Adalimumab and biosimilars side-by-side comparison

April 2024

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Executive Summary

Introduction

The first adalimumab biosimilar (Amjevita) was approved on September 23, 2016 and launched in the US market in January 2023. Since the FDA approval of the first adalimumab biosimilar there have been 9 other products approved, for a total of 10 adalimumab biosimilar products. These products were approved under section 351(k) of the Public Health Service Act by demonstrating high similarity to the US reference product adalimumab (Humira) through comparative structural and physiochemical analyses, functional and biological analyses, and non-clinical and clinical analysis. All 10 adalimumab biosimilars have received approval in the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, and uveitis. Reference Humira is the only adalimumab product approved for use in adolescent hidradenitis suppurativa, pediatric uveitis, and pediatric ulcerative colitis. On October 15, 2021, adalimumab-abdm (Cyltezo) became the first adalimumab biosimilar to be granted interchangeability status with 1 year of exclusivity following commercial marketing pursuant to section 351(k)(6) of the Public Health Service Act. Subsequently, adalimumab-afzb (Abrilada), adalimumab-adaz (Hyrimoz), and adalimumab-ryvk (Simlandi) have also been granted an interchangeability designation. The interchangeability designation for adalimumab-adaz (Hyrimoz) is specific to the prefilled syringe formulation (all concentrations except the 0.4 mg/0.4 mL concentration are designated as interchangeable for the prefilled syringes); the auto-injector formulations for adalimumab-adaz (Hyrimoz) are not designated as interchangeable. Biosimilar adalimumab-atto (Amjevita), adalimumab-bwwd (Hadlima), adalimumab-fkjp (Hulio), and adalimumab-aaty (Yuflyma) are currently in the process of seeking interchangeability status.[1-12] Detailed information on the totality of evidence submitted for approval is available on the FDA website for each biosimilar.

Adalimumab biosimilars

All FDA-approved adalimumab biosimilars have demonstrated high similarity to reference Humira in comparative structural and physiochemical analysis; functional and biological analysis; and in safety, immunogenicity, and pharmacokinetic evaluations conducted in phase 1 studies. Each of the adalimumab biosimilars also demonstrated high similarity in efficacy when compared with reference Humira across phase 3 studies. Patient populations selected for phase 3 studies are those in which the population is expected to be sensitive to the study drugs; data from these studies may then be extrapolated to other indications as part of the biosimilar approval process. Adalimumab-atto (Amjevita), adalimumab-bwwd (Hadlima), adalimumab-adbm (Cyltezo), adalimumab-fkjp (Hulio), adalimumab-adaz (Hyrimoz), adalimumab-afzb (Abrilada), adalimumab-aacf (Idacio), and adalimumab-aaty (Yuflyma) were compared with reference product in phase 3 trials in adult patients with rheumatoid arthritis. Adalimumab-atto (Amjevita), adalimumab-adbm (Cyltezo), adalimumab-adaz (Hyrimoz), adalimumab-avqh (Yusimry), adalimumab-aacf (Idacio), and adalimumab-ryvk (Simlandi) were compared with reference product in phase 3 trials in adult patients with plaque psoriasis. Adalimumab-adbm (Cyltezo) was also compared with reference product in adult patients with Crohn's disease in a phase 3 trial. Each biosimilar product has shown, in respective phase 3 trials, that switching once with reference product did not impact patient safety, immunogenicity, or efficacy. Adalimumab-adbm (Cyltezo), adalimumab-afzb (Abrilada), adalimumab-adaz (Hyrimoz), and adalimumab-ryvk (Simlandi) were each additionally evaluated in studies in which multiple switches between the biosimilar product and reference product were performed to support interchangeability.[17-40]

Conclusion

The 10 approved biosimilar adalimumab products have shown comparable safety, immunogenicity and efficacy as the reference product, Humira. The selection among the adalimumab products is complex and will likely depend on non-clinical factors such as availability of auto-injector device/prefilled syringes, citrate-free formulations, and high-concentration formulations; acquisition cost; payor preference; reimbursement; patient assistance; and operational factors.

