

5.25 TOCILIZUMAB,

Concentrate for injection 80 mg in 4 mL

Concentrate for injection 200 mg in 10 mL

Concentrate for injection 400 mg in 20 mL

Injection 162 mg in 0.9 mL single use pre-filled pen

Injection 162 mg in 0.9 mL single use pre-filled syringe,

Avtozma[®],

Celltrion Healthcare Australia Pty Ltd

1 Purpose of Submission

- 1.1 The Category 3 submission requested General Schedule Authority Required and Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new tocilizumab biosimilar on a cost-minimisation basis and under the same conditions as its reference biologic (Actemra[®]), for the same indications.

2 Background

- 2.1 Avtozma was TGA registered on 30 May 2025 and determined to be a biosimilar medicine to the reference brand, Actemra.
- 2.2 Avtozma is the first biosimilar brand for tocilizumab to request PBS listing and has not previously been considered by the PBAC.

3 Requested listing

- 3.1 The submission requested listing Avtozma under the same circumstances as Actemra for the same indications. The submission also requested that the listings for Avtozma be consistent with the biosimilar uptake driver policy.
- 3.2 At its March 2022 meeting, the PBAC recommended changes to the authority requirements for the following biological and immunomodulator medicines listed on the PBS for the treatment of rheumatoid arthritis – adalimumab, abatacept, baricitinib, certolizumab, etanercept, golimumab, infliximab, tocilizumab and tofacitinib. These changes were implemented on 1 November 2023¹ and included the following:

¹ [Pharmaceutical Benefits Scheme \(PBS\) | 1 November 2023 Changes to the PBS Listings of Medicines for Severe Active Rheumatoid Arthritis](#)

- The PBS listings of biosimilar medicines for initial therapy will change from Authority Required (Written) to Authority Required (Telephone/Immediate online assessment).
- The PBS listings of biosimilar medicines for first continuing therapy will change to Authority Required (Streamlined).
- The PBS listings for subsequent continuing therapy for the originator (or ‘reference’) brands of the biological and immunomodulator medicines listed above will also change from Authority Required (Written) to Authority Required (Streamlined).

3.3 There are also different rules for severe active juvenile idiopathic arthritis. Biosimilars (for e.g. etanercept, adalimumab) for this indication should have the following authority types:

- Paediatric listings (< 18 years) – Initial treatment is Authority Required (Telephone/Online); Continuing treatment is Authority Required (Streamlined).
- Adult listings (> 18 years) – Initial treatment is Authority Required (Written); First continuing treatment is Authority Required (Written); and Subsequent continuing treatment is Authority Required (Streamlined).

3.4 Table 1 presents the key components of the current PBS listings for Actemra and the requested listings in the submission for Avtozma. During the evaluation, suggested additions to the authority levels based on paragraphs 3.2 and 3.3 were proposed in italics and deletions in strikethrough. The application of the biosimilar uptake driver (i.e. lowering the authority level) does not apply where the authority level for Avtozma is the same as the authority level for Actemra.

Table 1: Current PBS listing of Actemra versus requested listing for Avtozma:

Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma
Active giant cell arthritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11744D	Initial treatment	Authority Required (Written)	Authority Required (Written)
		11722Y	Continuing treatment	Authority Required (Telephone/Online)	Authority Required (STREAMLINED)
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11743C	Initial treatment	Authority Required (Written)	Authority Required (Written)
		11721X	Continuing treatment	Authority Required (Telephone/Online)	Authority Required (STREAMLINED)
Systemic juvenile idiopathic arthritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12083Y	Initial 1 (new pt >30kg) Initial 2 (retrial or recommencement after break <12m for pt >30kg)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma	
			Initial 3 ((retrial or recommencement after break >12m for pt >30kg)			
		12085C	Initial 1 (new pt <30kg)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)	
			Initial 2 (retrial or recommencement after break <12m for pt <30kg)			
			Initial 3 ((retrial or recommencement after break >12m for pt <30kg)			
		12094M	Balance of supply for initial 1 (new)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)	
			Balance of supply for initial 2 (retrial or recommencement after break <12m)			
			Balance of supply for initial 3 (retrial or recommencement after break >12m)			
		12084B	Continuing (pt >30kg)	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)	
		12090H	Continuing (pt <30kg)	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)	
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12095N	Initial 1 (new pt at least 30kg)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)	
						Initial 2 (retrial or recommencement after break <12m for pt at least 30kg)
						Initial 3 ((retrial or recommencement after break >12m for pt at least 30kg)

