Medical Policy and Prior Authorization Notice

Biosimilar Utilization Management Strategy

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PURPOSE:

The purpose of this medical policy is to establish a biosimilar-first utilization management strategy for clinician administered drugs (CADs) administered under the medical benefit and reimbursed via NDC-HCPCS crosswalk at Parkland Community Health Plan (PCHP). This policy requires preferential use of FDA-approved biosimilar products over the reference product. It ensures consistent application of regulatory standards, promotes clinically appropriate utilization, and supports cost-effective care while maintaining compliance with federal and state requirements, including those applicable to Texas Medicaid Managed Care programs.

SCOPE:

This policy applies to all clinical reviews (utilization management reviews, prior authorization determinations) and claim adjudication determinations for CADs involving biosimilar products covered under the medical benefit for members in STAR and CHIP line of business.

DEFINITIONS / ACRONYMS:

Biosimilar: A biologic product approved by the FDA as highly similar to a reference product with no clinically meaningful differences in safety, purity, or potency.

NDC–HCPCS Crosswalk: Billing framework linking National Drug Codes (NDCs) to HCPCS codes for reimbursement under the medical benefit.

POLICY:

A. Coverage Requirements:

a. The biosimilar product is approved by the U.S. Food and Drug Administration (FDA) for the requested indication
b. The requested use is consistent with the FDA-approved labeling or supported by nationally recognized clinical guidelines or compendia when applicable
c. The use meets applicable medical necessity criteria
d. Coverage complies with Texas Medicaid and other applicable regulatory requirements such as but not limited to NDC-HCPCS crosswalk benefit.

B. Preferred Product Utilization

When a biosimilar product is available for a reference product:

a. PCHP may designate one or more preferred biosimilar products
b. Coverage will require the use of the preferred biosimilar product prior to approval of the reference product or other non-preferred biosimilars
c. Requests for the reference product or non-preferred biosimilars WILL require clinical justification and prior authorization

C. Prior Authorization

Biosimilar products will be subject to prior authorization based on the following factors but not limited to:

a. Clinical indication
b. Site of care
c. Prescribing provider specialty
d. Step therapy requirements
e. Compliance with preferred product policies

D. Continuity of Care

Member who is stable on a reference product or biosimilar may be eligible for continued coverage when:

a. The treatment is medically necessary, and member continues to respond well to preferred maintenance therapy
b. Transitioning to another product would present a clinical concern

Continuity of care considerations may apply during formulary changes, new biosimilar market entry, or member transitions between plans

E. Coding and Billing (Medical Benefit)

Coding and billing for biosimilars must:

a. Be billed with the appropriate HCPCS code, National Drug Code (NDC), and modifiers when applicable**.**
b. Meet PCHP coverage criteria and authorization requirements.
c. Follow Vendor Drug Program and Texas Medicaid billing guidance for biologics and biosimilars.

F. Biosimilars & HCPCS codes

This list is subject to regular updates

Name of the CAD	**Generic Name of CAD**	**HCPCS Code**
Actemra®	Tocilizumab	J3262
Tyenne	Tocilizumab-aazg	Q5135
Tofidence	Tocilizumab-bavi	Q5133
Avtozma	Tocilizumab-anoh	Q5156
Avastin ®	Bevacizumab	J9035
Zirabev	Bevacizumab-bvzr	Q5118
Mvasi	Bevacizumab-awwb	Q5107
Vegzelma	Bevacizumab-adcd	Q5129
Alymsys	Bevacizumab-maly	Q5126
Neupogen®	Filgrastim	J4112
Nivestym	Filgrastim-aafi	Q5110
Zarxio	Filgrastim-sndz	Q5101

Releuko	Filgrastim-ayow	Q5125
Remicade®	Infliximab	J1745
Inflectra	Infliximab-dyyb	Q5103
Avsola	Infliximab-axxq	Q5121
Renflexis	Infliximab-abda	Q5104
Rituxan®	Rituximab	J9312
Ruxience	Rituximab-pvvr	Q5119
Riabni	Rituximab-arrx	Q5123
Soliris®	Eculizumab	J1299
Epysqli	Eculizumab-aagh	Q5151
Bkemv	Eculizumab-aeeb	Q5152
Stelara®	Ustekinumab	J3358
Yesintek	Ustekinumab-kfce	Q5100
Otulfi	Ustekinumab-aauz	Q9999
Pyzchiva	Ustekinumab-ttwe	Q9996/Q9997
Selardi	Ustekinumab-aekn	Q9998
Steqeyma	Ustekinumab-stba	Q5099

