



Appendix A: Biosimilars Approved as of 2024

Biosimilar	Reference Product	Non-Proprietary Name	FDA Approval Date	Time from BLA Submission to Approval	Initial Commercial Launch Date	Reported Discount at Launch
Avtozma [®] (Celltrion)	Actemra [®] (Genentech)	tocilizuma b-anoh	Jan. 24, 2025	12 months		
Steqeyma [®] (Celltrion)	Stelara [®] (Johnson & Johnson / Janssen)	ustekinum ab-stba	Dec. 17, 2024	17.5 months	Licensed entry date on Mar. 7, 2025, per settlement	
Yesintek [™] (Biocon)	Stelara [®] (Johnson & Johnson / Janssen)	ustekinum ab-kfce	Nov. 29, 2024	12 months	Licensed entry date no later than Feb. 22, 2025, per settlement	
Imuldosa [™] (Accord)	Stelara [®] (Johnson & Johnson / Janssen)	ustekinum ab-slrf	Oct. 10, 2024	12 months	Licensed entry date no later than May 15, 2025	
Otulfi [™] (Fresenius Kabi / Formycon)	Stelara [®] (Johnson & Johnson / Janssen)	ustekinum ab-aauz	Sept. 27, 2024	12 months	Licensed entry date no later than Apr. 15, 2025, per settlement	
Pavblu [™] (Amgen)	Eylea [®] (Regeneron)	afibercept -ayyh	Aug. 23, 2024	12 months	Oct. 30, 2024	10% off WAC of Eylea [®]

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Enzeevu™ (Sandoz)	Eylea® (Regeneron)	aflibercept-abzv	Aug. 9, 2024 (Interchangeable)	12 months		
Epysqli® (Samsung Bioepis / Teva)	Soliris® (AstraZeneca / Alexion)	eculizumab-aagh	July 19, 2024	15 months		
Ahzantive® (Formycon / Klinge)	Eylea® (Regeneron)	aflibercept-mrbb	June 28, 2024	12 months		
Nypozi™ (Tanvex)	Neupogen® (Amgen)	filgrastim-txid	June 28, 2024	5 years, 9 months		
Pyzchiva® (Samsung Bioepis / Sandoz)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-ttwe	July 4, 2024	15 months	Licensed entry date on Feb. 22, 2025, per settlement	
Bkemv™ (Amgen)	Soliris® (AstraZeneca / Alexion)	eculizumab-aeeb	May 28, 2024 (Interchangeable)	15 months	Licensed entry date no later than Mar. 1, 2025, per settlement	
Yesafili™ (Biocon)	Eylea® (Regeneron)	aflibercept-jbvf	May 20, 2024 (Interchangeable)	31 months		

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Opuviz™ (Samsung Bioepis)	Eylea® (Regeneron)	aflibercept-yszy	May 20, 2024 (Interchangeable)	15 months		
Hercessi™ (Henlius / Accord)	Herceptin® (Roche / Genentech)	trastuzumab-strf	Apr. 25, 2024	16 months	Nov. 29, 2024	Not announced
Selarsdi™ (Alvotek / Teva)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-aekn	Apr. 16, 2024	18 months	Licensed entry date no later than Feb. 21, 2025, per settlement	
Tyenne® (Fresenius Kabi)	Actemra® (Genentech)	tocilizumab-aazg	Mar. 5, 2024	21 months	July 2, 2024	26% off WAC of Actemra®
Jubbonti® and Wyost® (Sandoz)	Prolia® and Xgeva® (Amgen)	denosumab-bbdz	Mar. 5, 2024 (Interchangeable)	21 months	Licensed entry date no later than May 31, 2025, per settlement	
Simlandi® (Alvotek / Teva)	Humira® (AbbVie)	adalimumab-ryvk	Feb. 23, 2024 (Interchangeable)	26 months	May 21, 2024	Launched at 85% off WAC of Humira®; private label adalimumab-ryvk launched at 46% off WAC of Humira®

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Avzivi® (Bio-Thera / Sandoz)	Avastin® (Roche / Genentech)	bevacizumab-tbjn	Dec. 6, 2023	36 months (first submission Nov. 2020; resubmitted Oct. 2022)		
Wezlana™ (Amgen)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-auub	Oct. 31, 2023 (Interchangeable)	12 months	Jan. 1, 2025	Launched high WAC version at 5.5% off WAC of Stelara® and low WAC version at 81% off WAC of Stelara®
Tofidence™ (Biogen / Bio-Thera)	Actemra® (Roche / Genentech)	tocilizumab-bavi	Sept. 29, 2023	12 months	May 6, 2024	16% off WAC of Actemra®
Tyruko® (Sandoz)	Tysabri® (Biogen)	natalizumab-sztn	Aug. 24, 2023	15 months		
Yuflyma® (Celltrion)	Humira® (AbbVie)	adalimumab-aaty	May 23, 2023	30 months (first submission Nov. 2020; resubmitted May and Nov. 2022)	July 2, 2023	Launched branded Yuflyma® at 5% off WAC of Humira® and unbranded adalimumab-aaty at 85% off WAC of Humira®