Adalimumab and biosimilars side-by-side comparison

	Brand name (generic name)										
	Humira[1] (adalimumab) *reference product*	Amjevita[2] (adalimumab-atto)	Hadlima[3] (adalimumab-bwwd)	Cyltezo[4] (adalimumab-adbm)	Hulio[5] (adalimumab-fkjp)	Hyrimoz[6] (adalimumab-adaz)	Abrilada[7] (adalimumab-afzb)	Yusimry[8] (adalimumab-aqvh)	Idacio[9] (adalimumab-aacf)	Yuflyma[10] (adalimumab-aaty)	Simlandi[11] (adalimumab-ryvk)
Manufacturer	Abbvie	Amgen	Samsung Bioepis	Boehringer Ingelheim	Mylan	Sandoz / Cordavis	Pfizer	Coherus BioScience	Fresenius Kabi	Celltrion	Alvotech
Approval date	12/31/2002	9/23/2016	7/23/2019	8/25/2017	7/6/2020	10/30/2018	11/15/2019	12/20/2021	12/13/2022	5/23/2023	2/23/2024
Anticipated US launch date[12]	Launched	Launched	Launched	Launched	Launched	Launched	Launched	Launched	Launched	Launched	Q2 2024
Unbranded product approved[12]	Yes	No	No	Yes	Yes	Yes	No	No	Yes	Yes	No
Unbranded product launched[12]	No	NA	NA	Yes	Yes	Yes (40 mg/0.4 mL only)	NA	NA	Yes	No	NA
Inter-changeable	NA – reference product	Seeking[12] (HC product)	Seeking[12]	Yes	Seeking[12]	Yes (depending on formulation)	Yes	No	No	Seeking[12]	Yes
Citrate-free formulation	Yes	Yes	Yes (HC product)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
High-concentration formulation available	Yes	Yes	Yes	Seeking[12]	No	Yes	No	Seeking[12]	No	Yes	Yes
Auto-injector available	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
FDA-approved indications											
RA	X	X	X	X	X	X	X	X	X	X	X
PsA	X	X	X	X	X	X	X	X	X	X	X
AS	X	X	X	X	X	X	X	X	X	X	X
JIA	X (≥ 10 kg)	X (≥ 10 kg)	X (≥ 10 kg)	X (≥ 10 kg)	X (≥ 15 kg)	X (≥ 10 kg)	X (≥ 10 kg)	X (≥ 30 kg)	X (≥ 30 kg)	X (≥ 15 kg)	X (≥ 30 kg)
Adult CD	X	X	X	X	X	X	X	X	X	X	X

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Pediatric CD	X (≥ 17 kg)	X (≥ 17 kg)	X (≥ 17 kg)	X (≥ 17 kg)	X (≥ 17 kg)	X (≥ 17 kg)	X (≥ 17 kg)	X (≥ 40 kg)	X (≥ 40 kg)	X (≥ 17 kg)	X (≥ 40 kg)
Adult UC	X	X	X	X	X	X	X	X	X	X	X
Pediatric UC	ODE thru 2/24/28[12]										
Ps	X	X	X	X	X	X	X	X	X	X	X
Adult UV	X	X	X	X	X	X	X	X	X	X	X
Pediatric UV	ODE thru 9/28/25[12]										
Adult HS	X	X	X	X	X	X	X	X	X	X	X
Adolescent HS	ODE thru 10/16/25[12]										
Dosage forms and strengths											
Prefilled auto-injector	Humira Pen: • 80 mg/0.8 mL • 40 mg/0.4 mL	Amjevita SureClick: • 80 mg/0.8 mL • 40 mg/0.8 mL • 40 mg/0.4 mL	Hadlima PushTouch: • 40 mg/0.8 mL • 40 mg/0.4 mL	Cyltezo Pen: • 40 mg/0.8 mL (I)	Hulio Pen: • 40 mg/0.8 mL	Sensoready Pen: • 80 mg/0.8 mL • 40 mg/0.8 mL • 40 mg/0.4 mL	Abrilada pen: • 40 mg/0.8 mL (I)	Yusimry pen: • 40 mg/0.8 mL	Idacio pen: • 40 mg/0.8 mL	Yuflyma AI: • 80 mg/0.8 mL • 40 mg/0.4 mL	Autoinjector: • 40 mg/0.4 mL (I)
Single-dose PFS	• 40 mg/0.4 mL • 20 mg/0.2 mL • 10 mg/0.1 mL	• 80 mg/0.8 mL • 40 mg/0.8 mL • 40 mg/0.4 mL • 20 mg/0.4 mL • 20 mg/0.2 mL • 10 mg/0.2 mL	• 40 mg/0.8 mL • 40 mg/0.4 mL	• 40 mg/0.8 mL (I) • 20 mg/0.4 mL (I) 10 mg/0.2 mL (I)	• 40 mg/0.8 mL • 20 mg/0.4 mL	• 80 mg/0.8 mL (I) • 40 mg/0.8 mL (I) • 40 mg/0.4 mL • 20 mg/0.4 mL (I) • 20 mg/0.2 mL (I) • 10 mg/0.2 mL (I)	• 40 mg/0.8 mL (I) • 20 mg/0.4 mL (I) • 10 mg/0.2 mL (I)	• 40 mg/0.8 mL	NA	• 80 mg/0.8 mL • 40 mg/0.4 mL • 20 mg/0.2 mL	NA

