri F, et al. Clinical outcomes after ustekinumab biosimilar switching in Crohn's disease: the USBIOS-Italian Group study. *Clin Gastroenterol Hepatol*. Published online August 27, 2026.
- [4] Kritzinger J, Candel I, Kotrri G, et al. Clinical outcomes and drug sustainability after non-medical switch from ustekinumab originator to biosimilars in inflammatory bowel disease. *World J Gastroenterol*. 2025;31(48):114355. doi:10.3748/wjg.v31.i48.114355.
- [5] U.S. Food and Drug Administration. Biosimilar Product Information and Purple Book Database.
- [6] Biosimilars Council. 2026 U.S. Generic & Biosimilar Medicines Savings Report. Published September 10, 2026.