



# Adalimumab Biosimilars

---

Johnny Chang, PharmD

Specialty Pharmacist

Multicare Specialty Pharmacy

# Agenda

---

- Introduction to Biosimilar
- Reference Product
- Biosimilars on the Market
- Summary





# Introduction

---

- Biosimilar
- Reference Product

# Introduction to Biosimilars

---

- Biologics (*Overview for Health Care Professionals 2024*)
  - Large, complex molecules that are made from living sources
  - Inherently contains many slight variations from batch to batch
- FDA-approved biological products that are comparable to the reference biological product (*Overview for Health Care Professionals 2024*)
  - Achieve the same clinical outcome
  - No *meaningful* difference in pharmacokinetics, pharmacodynamics, and immunogenicity
  - No clinically meaningful differences in terms of safety, purity, and potency
- Increase market competition to lower healthcare costs and promote innovation

# Biosimilar Approval Process



Biosimilar is compared with its reference product under (*Review and Approval 2022*)

- Analytical studies: Structural and functional similarity
- Animal studies: Toxicology or pharmacology information
- A clinical study or studies: address any potential residual uncertainty

(Review and Approval 2022)

# Interchangeability

---

- Per FDA - An interchangeable biosimilar MAY be substituted for the reference product by a pharmacist without prescriber intervention
  - Not all biosimilars are interchangeable
  - Requires additional data supplied by the manufacturer
- However, state law can prohibit pharmacist's ability to substitute
  - Washington State **does not allow pharmacists to make automatic substitutions.**
  - "Under Washington law, a less expensive interchangeable biological product or equivalent drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information." RCW 69.41.160: Pharmacy signs as to substitution for prescribed drugs

# Unbranded Biologics

---

- Branded product but without the brand name on the label
- Per Purple Book FAQs, (a)n “unbranded biologic” **is not an “interchangeable biosimilar.”** However, an unbranded biologic is considered by FDA to be **equivalent to its brand name biological product** because it is the same product as the brand name biological product under the same BLA (biologics license applications)
- Most branded adalimumab biosimilars are priced higher (~5% discount to reference product) vs unbranded adalimumab are priced much lower (~81% discount to reference product)



# Reference Product

---

Adalimumab



# Reference Product – Adalimumab

Formulation	Doses	Storage and Stability	CF* and non-CF available	Latex allergy concern
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe</li><li>• Vials</li><li>• Various starter kits</li></ul>	<ul style="list-style-type: none"><li>• 10 mg/0.1 mL</li><li>• 10 mg/0.2 mL</li><li>• 20 mg/0.2 mL</li><li>• 20 mg/0.4 mL</li><li>• 40 mg/0.4 mL</li><li>• 40 mg/0.8 mL</li><li>• 80 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Refrigerated at 36°F to 46°F (2°C to 8°C)</li><li>• Stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 14 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>• Both available</li></ul>	The needle cover may contain natural rubber latex

\*CF: citrate-free

# Adalimumab – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Hidradenitis suppurativa	Age: $\geq 12y$
Juvenile idiopathic arthritis	Age: $\geq 2y$
Ulcerative colitis	Age: $\geq 5y$
Uveitis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis



# FDA Biosimilars

---

10 FDA-approved products on the market

# Interchangeables Biosimilars

---

**Adalimumab  
-afzb**

**Adalimumab  
-adbm**

**Adalimumab  
-ryvk**

# Adalimumab-afzb

Formulation	Doses	Storage and Stability	CF and non-CF available	Latex allergy concern	Unbranded version ?
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe</li><li>• Vials</li></ul>	<ul style="list-style-type: none"><li>• 10 mg/0.2 mL</li><li>• 20 mg/0.4 mL</li><li>• 40 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Refrigerated at 36°F to 46°F (2°C to 8°C)</li><li>• Stored at room temperature up to a maximum of 86°F (30°C) for a period of up to 30 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>• CF only</li></ul>	Latex Free	No

\*CF: citrate-free

# Adalimumab-afzb – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis
Ulcerative colitis
Hidradenitis suppurativa
Uveitis