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						• 10 mg/0.1 mL (I)					
Single-dose vial institutional use	NA	NA	40 mg/0.8 mL	NA	NA	NA	40 mg/0.8 mL	NA	NA	NA	NA
Product composition											
Low concentration product* **other product sizes than what is listed here for example may be available*	NA	**40 mg/0.8 mL** • 40 mg adalimu-mab-atto • 0.48 mg glacial acetic acid • 0.8 mg polysorbate 80 • 72 mg hydroxide • Water for injection • pH 5.2	**40 mg/0.8 mL** • 40 mg adalimu-mab-bwwd • 0.544 mg citric acid mono-hydrate • 0.96 mg L-histidine • 8.64 mg L-histidine hydro-chloride mono-hydrate • 0.64 mg polysorbate 20 • 1.6 mg sodium citrate dihydrate • 20.0 mg sorbitol • Water for injection	**40 mg/0.8 mL** • 40mg adalimu-mab-adbm • 0.13 mg glacial acetic acid • 0.8 mg polysorbate 80 • 2.4 mg sodium acetate trihydrate • 65.0 mg trehalose dihydrate • Water for injection	**40 mg/0.8 mL** • 40 mg adalimu-mab-fkjp • 0.60 mg methionine • 1.50 mg mono-sodium glutamate • 0.80 mg polysorbate 80 • 38.2 mg sorbitol • Water for injection • Hydro-chloric acid is added as necessary to adjust pH	**40 mg/0.8 mL** • 40 mg adalimu-mab-adaz • 2.69 mg adipic acid • 0.206 mg citric acid mono-hydrate • 9.6 mannitol • 0.8 mg polysorbate 80 • 4.93 mg sodium chloride • Water for injection • Hydro-chloric acid and sodium hydroxide added as necessary to adjust pH	**40 mg/0.8 mL** • 40 mg adalimu-mab-afzb • 0.04 mg edetate disodium dihydrate • 0.63 mg L-histidine • 2.51 mg L-histidine hydro-chloride mono-hydrate • 0.16 mg L-methionine • 0.16 mg polysorbate 80 • 68 mg sucrose • Water for injection	**40 mg/0.8 mL** • 40 mg adalimu-mab-aqvh • 9.61 mg glycine • 0.51 L-histidine • 4.34 L-histidine hydro-chloride mono-hydrate • 0.80 mg polysorbate 80 • 2.06 sodium chloride • Water for injection • Sodium hydroxide is added as necessary to adjust for pH	**40 mg/0.8 mL** • 40 mg adalimu-mab-aacf • 0.5 mg glacial acetic acid • 54.8 mg trehalose • 0.8 mg polysorbate 80 • 2.3 mg sodium chloride • Water for injection • Sodium hydroxide is added to adjust for pH	NA	NA