G. Dosage and Administration

Note: Reference Medical guidelines for the most up to date information

Biologic Reference	Indication	Dosing Regimen	Maximum Dose
Actemra			
Tocilizumab (Actemra®) and biosimilars • Tocilizumab-anoh (Avtozma), • Tocilizumab-bavi (Tofidence), • Tocilizumab-aazg (Tyenne)	PJIA (polyarticular juvenile idiopathic arthritis)	**Actemra®, Avtozma, Tofidence, Tyenne:** • Weight < 30 kg: 10 mg/kg IV every 4 weeks • Weight ≥ 30 kg: 8 mg/kg IV every 4 weeks	IV: 10 mg/kg every 4 weeks
	RA (rheumatoid arthritis)	**Actemra®, Avtozma, Tofidence, Tyenne:** IV: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response	IV: 800 mg every 4 weeks
	SJIA (systemic juvenile idiopathic arthritis)	**Actemra®, Avtozma, Tofidence, Tyenne:** IV:	IV: 12 mg/kg every 2 weeks

		Weight < 30 kg: 12 mg/kg IV every 2 weeks Weight ≥ 30 kg: 8 mg/kg IV every 2 weeks	
	GCA (giant cell arteritis)	**Actemra®, Avtozma, Tofidence, Tyenne:** IV: 6 mg/kg every 4 weeks in combination with a tapering course of glucocorticoids	IV: 6 mg/kg every 4 weeks
• Tocilizumab-bavi (Tofidence), • Tocilizumab-aazg (Tyenne)	CRS (cytokine release syndrome)	Weight < 30 kg: 12 mg/kg IV per infusion Weight ≥ 30 kg: 8 mg/kg IV per infusion If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses of tocilizumab may be administered. The interval between consecutive doses should be at least 8 hours.	IV: 800 mg/infusion, up to 4 doses
Avastin®			
Avastin® and biosimilars: • Bevacizumab-maly(Alymsys), • Bevacizumab-awwb (Mvasi), • Bevacizumab-bvzr (Zirabev)	Cervical cancer, persistent, recurrent, or metastatic	Adults: IV: 15 mg/kg infusion over 90 minutes every 3 weeks in combination with a chemotherapy regimen	
Avastin® and biosimilars: • Bevacizumab-maly(Alymsys), • Bevacizumab-awwb (Mvasi), • Bevacizumab-bvzr (Zirabev)	Colorectal cancer, metastatic	Adults: IV: 5 mg/kg once every 2 weeks or 7.5 mg/kg IV once every 3 weeks over 90 minutes	
Avastin® and biosimilars: • Bevacizumab-maly(Alymsys), • Bevacizumab-awwb (Mvasi), • Bevacizumab-bvzr (Zirabev)	Glioblastoma, recurrent	Adults: IV: 10 mg/kg infusion over 90 minutes once every 2 weeks.	
Avastin® **ONLY**	Hepatocellular carcinoma,	Adults: IV**:** 15 mg/kg once every 3 weeks	

	unresectable or metastatic		
Avastin® and biosimilars: • Bevacizumab-maly(Alymsys), • Bevacizumab-awwb (Mvasi), • Bevacizumab-bvzr (Zirabev)	Non–small cell lung cancer, nonsquamous	Adults: IV: 15 mg/kg infusion over 90 minutes once every 3 weeks	
Avastin® and biosimilars: • Bevacizumab-maly(Alymsys), • Bevacizumab-awwb (Mvasi), • Bevacizumab-bvzr (Zirabev)	Ovarian (epithelial), fallopian tube, or primary peritoneal cancer	Adults: IV: 15 mg/kg infusion over 90 minutes every 3 weeks	
Avastin® and biosimilars: • Bevacizumab-maly(Alymsys), • Bevacizumab-awwb (Mvasi), • Bevacizumab-bvzr (Zirabev)	Renal cell carcinoma, metastatic	Adults: IV: 10 mg/kg infusion over 90 minutes once every 2 weeks in	
Neupogen®			
Filgrastim (Neupogen & biosimilars • Filgrastim-sndz (Zarxio) • filgrastim-aafi (Nivestym) • filgrastim-ayow (Releuko) • filgrastim-txid (Nypozi)	Chemotherapy induced neutropenia	5 mcg/kg SC or IV QD Dose may be increased in increments of 5 mcg/kg for each chemotherapy cycle, according to the duration and severity of the ANC Do not administer 24 hours before and after chemotherapy	30 mcg/kg/day [IV] or 24 mcg/kg/day [SC]
Filgrastim (Neupogen & biosimilars • filgrastim-sndz (Zarxio) • filgrastim-aafi (Nivestym) • filgrastim-ayow (Releuko) • filgrastim-txid (Nypozi)	Chronic neutropenia	Congenital: 6 mcg/kg SC BID Idiopathic or cyclic: 5 mcg/kg SC QD	30 mcg/kg/day [IV] or 24 mcg/kg/day [SC]
Filgrastim (Neupogen & biosimilars • filgrastim-sndz (Zarxio) • filgrastim-aafi (Nivestym)	Bone Marrow Transplant	10 mcg/kg IV infusion QD	10 mcg/kg/day