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma	
		12105D	Initial 1 (new pt <30kg)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)	
			Initial 2 (retrial or recommencement after break <12m for pt <30kg)			
			Initial 3 (retrial or recommencement after break >12m for pt <30kg)			
		12102Y	Balance of supply for initial 1 (new)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)	
			Balance of supply for initial 2 (retrial or recommencement after break <12m)			
			Balance of supply for initial 3 (retrial or recommencement after break >12m)			
		12099T	Continuing treatment (pt at least 30kg)	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)	
		12086D	Continuing treatment (pt <30kg)	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)	
		tocilizumab 80 mg/4 mL injection, 4 mL vial	1419Q 1476Q	Initial 1 (new)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
				Initial 2 (retrial or recommencement after break <12m)		
				Initial 3 (retrial or recommencement after break >12m)		
				Balance of supply		
13304F 13315T	Continuing treatment		Authority Required (STREAMLINED)	Authority Required (STREAMLINED)		
	1423X	Initial 1 (new pt)				

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma		
	tocilizumab 200 mg/10 mL injection, 10 mL vial		Initial 2 (retrial or recommencement after break <12m)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)		
			Initial 3 (retrial or recommencement after break >12m)				
			Balance of supply				
		1481Y	Initial 1 (new pt)			Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
			Initial 2 (retrial or recommencement after break <12m)				
			Initial 3 (retrial or recommencement after break >12m)				
	Balance of supply						
	13329M 13330N	Continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)			
		tocilizumab 400 mg/20 mL injection, 20 mL vial	1464C 1482B	Initial 1 (new pt)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)	
	Initial 2 (retrial or recommencement after break <12m)						
	Initial 3 (retrial or recommencement after break >12m)						
	Balance of supply						
13299Y 13323F	Continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)				
Severe active rheumatoid arthritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11565Q	Initial 1 (new)	Authority Required (Written)	Authority Required (Telephone/Online)		
			Initial 2 (change or recommencement after break in biologics <24m)				
			Initial 3 (change or recommencement after break in biologics >24m)				

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma
			Initial - Balance of supply	Authority Required (Telephone/Online)	
		12792G	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Authority Required (Telephone/Online)
		11567T	First continuing treatment	Authority Required (Written)	Authority Required (Telephone/Online)
			First continuing treatment – balance of supply	Authority Required (Telephone/Online)	Authority Required (STREAMLINED)
		13720D	Subsequent continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	10951J	Initial 1 (new)	Authority Required (Written)	Authority Required (Telephone/Online)
			Initial 2 (change or recommencement after break in biologics <24m)		
			Initial 3 (change or recommencement after break in biologics >24m)		
			Initial - Balance of supply		
		12806B	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Authority Required (Telephone/Online)
		10954M	First continuing treatment	Authority Required (Written)	Authority Required (Telephone/Online)
			First continuing treatment – balance of supply	Authority Required (Telephone/Online)	Authority Required (STREAMLINED)
		13685G	Subsequent continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)
	tocilizumab 80 mg/4 mL injection, 4 mL vial	9657G 9671B	Initial 1 (new)	Authority Required (Written)	Authority Required (Telephone/Online)
			Initial 2 (change or recommencement after break in biologics <24m)		