# Adalimumab-adbm

Formulation	Doses	Storage and Stability	CF and non-CF available	Latex allergy concern	Unbranded version ?
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe</li><li>• Starter kits for psoriasis, uveitis, Crohn's disease, ulcerative colitis, and hidradenitis suppurativa</li></ul>	<ul style="list-style-type: none"><li>• 10 mg/0.2 mL</li><li>• 20 mg/0.4 mL</li><li>• 40 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Refrigerated at 36°F to 46°F (2°C to 8°C)</li><li>• Stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 14 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>• CF only</li></ul>	The needle cover may contain natural rubber latex	Yes

\*CF: citrate-free

# Adalimumab-adbm – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis
Ulcerative Colitis
Hidradenitis suppurativa
Uveitis



# Adalimumab-ryvk

Formulation	Doses	Storage and Stability	CF and non-CF available	Latex allergy concern	Unbranded available?
<ul style="list-style-type: none"><li>Pens</li></ul>	<ul style="list-style-type: none"><li>40 mg/0.4 mL</li></ul>	<ul style="list-style-type: none"><li>Refrigerated at 36°F to 46°F (2°C to 8°C)</li><li>Stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 14 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>CF only</li></ul>	No	Yes

\*CF: citrate-free

# Adalimumab-ryvk – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis
Ulcerative Colitis
Hidradenitis suppurativa
Uveitis

# Noninterchangeables Biosimilars

---

Adimumab-  
atto

Adalimumab-  
bwwd

Adalimumab-  
fkjp

Adalimumab-  
adaz

Adalimumab-  
aacf

Adalimumab-  
aaty

Adalimumab-  
aqvh

# Adalimumab-atto

Formulation	Doses	Storage and Stability	CF and non-CF available	Latex allergy concern	Unbranded version ?
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe</li><li>• Vials</li></ul>	<ul style="list-style-type: none"><li>• 10 mg/0.2 mL</li><li>• 20 mg/0.2 mL</li><li>• 20 mg/0.4 mL</li><li>• 40 mg/0.4 mL</li><li>• 40 mg/0.8 mL</li><li>• 80 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Refrigerated at 36°F to 46°F (2°C to 8°C)</li><li>• Stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 14 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>• CF only</li></ul>	No latex concern	No

\*CF: citrate-free

# Adalimumab-atto – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis
Ulcerative Colitis
Hidradenitis suppurativa
Uveitis

# Adalimumab-bwwd

Formulation	Doses	Storage and Stability	CF and non-CF available	Latex allergy concern	Unbranded available ?
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe</li><li>• Vials</li></ul>	<ul style="list-style-type: none"><li>• 40 mg/0.4 mL</li><li>• 40 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Refrigerated at 36°F to 46°F (2°C to 8°C)</li><li>• Stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 14 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>• Both are available</li></ul>	Latex Free	No

\*CF: citrate-free

# Adalimumab-bwwd – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis
Ulcerative Colitis
Hidradenitis suppurativa
Uveitis

# Adalimumab-fkjp

Formulation	Doses	Storage and Stability	CF and non-CF available	Latex allergy concern	Unbranded available ?
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe</li></ul>	<ul style="list-style-type: none"><li>• 20 mg/0.4 mL</li><li>• 40 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Refrigerated at 36°F to 46°F (2°C to 8°C)</li><li>• Stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 14 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>• CF only</li></ul>	Latex Free	Yes

\*CF: citrate-free



# Adalimumab-fkjp – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis
Ulcerative Colitis
Hidradenitis suppurativa
Uveitis

# Adalimumab-adaz

Formulation	Doses	CF and non-CF available	Latex allergy concern	Unbranded available ?
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe (with and without safety guard)</li><li>• Starter pack for Pediatric Crohn's Disease</li><li>• Starter pack for CD, UC, or HS</li><li>• Start pack for Ps</li></ul>	<ul style="list-style-type: none"><li>• 10 mg/0.1 mL</li><li>• 10 mg/0.2 mL</li><li>• 20 mg/0.2 mL</li><li>• 20 mg/0.4 mL</li><li>• 40 mg/0.4 mL</li><li>• 40 mg/0.8 mL</li><li>• 80 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Both are available</li></ul>	Latex Free	Yes

\*CD: Crohn's disease; CF: citrate-free; HS: hidradenitis suppurativa; Ps: plaque psoriasis; UC: ulcerative colitis