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Idacio® (Fresenius Kabi)	Humira® (AbbVie)	adalimumab-aacf	Dec. 13, 2022	12 months	July 3, 2023	Launched branded Idacio® at 5% off WAC of Humira® and unbranded adalimumab-aacf at 87% off WAC of Humira®
Vegzelma® (Celltrion)	Avastin® (Roche / Genentech)	bevacizumab-adcd	Sept. 27, 2022	12 months	Apr. 17, 2023	Not announced
Stimufend® (Fresenius Kabi)	Neulasta® (Amgen)	pegfilgrastim-fpgk	Sept. 1, 2022	17 months	Feb. 16, 2023	Not announced
Cimerli® (Coherus / Bioeq)	Lucentis® (Roche / Genentech)	ranibizumab-eqrn	Aug. 2, 2022 (Interchangeable)	12 months	Oct. 3, 2022	30% off WAC of Lucentis®
Fylnetra® (Amneal / Kashiv)	Neulasta® (Amgen)	pegfilgrastim-pbbk	June 3, 2022	22 months (first submission Aug. 2020; resubmitted Nov. 2021)	May 16, 2023	Not announced
Almysys® (Amneal / mAbxience)	Avastin® (Roche / Genentech)	bevacizumab-maly	Apr. 13, 2022	12 months	Oct. 3, 2022	Not announced

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Releuko® (Amneal / Kashiv)	Neupogen® (Amgen)	filgrastim-ayow	Feb. 25, 2022	43.5 months (first submission July 2017; resubmitted Aug. 2021)	Nov. 22, 2022	52% off WAC of Neupogen®
Yusimry® (Coherus)	Humira® (AbbVie)	adalimum ab-aqvh	Dec. 17, 2021	12 months	July 3, 2023	86% off WAC of Humira®
Rezvoglar™ (Eli Lilly)	Lantus® (Sanofi)	insulin glargine-aglr	Dec. 17, 2021 (Interchangeable: Nov. 16, 2022)	12 months	Apr. 1, 2023	78% off WAC of Lantus®
Byooviz™ (Samsung Bioepis / Biogen)	Lucentis® (Roche / Genentech)	ranibizum ab-nuna	Sept. 17, 2021 (Interchangeable: Oct. 3, 2023)	12 months	June 2, 2022	40% off WAC of Lucentis®
Semglee® (Mylan (Viatris) / Biocon)	Lantus® (Sanofi)	insulin glargine-yfgn	July 28, 2021 (Interchangeable)	31 months ¹	Aug. 31, 2020 (Interchangeable: November 2021)	Launched unbranded insulin glargine-yfgn at 65% off WAC of Lantus® and branded Semlgee® at 5% off WAC of Lantus®

¹ Mylan filed its New Drug Application (NDA) for Semglee® on April 27, 2017, and on March 23, 2020, Mylan's NDA was deemed to be a BLA.

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Riabni® (Amgen)	Rituxan® (Roche / Genentech)	rituximab-arrx	Dec. 17, 2020	12 months	Jan. 12, 2021	16.7% off ASP and 23.7% off WAC of Rituxan®; and 15.2% off WAC of Truxima®
Hulio® (Mylan (Viatris) / Biocon)	Humira® (AbbVie)	adalimumab-fkjp	July 6, 2020	12 months	July 3, 2023	Launched branded Hulio® at 5% off WAC of Humira® and unbranded adalimumab-fkjp at 85% off WAC of Humira®.
Nyvepria™ (Pfizer)	Neulasta® (Amgen)	pegfilgrastim-apgf	June 10, 2020	12 months	Dec. 2020	37% off WAC of Neulasta®
Avsola® (Amgen)	Remicade® (Johnson & Johnson / Janssen)	infliximab-axxq	Dec. 6, 2019	12 months	July 2020	57% off WAC of Remicade®
Abrilada™ (Pfizer)	Humira® (AbbVie)	adalimumab-afzb	Nov. 15, 2019 (Oct. 5, 2023)	12 months	Oct. 2023	Launched high WAC version at 5% off WAC of Humira® and low WAC version at 60% off WAC of Humira®
Ziextenzo® (Sandoz)	Neulasta® (Amgen)	pegfilgrastim-bmez	Nov. 4, 2019	50 months (first submission Nov. 2015; resubmitted Feb. 2019)	Nov. 15, 2019	37% off WAC of Neulasta®

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Hadlima™ (Samsung Bioepis / Organon)	Humira® (AbbVie)	adalimum ab-bwwd	July 23, 2019	12 months	July 1, 2023	85% off WAC of Humira®
Ruxience® (Pfizer)	Rituxan® (Roche / Genentech)	rituximab-pvvr	July 23, 2019	12 months	Jan. 23, 2020	24% off WAC of Rituxan®
Kanjinti® (Amgen/ Allergan)	Herceptin® (Roche / Genentech)	trastuzum ab-anns	June 13, 2019	22.5 months (first submission July 2017; resubmitted Dec. 2018)	July 18, 2019	13% off ASP and 15% off WAC of Herceptin®
Zirabev® (Pfizer)	Avastin® (Roche / Genentech)	bevacizu mab-bvzr	June 27, 2019	12 months	Dec. 31, 2019	23% off WAC of Avastin®
Eticovo™ (Samsung Bioepis)	Enbrel® (Amgen)	etanercept -ykro	Apr. 25, 2019	23 months (first submission May 2017; resubmitted Oct. 2018)		