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High concentration product* **other product sizes than what is listed here for example may be available*	**80 mg/0.8 mL** • 80 mg adalimumab • 33.6 mg mannitol • 0.8 mg polysorbate 80 • Water for Injection	**80 mg/0.8 mL** • 80 mg adalimumab-atto • 1.7 mg L-lactic acid • 0.8 mg polysorbate 80 • Sodium hydroxide for pH adjustment • Sucrose 67 mg • Water for Injection	**40 mg/0.4 mL** • 40 mg adalimumab-bwwd • 0.376 mg L-histidine • 4.436 mg L-histidine hydrochloride monohydrate • 12 mg mannitol • 0.32 mg polysorbate 20 • 0.0008 mg sodium phosphate dibasic heptahydrate • 0.14 mg sodium phosphate monobasic monohydrate • 0.196 mg sodium succinate dibasic • 0.096 mg succinic acid • Water for injection	NA	NA	**80 mg/0.8 mL** • 80 mg adalimumab-adaz • 1.75 mg adipic acid • 33.6 mg mannitol • 0.32 mg polysorbate 80 • Water for injection • Hydrochloric acid and sodium hydroxide added as necessary to adjust pH	NA	NA	NA	**40 mg/0.4 mL** • 40 mg adalimumab-aaty • 0.06 mg acetic acid • 7.51 mg glycine • 0.4 mg polysorbate 80 • 0.24 mg sodium acetate • Water for injection	**40 mg/0.4 mL** • 40 mg adalimumab-ryvk • 0.4 mg polysorbate 80 • 0.23 mg sodium chloride • Sucrose 34.9 mg • Water for injection • Hydrochloric acid and sodium hydroxide added as necessary to adjust pH

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Safety											
Boxed warning	• **Serious infections:** Increased risk of serious infections leading to hospitalization or death, including tuberculosis, bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens. • **Malignancy:** Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab. Post-marketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treated with TNF blockers including adalimumab.										
Contra-indications	None										
Warnings / precautions	• **Serious infections:** Do not start adalimumab during an active infection. If an infection develops, monitor carefully, and stop adalimumab if infection becomes serious. • **Invasive fungal infections:** For patients who develop a systemic illness on adalimumab consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic. • **Malignancies:** Incidence of malignancies was greater in adalimumab treated patients than in controls. • **Anaphylaxis:** Anaphylaxis or serious allergic reactions may occur. • **Hepatitis B virus reactivations:** Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop adalimumab and begin anti-viral therapy. • **Demyelinating disease:** Exacerbation or new onset may occur. • **Cytopenia, pancytopenia:** Advise patients to seek immediate medical attention if symptoms develop and consider stopping adalimumab. • **Heart failure:** Worsening or new onset, may occur. • **Lupus-like syndrome:** Stop adalimumab if syndrome develops.										
Adverse reactions	**More Common (incidence ≥ 5%):** • **Respiratory:** upper respiratory infections, sinusitis, flu syndrome • **Gastrointestinal:** nausea, abdominal pain • **Lab test abnormalities:** hypercholesterolemia, hyperlipidemia, hematuria, alkaline phosphatase increased • **Other:** headache, rash, accidental injury, injection site reaction, back pain, urinary tract infection, hypertension **Less common:** • **Body as whole:** pain in extremity, pelvic pain, surgery, thorax pain • **Cardiac:** arrhythmia, atrial fibrillation chest pain, coronary artery disorder, heart arrest, hypertensive encephalopathy, myocardial infarct, palpitation, pericardial effusion, pericarditis, syncope, tachycardia • **Digestive system:** cholecystitis, cholelithiasis, esophagitis, gastroenteritis, gastrointestinal hemorrhage, hepatic necrosis, vomiting • **Endocrine system**: parathyroid disorder • **Hemic and lymphatic system:** agranulocytosis, polycythemia • **Metabolic and nutritional disorders:** dehydration healing abnormal, ketosis, paraproteinemia, peripheral edema										