# Adalimumab-adaz Storage and Handling

Formulation	Temperature and Days
All	Refrigerated at 36°F to 46°F (2°C to 8°C)
<b>Pen - 40 mg/0.8 mL</b> <b>Prefilled syringe with safeguard –</b> 20 mg/0.4 mL and 40 mg/0.8 mL <b>Prefilled syringe w/out safeguard –</b> 10 mg /0.2 mL	May be stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 21 days, with protection from light
<b>Pen - 40 mg/0.4 mL and 80 mg/0.8 mL</b> <b>Prefilled syringe with safeguard –</b> 40 mg/0.4 mL , 80 mg/0.8 mL <b>Prefilled syringe w/out safeguard –</b> 10 mg /0.1 mL and 20 mg/0.2 mL	may be stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 14 days

# Adalimumab-adaz – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis
Ulcerative colitis
Hidradenitis suppurativa

# Adalimumab-aacf

Formulation	Doses	Storage and Stability	CF and non-CF available	Latex allergy concern	Unbranded available?
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe (with and safety guard)</li><li>• Starter pack for CD, UC, or HS</li><li>• Start pack for Ps or UV</li></ul>	<ul style="list-style-type: none"><li>• 40 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Refrigerated at 36° F to 46° F (2° C to 8° C)</li><li>• Stored at room temperature up to a maximum of 77° F (25° C) for a period of up to 28 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>• Only CF</li></ul>	Latex Free	Yes

\*CD: Crohn's disease; CF: citrate-free; HS: hidradenitis suppurativa; Ps: plaque psoriasis; UC: ulcerative colitis; UV: Uveitis

# Adalimumab-aacf – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis
Ulcerative Colitis
Hidradenitis suppurativa
Uveitis

# Adalimumab-aaty

Formulation	Doses	Storage and Stability	CF and non-CF available	Latex allergy concern	Unbranded available?
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe (with and without safety guard)</li><li>• Starter pack for Ped UC</li><li>• Starter pack for CD, UC, or HS</li><li>• Start pack for Ps</li></ul>	<ul style="list-style-type: none"><li>• 20 mg/0.2 mL</li><li>• 40 mg/0.4 mL</li><li>• 80 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Refrigerated at 36°F to 46°F (2°C to 8°C)</li><li>• Stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 31 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>• Only CF</li></ul>	Latex Free	Yes

\*CD: Crohn's disease; CF: citrate-free; HS: hidradenitis suppurativa; Ped: pediatric; Ps: plaque psoriasis; UC: ulcerative colitis; UV: Uveitis

# Adalimumab-aaty – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Axial spondylitis
Psoriatic arthritis
Ulcerative Colitis
Hidradenitis suppurativa
Uveitis



# Adalimumab-aqvh

Formulation	Doses	Storage and Stability	CF and non-CF available	Latex allergy concern	Unbranded available ?
<ul style="list-style-type: none"><li>• Pens</li><li>• Pre-filled syringe</li></ul>	<ul style="list-style-type: none"><li>• 40 mg/0.8 mL</li></ul>	<ul style="list-style-type: none"><li>• Refrigerated at 36°F to 46°F (2°C to 8°C)</li><li>• Stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 14 days, with protection from light</li></ul>	<ul style="list-style-type: none"><li>• Only CF</li></ul>	Latex Free	No

\*CD: Crohn's disease; CF: citrate-free; HS: hidradenitis suppurativa; Ped: pediatric; Ps: plaque psoriasis; UC: ulcerative colitis; UV: Uveitis

# Adalimumab-aqvh – Indications

Adult and pediatric patients	
Crohn's disease	Age: $\geq 6y$
Juvenile idiopathic arthritis	Age: $\geq 2y$

Adults only
Plaque psoriasis
Rheumatoid arthritis
Psoriatic Arthritis
Ankylosing Spondylitis
Ulcerative Colitis
Hidradenitis suppurativa
Uveitis

# Summary - Indications

	CD*	JIA**	Ps***	RA***	AS***	PsA***	UC***	HS***	UV***
All other biosimilars except Adalimumab-adaz	X	X	X	X	X	X	X	X	X
Adalimumab-adaz	X	X	X	X	X	X	X	X	

\*Indicated for age  $\geq 6y$  \*\* Indicated for age  $\geq 2y$  \*\*\*Indicated for adults only