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma
			Initial 3 (change or recommencement after break in biologics >24m)		
			Initial - Balance of supply	Authority Required (Telephone/Online)	
		9657G 9671B	First continuing treatment	Authority Required (Written)	<i>Authority Required (STREAMLINED)</i>
		<i>NEW item codes for biosimilar</i>	First continuing treatment – balance of supply	Authority Required (Telephone/Online)	
		12775J 12787B	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Authority Required (Telephone/Online)
		13690M 13696W	Subsequent continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)
	tocilizumab 200 mg/10 mL injection, 10 mL vial	9658H 9672C	Initial 1 (new)	Authority Required (Written)	Authority Required (Telephone/Online)
			Initial 2 (change or recommencement after break in biologics <24m)		
			Initial 3 (change or recommencement after break in biologics >24m)		
			Initial - Balance of supply		
		9658H 9672C	First continuing treatment	Authority Required (Written)	<i>Authority Required (STREAMLINED)</i>
			<i>NEW item codes for biosimilar</i>	First continuing treatment – balance of supply	
		12766X 12791F	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Authority Required (Telephone/Online)
		13684F 13716X	Subsequent continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)
	9659J	Initial 1 (new)			

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma
	tocilizumab 400 mg/20 mL injection, 20 mL vial	9673D	Initial 2 (change or recommencement after break in biologics <24m)	Authority Required (Written)	Authority Required (Telephone/Online)
			Initial 3 (change or recommencement after break in biologics >24m)		
			Initial - Balance of supply		
		9659J 9673D	First continuing treatment	Authority Required (Written)	<i>Authority Required (STREAMLINED)</i>
		<i>NEW item codes for biosimilar</i>	First continuing treatment – balance of supply	Authority Required (Telephone/Online)	
12763R 12805Y	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Authority Required (Telephone/Online)		
13715W 13731Q	Subsequent continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)		
Severe active juvenile idiopathic arthritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11725D	Initial 1 (new pt)	Authority Required (Written)	Authority Required (Telephone/Online) <i>Authority Required (Written)</i>
			Initial 2 (change or recommencement following break in biologics <24m)		
			Initial 3 (recommencement following break in biologics >24m)		
			Initial - Balance of supply		
		11734N <i>(Paediatric)</i>	Initial (new pt)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
			Initial 2 (change or recommencement following break in biologics <12m)		
			Initial 3 (recommencement following break in biologics >12m)		

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma
			Initial - Balance of supply		
		12761P	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Authority Required (Telephone/Online) Authority Required (Written)
		12767Y (Paediatric)	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Authority Required (Telephone/Online)
		11750K	Continuing treatment	Authority Required (Written)	Authority Required (Telephone/Online) Authority Required (Written)
			Continuing treatment - Balance of supply	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
		11742B (30kg or over) 13306H (<30kg)	Continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11741Y	Initial 1 (new)	Authority Required (Written)	Authority Required (Telephone/Online) Authority Required (Written)
			Initial 2 (change or recommencement after break in biologics <24m)		
			Initial 3 (change or recommencement after break in biologics >24m)		
			Initial - Balance of supply	Authority Required (Telephone)	Authority Required (Telephone)
		11748H (Paediatric)	Initial 1 (new)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
	Initial 2 (change or recommencement after break in biologics <12m)				
	Initial 3 (change or recommencement after break in biologics >12m)				
	Initial - Balance of supply				