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Trazimera® (Pfizer)	Herceptin® (Roche / Genentech)	trastuzumab-qyyp	Mar. 11, 2019	20.5 months (first submission June 22, 2017; resubmitted Sept. 28, 2018)	Feb. 15, 2020	22% off WAC of Herceptin®
Ontruzant® (Samsung Bioepis / Merck)	Herceptin® (Roche / Genentech)	trastuzumab-dttb	Jan. 18, 2019	15 months	Apr. 15, 2020	15% off WAC of Herceptin®
Herzuma® (Celltrion / Teva)	Herceptin® (Roche / Genentech)	trastuzumab-pkrb	Dec. 14, 2018	18.5 months (first submission May 2017; resubmitted June 2018)	Mar. 16, 2020	10% off WAC of Herceptin®
Truxima® (Celltrion / Teva)	Rituxan® (Roche / Genentech)	rituximab-abbs	Nov. 28, 2018	19 months (first submission April 2017; resubmitted May 2018)	Nov. 11, 2019	10% off WAC of Rituxan®

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Udenyca® (Coherus)	Neulasta® (Amgen)	pegfilgrastim-cbqv	Nov. 2, 2018	27 months (first submission Aug. 2016; resubmitted May 2018)	Jan. 3, 2019	33% off WAC of Neulasta®
Hyrimoz® (Sandoz)	Humira® (AbbVie)	adalimumab-adaz	Oct. 30, 2018 (Interchangeable: Apr. 5, 2024)	12 months	July 1, 2023	Launched branded Hyrimoz® at 5% off WAC of Humira® and unbranded adalimumab-adaz at 81% off WAC of Humira®; private label Hyrimoz® launched at 81% off WAC of Humira®
Nivestym® (Pfizer / Hospira)	Neupogen® (Amgen)	filgrastim-aafi	July 20, 2018	10 months	Oct. 1, 2018	30.3% off WAC of Neupogen®; 20.3% off WAC of Zarxio®; and 14.1% off WAC of Granix®
Fulphila® (Mylan / Biocon)	Neulasta® (Amgen)	pegfilgrastim-jmdb	June 4, 2018	18 months (first submission Feb. 2017; resubmitted Dec. 2017)	July 26, 2018	33% off WAC of Neulasta®

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Retacrit® (Pfizer/ Hospira)	Epogen®/ Procrit® (Amgen / Johnson & Johnson)	epoetin alfa-epbx	May 15, 2018	41 months (first submission Jan. 2015; resubmitted Dec. 2016)	Nov. 12, 2018	33.5% off WAC of Epogen®; 57.1% off WAC of Procrit®
Ixifi™ (Pfizer)	Remicade® (Johnson & Johnson / Janssen)	infliximab- qbtx	Dec. 13, 2017	10 months	No U.S. launch intended	
Ogivri® (Mylan)	Herceptin® (Roche / Genentech)	trastuzum ab-dkst	Dec. 1, 2017	13 months	Dec. 2, 2019	15% off WAC of Herceptin®
Mvasi® (Amgen / Allergan)	Avastin® (Roche / Genentech)	bevacizu mab- awwb	Sept. 14, 2017	10 months	July 18, 2019	12% off ASP and 15% off WAC of Avastin®
Cyltezo® (Boehringer Ingelheim)	Humira® (AbbVie)	adalimum ab-adbm	Aug. 25, 2017 (Interchangeabl e: Oct. 15, 2021)	10 months	July 1, 2023	Launched branded Cyltezo® at 5% off WAC of Humira® and unbranded adalimumab-adbm at 81% off WAC of Humira®; private label adalimumab- adbm launched at 46% off WAC of Humira®

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Renflexis® (Samsung Bioepis / Merck)	Remicade® (Johnson & Johnson / Janssen)	infliximab-abda	Apr. 21, 2017	13 months	July 2017	35% off WAC of Remicade®
Amjevita® (Amgen)	Humira® (AbbVie)	adalimum ab-atto	Sept. 23, 2016	10 months	Jan. 31, 2023	Launched low WAC version at 55% off WAC of Humira® and high WAC version at 5% off WAC of Humira®
Erelzi® (Sandoz)	Enbrel® (Amgen)	etanercept-szsz	Aug. 30, 2016	13 months		
Inflectra® (Pfizer / Celltrion)	Remicade® (Johnson & Johnson / Janssen)	infliximab-dyyb	Apr. 5, 2016	20 months (first submission Aug. 2014; resubmitted Oct. 2015)	Nov. 2016	15% off WAC of Remicade®
Zarxio® (Sandoz)	Neupogen® (Amgen)	filgrastim-sndz	Mar. 6, 2015	10 months	Sept. 2015	15% off WAC of Neupogen®