• filgrastim-ayow (Releuko) • filgrastim-txid (Nypozi)			
Filgrastim (Neupogen & biosimilars • filgrastim-sndz (Zarxio) • filgrastim-aafi (Nivestym) • filgrastim-ayow (Releuko) • filgrastim-txid (Nypozi)	Peripheral Blood progenitor cell	10 mcg/kg SC bolus or continuous infusion QD	10 mcg/kg/day
Remicade®			
Infliximab (Remicade®) and biosimilars: • Infliximab-axxq (Avsola) • Infliximab-dyyb (Inflectra), • Infliximab-abda (Renflexis)	Crohn's Disease (CD), Ulcerative Colitis (UC)	Initial dose: **Avsola, Inflectra, Remicade®, Renflexis:** Adults/Pediatrics*:* 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: **Avsola, Inflectra, Remicade, Renflexis**: Adults/Pediatrics: 5 mg/kg IV every 8 weeks. For CD: Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response.	CD, Adults: 10 mg/kg IV every 8 weeks UC, Adults: 5 mg/kg IV every 8 weeks
Infliximab (Remicade®) and biosimilars: • Infliximab-axxq (Avsola) • Infliximab-dyyb (Inflectra), • Infliximab-abda (Renflexis)	Psoriatic Arthritis (PsA)	Initial Dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 8 weeks	5 mg/kg every 8 weeks
Infliximab (Remicade®) and biosimilars: • Infliximab-axxq (Avsola) • Infliximab-dyyb (Inflectra), • Infliximab-abda (Renflexis)	Rheumatoid Arthritis	In conjunction with MTX Initial dose: 3 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 3 mg/kg IV every 8 weeks	10 mg/kg every 4 weeks

		Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.	
Infliximab (Remicade®) and biosimilars: • Infliximab-axxq (Avsola) • Infliximab-dyyb (Inflectra), • Infliximab-abda (Renflexis)	Ankylosing Spondylitis (AS)	Initial dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 6 weeks	5 mg/kg every 6 weeks
Rituxan®			
Rituxan® and rituximab biosimilars	Low-grade and follicular B-cell NHL	375 mg/m2 IV infusion with dosing schedule	375 mg/m2 IV infusion
Rituxan®	Pediatric patients ≥ 6 months with previously untreated mature B-cell Non-Hodgkin's lymphoma (NHL/ B-AL: b-cell acute leukemia)	375 mg/m2 IV infusion with chemotherapy combination	375 mg/m2 IV infusion
Rituxan® and rituximab biosimilars	diffuse large B-cell lymphoma (DLBCL) (a B-cell NHL)	375 mg/m2 IV infusion on Day 1 of each cycle of chemotherapy for up to 8 doses total.	375 mg/m2 IV infusion
Rituxan® and rituximab biosimilars	chronic lymphocytic leukemia(CLL) (a B-cell NHL)	375 mg/m2 IV infusion on the day prior to initiation of chemotherapy	500 mg/m2 per day
Rituxan® and rituximab biosimilars	Rheumatoid Arthritis (RA)	Two 1,000 mg IV infusions separated by 2 weeks (i.e., day 1 and day 15), followed by two 1,000 mg IV infusions every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks. Rituximab is given in combination with MTX.	Initial: 1,000 mg on day 1 and 15 Maintenance: 1,000 mg every 16 weeks
Rituxan® and rituximab biosimilars	Pediatric B-cell NHL/B-AL	375 mg/m2 IV infusions for a total of 6 doses	375 mg/m2 for total 6 doses