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma
		12762Q	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Authority Required (Telephone/Online) Authority Required (Written)
		12768B (Paediatric)	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Authority Required (Telephone/Online)
		11730J	Continuing treatment	Authority Required (Written)	Authority Required (Telephone/Online) Authority Required (Written)
			Continuing treatment – Balance of supply	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
		11720W (30kg or over)	Continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)
	13301C (<30kg)				
	tocilizumab 80 mg/4 mL injection, 4 mL vial	10073E 10081N	Initial 1 (new)	Authority Required (Written)	Authority Required (Telephone/Online) Authority Required (Written)
			Initial 2 (change or recommencement after break in biologics <24m)		
			Initial 3 (change or recommencement after break in biologics >24m)		
			Initial - Balance of supply	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
			Continuing treatment	Authority Required (Written)	Authority Required (Written)
			Continuing treatment – Balance of supply	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
		10068X (Paediatric) 10077J (Paediatric)	Initial 1 (new)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
Initial 2 (change or recommencement after break in biologics <12m)					

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma
			Initial 3 (change or recommencement after break in biologics >12m)		
			Initial - Balance of supply		
		12794J (Adult and paediatric) 12811G (Adult and paediatric)	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Adult – Authority Required (Written) Paediatric – Authority Required (Telephone/Online)
		13311N 13324G	Continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)
	tocilizumab 200 mg/10 mL injection, 10 mL vial	10056G (Paediatric) 10079L (Paediatric)	Initial 1 (new)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
			Initial 2 (change or recommencement after break in biologics <12m)		
			Initial 3 (change or recommencement after break in biologics >12m)		
			Initial - Balance of supply		
		10058J 10071C	Initial 1 (new)	Authority Required (Written)	Authority Required (Telephone/Online) Authority Required (Written)
			Initial 2 (change or recommencement after break in biologics <24m)		
			Initial 3 (change or recommencement after break in biologics >24m)		
			Initial - Balance of supply	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
			Continuing treatment	Authority Required (Written)	Authority Required (Written)
			Continuing treatment – Balance of supply	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)

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Indication	Form	PBS item code	Treatment phase	Current restriction level – Actemra	Requested restriction level – Avtozma
		12795K (Adult and paediatric) 12796L (Adult and paediatric)	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Adult – Authority Required (Written) Paediatric – Authority Required (Telephone/Online)
		13305G 13312P	Continuing treatment	Authority Required (STREAMLINED)	Authority Required (STREAMLINED)
	tocilizumab 400 mg/20 mL injection, 20 mL vial	10060L (Paediatric) 10064Q (Paediatric)	Initial 1 (new)	Authority Required (Telephone/Online)	Authority Required (Telephone/Online)
			Initial 2 (change or recommencement after break in biologics <12m)		
			Initial 3 (change or recommencement after break in biologics >12m)		
			Initial - Balance of supply		
		10072D 10078K	Initial 1 (new)	Authority Required (Written)	Authority Required (Telephone/Online) Authority Required (Telephone/Online) Authority Required (Written)
			Initial 2 (change or recommencement after break in biologics <24m)		
			Initial 3 (change or recommencement after break in biologics >24m)		
			Initial - Balance of supply		
			Continuing treatment		
			Continuing treatment – Balance of supply		
		12802T (Adult and paediatric) 12810F (Adult and paediatric)	Initial 4 (temporary listing after critical shortage)	Authority Required (Written)	Adult – Authority Required (Written) Paediatric – Authority Required (Telephone/Online)
			13338B 13339C	Continuing treatment	Authority Required (STREAMLINED)

Source: Compiled by the PBAC Secretariat during evaluation.

3.5 As the submission requested the same restrictions as the reference brand, the full restrictions have not been reproduced here.

3.6 Add new item codes or new brand to existing items, where relevant:

Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
Active giant cell arteritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11721X	1	4	6	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11722Y	1	4	6	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11743C	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11744D	1	4	5	Actemra ^a Avtozma ^a
Severe active juvenile idiopathic arthritis	tocilizumab 200 mg/10 mL injection, 10 mL vial	10056G	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	10058J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	10060L	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	10064Q	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	10068X	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	10071C	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	10072D	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	10073E	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	10077J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	10078K	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	10079L	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	10081N	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11720W	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11725D	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11730J	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11734N	1	4	1	Actemra ^a Avtozma ^a
tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11741Y	1	4	3	Actemra ^a Avtozma ^a	
tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11742B	1	4	2	Actemra ^a Avtozma ^a	