CD: Chron's disease; JIA: Juvenile idiopathic arthritis; PsA: Psoriatic arthritis; AS: Ankylosing spondylitis; UC: Ulcerative colitis; PS: Plaque psoriasis; HS: Hidradenitis suppurativa; UV: Uveitis

# Summary – Formulations

	Pen	Syringe	Vial	CF or Latex free	Start packs
Adalimumab-afzb*	LC: 40 mg	LC: 10 mg, 20 mg, 40 mg	LC: 40 mg	CF Latex free	None
Adalimumab-atto	LC: 40 mg HC: 40 mg, 80 mg	LC: 10 mg, 20 mg, 40 mg HC: 20 mg, 40 mg, 80 mg	none	CF Pen and needle caps contain latex	None
Adalimumab-adbm*	LC: 40 mg	LC: 10 mg; 20 mg; 40 mg	None	CF Pen and needle caps contain latex	- Ps or UV - CD, UC, or HS
Adalimumab-bwwd	LC: 40 mg HC:40 mg	LC: 40 mg HC: 40 mg	LC: 40 mg	HC: CF LC: Non-CF Latex free	None
Adalimumab-fkjp	LC: 40 mg	LC: 20 mg; 40 mg	None	CF Latex Free	None
Adalimumab-adaz **	LC: 40 HC: 40 mg; 80 mg	LC: 10 mg; 20 mg; 40 mg HC: 10 mg; 20 mg; 40 mg; 80 mg	None	HC: CF LC: Non-CF Latex free	-CD, UC, OR HS -Ps -Ped CD
Adalimumab-aacf	LC: 40 mg	LC: 40 mg	None	CF Latex free	-PS or UV -CD, UC, or HS
Adalimumab-ryvk*	HC: 40 mg	none	none	CF Latex free	none
Adalimumab-aaty**	HC: 40 mg; 80 mg	HC: 20mg; 40 mg; 80 mg	None	CF Latex free	-Ps -CD, UC, HS, or ped HS
Adalimumab-aqvh	LC: 40 MG	LC: 40 mg	None	CF Latex free	None

\*Interchangeable  
\*\*syringe with and without safety guard

LC: Low concentration- 50 mg/mL;  
HC: High concentration – 100 mg/ mL;  
CF: citric free

CD: Chron’s disease; JIA: Juvenile idiopathic arthritis; PsA: Psoriatic arthritis; AS: Ankylosing spondylitis; UC: Ulcerative colitis; PS: Plaque psoriasis; HS: Hidradenitis suppurativa; UV: Uveitis

# Biosimilars with Unbranded products

Proprietary name	Unbranded version
adalimumab-atto	No
adalimumab-adbm	Yes
adalimumab-adaz	Yes
adalimumab-afzb	no
adalimumab-fkjp	yes
adalimumab-aacf	yes
adalimumab-aqvh	No
adalimumab-aaty	yes
adalimumab-ryvk	Yes
adalimumab-bwwd	No

# Summary

- Currently, there are 10 adalimumab biosimilars on the market, and 3 are interchangeable (adalimumab-afzb, adalimumab-adbm, and adalimumab-ryvk)
- Most plans choose 2 to 3 biosimilars, usually with one unbranded version (low WAC)
- Biosimilars have most of the reference product's indications, mainly lacking in pediatrics
- All biosimilars have CF version, but not all have starter kits
- All biosimilars offer copay cards and financial assistance



# Thank you

---

Johnny Chang, PharmD, BCPS, CPS  
Specialty Pharmacy Pharmacist  
[Johnny.Chang@Multicare.org](mailto:Johnny.Chang@Multicare.org)

# References

---

- FDA. (2022, December 13). *Review and approval*. U.S. Food and Drug Administration. <https://www.fda.gov/drugs/biosimilars/review-and-approval>
- FDA. (2024, January 18). *Overview for health care professionals* . U.S. Food and Drug Administration. <https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals>
- FDA. (n.d.-b). *Purple Book Database of Licensed Biological Products FAQs*. FDA U.S. FOOD& DRUG ADMINISTRATION. <https://purplebooksearch.fda.gov/faqs#:~:text=An%20%E2%80%9Cunbranded%20biologic%E2%80%9D%20is%20not,product%20under%20the%20same%20BLA.>
- RCW 69.41.160 (2015, July 24). Washington State Legislature <https://app.leg.wa.gov/rcw/default.aspx?cite=69.41.160>