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	• **Musculoskeletal system:** arthritis, bone disorder, bone fracture (not spontaneous), bone necrosis, joint disorder, muscle cramps, myasthenia, pyogenic arthritis, synovitis, tendon disorder • **Neoplasia:** adenoma • **Nervous system:** confusion, paresthesia, subdural hematoma, tremor • **Respiratory system:** asthma, bronchospasm, dyspnea, lung function decreased, pleural effusion • **Special senses:** cataract • **Thrombosis:** thrombosis leg • **Urogenital system:** cystitis, kidney calculus, menstrual disorder										
Drug interactions	• **Methotrexate:** Reduced the apparent adalimumab clearance however no need for dose adjustment • **Abatacept:** Increased risk of serious infection • **Anakinra:** Increased risk of serious infection • **Live vaccines:** Avoid use with adalimumab • **Cytochrome P450 substrates:** The formation of CYP450 enzymes may be suppressed by increase concentration of cytokines (TNF alpha, IL-6) during chronic inflammation. It is possible for products that antagonize cytokine activity, such as adalimumab, to influence the formation of CYP 450 enzymes. Patients being treated with CYP450 substrates with narrow therapeutic index monitoring of the effect or drug concentration is recommended (eg, warfarin, cyclosporine, theophylline).										
Pharmacology	Adalimumab binds specifically to TNF-alpha and blocks its interaction with the p55 and p75 cell surface TNF receptors. Adalimumab also lyses surface TNF expressing cells *in vitro* in the presence of complement. Adalimumab does not bind or inactivate lymphotoxin (TNF-beta). TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Elevated concentrations of TNF are found in the synovial fluid of patients with RA, JIA, PsA, and AS and play an important role in both the pathologic inflammation and the joint destruction that are hallmarks of these diseases. Increased concentrations of TNF are also found in psoriasis plaques. In Ps, treatment with adalimumab may reduce the epidermal thickness and infiltration of cells. The relationship between these pharmacodynamic activities and the mechanism(s) by which adalimumab exerts its clinical effects is unknown. Adalimumab also modulates biological responses that are induced or regulated by TNF, including changes in the concentrations of adhesion molecules responsible for leukocyte migration.										
Storage and handling											
Recommended storage conditions	• Adalimumab must be refrigerated at 2°C to 8°C. Do not freeze. • Do not use if frozen even if it has been thawed. • Store in original carton until time of administration to protect from light. • Do not store adalimumab in extreme heat or cold. • If needed, for example when traveling, all adalimumab presentations may be stored at room temperature up to a maximum of 25°C for a period of time (varies by product; *see next row below*), with protection from light. Adalimumab should be discarded if not used within the specified time period. Record the date when adalimumab is first removed from the refrigerator in the spaces provided on the carton and dose tray.										
Maximum storage duration at room temperature	14 d	14 d	14 d	14 d	14 d	21 d	30 d	14 d	28 d	30 d	14 d

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Annual WAC (approximate)[12]											
Low concentration product	NA	**High WAC:** $85,500 **Low WAC:** $40,500	$13,500	**Brand:** $85,500 **Unbranded:** $17,100	**Brand:** $85,500 **Unbranded:** $12,900	$16,900 (*Cordavis Private label; Sandoz did not launch*)	**High WAC:** $85,500 **Low WAC:** $36,000	$12,900	**Brand:** $85,500 **Unbranded:** $11,700	NA	NA
High concentration product	**Brand:** $90,000 **Unbranded:** TBD	$18,000	$13,500	NA	NA	**Brand:** $85,500 **Unbranded:** $17,100 **Cordavis private label:** $16,900	NA	NA	NA	**Brand:** $85,500 **Unbranded:** TBD	$13,500 (*anticipated; not yet launched*)
Coverage considerations[13]											
Copay card	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	TBD
Patient assistance program	Yes	Yes	Yes	Yes	Yes	Yes	Yes[14]	No	Yes[15]	Yes	TBD
Bridge program	No	No	No	No	Yes	Yes	Yes	No	Yes	No	TBD
Cost Plus Drug Program[16]	NA	NA	Yes. Available for approximate annual WAC of $15,400.	NA	NA	NA	NA	Yes. Available for approximate annual WAC of $7,500.	NA	NA	NA

(I) = interchangeable

Abbreviations: AS= ankylosing spondylitis; CD= Crohn's disease; HC = high concentration; HS= hidradenitis suppurativa; JIA = Juvenile idiopathic arthritis; NA = not applicable; ODE = orphan drug exclusivity; PFS = prefilled syringe; PI = prescribing information; Ps= plaque psoriasis; PsA= psoriatic arthritis; RA= rheumatoid arthritis; TBD = to be determined; TNF = tumor necrosis factor; UC= ulcerative colitis; UV= uveitis

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