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Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11748H	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11750K	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12761P	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12762Q	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12767Y	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12768B	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	12794J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	12795K	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	12796L	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	12802T	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	12810F	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	12811G	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	13301C	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13305G	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	13306H	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13311N	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13312P	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13324G	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13338B	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13339C	1	1	5	Actemra ^a Avtozma ^a
Systemic juvenile idiopathic arthritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12083Y	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12084B	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12085C	1	4	1	Actemra ^a Avtozma ^a

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Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12086D	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12090H	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12094M	1	4	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12095N	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12099T	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12102Y	1	4	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12105D	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13299Y	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13304F	4	4	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13315T	4	4	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13323F	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13329M	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13330N	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	1419Q	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	1423X	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	1464C	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	1476Q	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	1481Y	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	1482B	1	1	0	Actemra ^a Avtozma ^a
Severe active rheumatoid arthritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	10951J	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	10954M	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11565Q	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11567T	1	4	5	Actemra ^a Avtozma ^a

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Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
	tocilizumab 400 mg/20 mL injection, 20 mL vial	12763R	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	12766X	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	12775J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	12787B	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	12791F	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12792G	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	12805Y	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12806B	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13684F	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	13685G	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13690M	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13696W	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13715W	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13716X	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	13720D	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13731Q	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	9657G	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	9658H	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	9659J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	9671B	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	9672C	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	9673D	1	1	0	Actemra ^a Avtozma ^a

Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
Prescribing rule	33164	Administrative Advice:* Biosimilar prescribing policy <i>Prescribing of the biosimilar brand where available is encouraged for treatment naive patients.</i>				
	29791	Administrative Advice:* <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).</i>				

Source: Compiled by the PBAC Secretariat during evaluation.

* The Administrative Advice will apply to the initial treatment phase item codes for the originator and biosimilar brands

- 3.7 The Secretariat has added administrative advice reflecting the biosimilar uptake policy (i.e. encouraging uptake of biosimilar prescribing for treatment-naïve patients).
- 3.8 The submission requested that Avtozma be considered equivalent ('a' flagged) to Actemra for the purpose of substitution.
- 3.9 Avtozma will have the same drug, form and manner of administration as the existing tocilizumab brand and, as such, will be required to have the same approved ex-manufacturer price (AEMP) as the existing tocilizumab brand as per Section 85C of the *National Health Act 1953*.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item.

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

Clinical evidence

- 4.3 As per the Product Information, the TGA has confirmed that "Avtozma is a biosimilar medicine to Actemra. The comparability of Avtozma with Actemra has been demonstrated with regard to physiochemical characteristics and efficacy and safety outcomes. The evidence for comparability supports the use of Avtozma for the listed indications."
- 4.4 The submission stated that the equi-effective doses are: 1 mg Avtozma = 1 mg Actemra.

Estimated PBS usage and financial implications

- 4.5 Listing of biosimilar brands does not change overall utilisation of the drug.

- 4.6 The submission stated that Avtozma is expected to substitute for the other brand of tocilizumab (Actemra) and, as such, there is expected to be nil financial impact to the PBS/RPBS with the proposed listing.