Rituxan® and rituximab biosimilars	granulomatosis with polyangiitis (Wegener's granulomatosis (GPA)/ microscopic polyangiitis (MPA)	Induction: • 375 mg/m2 IV once weekly for 4 weeks in combination with glucocorticoids Follow up treatment with induction treatment.	Induction: 375 mg/m2 per week Follow-up treatment: 500 mg/dose (see regimen for dosing frequency)
Rituxan® and rituximab biosimilars	Pemphigus Vulgaris (PV)	Initial and maintenance therapy: • Two 1,000 mg IV infusions separated by 2 weeks with a tapering course of glucocorticoids, then 500 mg IV at month 12 and every 6 months thereafter or based on clinical evaluation Relapse: • 1,000 mg IV once. Subsequent infusions may be administered no sooner than 16 weeks following the previous infusion.	Initial/ relapse: 1,000 mg/dose Maintenance: 500 mg/6 months
Soliris®			
Eculizumab (Soliris®), eculizumab-aeeb (Bkemv), eculizumab-aagh (Epysqli)	Paroxysmal nocturnal hemoglobinuria (PNH)	IV infusion: 600 mg weekly for the first 4 weeks, followed by 900 mg for the fifth dose 1 week later, then 900 mg every 2 weeks thereafter	900 mg/dose
Eculizumab (Soliris®), eculizumab-aeeb (Bkemv), eculizumab-aagh (Epysqli)	Atypical hemolytic uremic syndrome (aHUS)	Adults: IV infusion: 900 mg weekly for the first 4 weeks, followed by 1,200 mg for the fifth dose 1 week later, then 1,200 mg every 2 weeks thereafter* Pediatric: IV infusion based on body weight	Adult: 1,200 mg/dose Pediatric: Varies by body weight
Eculizumab (Soliris®), eculizumab-aeeb (Bkemv), eculizumab-aagh (Epysqli)	Generalized myasthenia gravis (gMG)	Adult: IV infusion: 900 mg weekly for the first 4 weeks, followed by 1,200 mg for the fifth dose 1 week later, then	Adult: 1,200 mg/dose

		1,200 mg every 2 weeks thereafter Pediatrics: IV infusion based on body weight	 Pediatric: Varies by body weight
Soliris®	Neuromyelitis Optica Spectrum Disorder (NMOSD)	IV infusion: 900 mg weekly for the first 4 weeks, followed by 1,200 mg for the fifth dose 1 week later, then 1,200 mg every 2 weeks thereafter	1,200 mg/dose
Stelara®			
Ustekinumab (Stelara®), ustekinumab-aauz (Otulfi), ustekinumab-ttwe (Pyzchiva), ustekinumab-aekn (Selarsdi), ustekinumab-stba (Steqeyma), ustekinumab-kfce (Yesintek)	Crohn's Disease (CD), Ulcerative Colitis (UC)	Weight based dosing IV at initial dose: Weight ≤ 55 kg: 260 mg Weight > 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg	90 mg every 8 weeks

G. Product Availability

Drug Name	Availability	Pharmacy Benefit
Actemra® & biosimilars i.e. • Tocilizumab-anoh (Avtozma) • Tocilizumab-aazg (Tyenne) • Tocilizumab-bavi (Tofidence)	• Single-use vial: 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL	Actemra ®-Subcutaneous (SC) route • 162 mg/0.9 mL
Avastin® & biosimilars i.e. • Bevacizumab-adcd (Vegzelma) • Avastin ® • Bevacizumab-maly(Alymsys) • Bevacizumab-awwb (Mvasi) • Bevacizumab-bvzr (Zirabev)	 • Single-use vial: 100 mg/4 mL, 400 mg/16 mL • Single-use vial: 100 mg/4 mL, 400 mg/16 mL • preservative free	N/A
Neupogen ® & biosimilars i.e. • Filgrastim-sndz (Zarxio)	• Single-dose prefilled syringes for injection:	• SC route

• Filgrastim-aafi (Nivestym) • Filgrastim-ayow (Releuko) • Filgrastim-txid (Nypozi) • Tbo-filgrastim (Granix)	300 mcg/0.5 mL, 480 mcg/0.8 mL • Single-dose vials for injection: 300 mcg/mL, 480 mcg/1.6 mL	• Filgrastim (Neupogen®) • Filgrastim-aafi (Nivestym) • Filgrastim-sndz (Zarxio) ○ 300mcg/0.5ml ○ 480mcg/0.8ml
Remicade® & biosimilars i.e • Infliximab-axxq (Avsola) • Infliximab-abda (Renflexis) • Infliximab-dyyb (Inflectra)	• Single-use vial: 100 mg/20 mL	
Rituxan® & biosimilars i.e. • Riabni • Ruxience	• Single-dose vials for IV injection: 100 mg/10 mL, 500 mg/50 mL	N/A
Soliris® & biosimilars • Bkemv • Epysqli	• Single-use vial 300 mg/30 mL	N/A
Stelara® & biosimilars i.e. • Ustekinumab-aauz (Otulfi) • Ustekinumab-ttwe (Pzychiva) • Ustekinumab-aekn (Selardi) • Ustekinumab-stba (Steqeyma) • Ustekinumab-kfce (Yestinek)	• Single-dose vial for IV infusion: 130 mg/26 mL • 1st dose ie. induction dose is IV preservative free	• SC route • Ustekinumab-ttwe (Pzychiva) • Ustekinumab-aekn (Selardi) • Ustekinumab-stba (Steqeyma) • Ustekinumab-kfce (Yestinek) ○ 45mg/0.5ml ○ 90mg/1ml

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