5 PBAC Outcome

- 5.1 The PBAC recommended the General Schedule Authority Required and Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new tocilizumab biosimilar on a cost-minimisation basis and under the same conditions as its reference biologic (Actemra[®]), for the same indications.
- 5.2 The PBAC advised the equi-effective doses to be 1 mg Avtozma = 1 mg Actemra.
- 5.3 The PBAC noted that the TGA has confirmed that Avtozma is a biosimilar medicine to Actemra.
- 5.4 The PBAC advised that the authority levels for the requested restrictions as presented in Table 1 are clinically appropriate for Avtozma (which includes lowering the authority level in some cases as per the biosimilar uptake policy). The PBAC also considered that adding administrative advice reflecting the biosimilar uptake policy (i.e. encouraging uptake of biosimilar prescribing for treatment-naïve patients) is clinically appropriate for Avtozma. The PBAC noted that some streamlined listings may need updates to their maximum quantities and repeats so prescribers do not need to seek approvals for the correct amounts (refer to Appendix B).
- 5.5 For active giant cell arteritis, the PBAC noted that the continuing restrictions include a criterion specifying 52 weeks for initial and continuing treatment combined. With a streamlined authority for continuing treatment, the PBAC noted that Services Australia would be unable to validate that the prescriber is keeping to 52 weeks which may result in leakage. The PBAC considered it would still be clinically appropriate to apply the biosimilar uptake driver policy in this case provided there is a review of these item codes (11722Y/11721X) 2 years after the date of listing to monitor for treatment beyond 52 weeks.
- 5.6 For severe active juvenile idiopathic arthritis, the PBAC noted that the continuing restrictions for the adult >18 years (PBS item codes: 11750K, 11730J, 10073E, 10081N, 10058J, 10071C, 10072D 10078K) would need to be split into an Authority Required (written) first continuing and an Authority required (streamlined) subsequent continuing, similar to current PBS listed drugs (i.e., etanercept and adalimumab) for this indication (refer to Appendix A). The PBAC noted that this is consistent with the biosimilar uptake driver.
- 5.7 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, Avtozma and Actemra should be considered equivalent for the purpose of substitution at the pharmacy level (i.e., 'a' flagged in the Schedule of Pharmaceutical Benefits).

- 5.8 The PBAC considered that the listing of Avtozma would not result in a net cost to the PBS as it would likely substitute for Actemra and not increase the overall market utilisation.
- 5.9 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Avtozma is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over Actemra, and is not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 5.10 The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

- 6.1 As the submission requested the same restrictions as the reference brand, the full restrictions have not been reproduced here.
- 6.2 Add new item codes or new brand to existing items, where relevant:

Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
Active giant cell arteritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11721X	1	4	6	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11722Y	1	4	6	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11743C	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11744D	1	4	5	Actemra ^a Avtozma ^a
Severe active juvenile idiopathic arthritis	tocilizumab 200 mg/10 mL injection, 10 mL vial	10056G	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	10058J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	10060L	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	10064Q	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	10068X	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	10071C	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	10072D	1	1	0	Actemra ^a Avtozma ^a

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Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
	tocilizumab 80 mg/4 mL injection, 4 mL vial	10073E	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	10077J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	10078K	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	10079L	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	10081N	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11720W	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11725D	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11730J	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11734N	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11741Y	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11742B	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11748H	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11750K	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12761P	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12762Q	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12767Y	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12768B	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	12794J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	12795K	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	12796L	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	12802T	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	12810F	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	12811G	1	1	0	Actemra ^a Avtozma ^a

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Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	13301C	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13305G	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	13306H	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13311N	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13312P	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13324G	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13338B	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13339C	1	1	5	Actemra ^a Avtozma ^a
Systemic juvenile idiopathic arthritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12083Y	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12084B	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12085C	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12086D	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12090H	1	4	2	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12094M	1	4	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12095N	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12099T	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12102Y	1	4	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12105D	1	4	1	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13299Y	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13304F	4	4	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13315T	4	4	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13323F	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13329M	2	2	5	Actemra ^a Avtozma ^a

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Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13330N	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	1419Q	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	1423X	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	1464C	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	1476Q	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	1481Y	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	1482B	1	1	0	Actemra ^a Avtozma ^a
Severe active rheumatoid arthritis	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	10951J	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	10954M	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11565Q	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11567T	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	12763R	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	12766X	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	12775J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	12787B	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	12791F	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	12792G	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	12805Y	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	12806B	1	4	3	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13684F	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	13685G	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13690M	2	2	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	13696W	2	2	5	Actemra ^a Avtozma ^a

Restriction	MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13715W	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	13716X	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	13720D	1	4	5	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	13731Q	1	1	5	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	9657G	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	9658H	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	9659J	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 80 mg/4 mL injection, 4 mL vial	9671B	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 200 mg/10 mL injection, 10 mL vial	9672C	1	1	0	Actemra ^a Avtozma ^a
	tocilizumab 400 mg/20 mL injection, 20 mL vial	9673D	1	1	0	Actemra ^a Avtozma ^a
Prescribing rule	33164	Administrative Advice:* Biosimilar prescribing policy Prescribing of the biosimilar brand where available is encouraged for treatment naive patients.				
	29791	Administrative Advice:* Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).				

* The Administrative Advice will apply to the initial treatment phase item codes for the originator and biosimilar brands

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

Appendix:

A. Severe active juvenile idiopathic arthritis – Continuing Restrictions

For severe active juvenile idiopathic arthritis, the PBAC noted that the continuing restrictions for the adult >18 years (PBS item codes: 11750K, 11730J, 10073E, 10081N, 10058J, 10071C, 10072D 10078K) would need to be split into an Authority Required (written) first continuing

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and an Authority required (streamlined) subsequent continuing, similar to current PBS listed drugs (i.e., etanercept and adalimumab) for this indication.

	Current PBS listings		Recommended PBS listings	
	<i>Originator Actemra</i>			
		Continuing	First Continuing & Subsequent Continuing <i>Originator Actemra</i> <i>Biosimilar Avtozma</i>	Subsequent Continuing <i>Biosimilar Avtozma</i>
tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	11750K	Authority Required (Written) <i>Max qty 4</i> <i>Max rpts 5</i>	Authority Required (Written) 11750K	Authority Required (Streamlined) <i>New item code</i> <i>Max qty 4 Max rpts 5</i>
tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	11730J	Authority Required (Written) <i>Max qty 4</i> <i>Max rpts 5</i>	Authority Required (Written) 11730J	Authority Required (Streamlined) <i>New item code</i> <i>Max qty 4 Max rpts 5</i>
tocilizumab 80 mg/4 mL injection, 4 mL vial	10073E 10081N	Authority Required (Written) <i>Max qty 1</i> <i>Max rpts 0</i>	Authority Required (Written) 10073E 10081N	Authority Required (Streamlined) <i>New Public/Private item codes</i> <i>Max qty 4 Max rpts 5</i>
tocilizumab 200 mg/10 mL injection, 10 mL vial	10058J 10071C	Authority Required (Written) <i>Max qty 1</i> <i>Max rpts 0</i>	Authority Required (Written) 10058J 10071C	Authority Required (Streamlined) <i>New Public/Private item codes</i> <i>Max qty 4 Max rpts 5</i>
tocilizumab 400 mg/20 mL injection, 20 mL vial	10072D 10078K	Authority Required (Written) <i>Max qty 1</i> <i>Max rpts 0</i>	Authority Required (Written) 10072D 10078K	Authority Required (Streamlined) <i>New Public/Private item codes</i> <i>Max qty 2 Max rpts 5</i>

B. Severe active rheumatoid arthritis – Max Quantities and Repeats

Current Written PBS listings for Originator (Actemra) – add biosimilar Avtozma brand

Initial 1,2,3, First continuing, First Continuing – balance of supply

(Max Qty 1; Max Rpt 0, Written listings only)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
tocilizumab 80 mg/4 mL injection, 4 mL vial	9657G	1	1	0	Actemra ^a Avtozma ^a
tocilizumab 200 mg/10 mL injection, 10 mL vial	9658H	1	1	0	Actemra ^a Avtozma ^a
tocilizumab 400 mg/20 mL injection, 20 mL vial	9659J	1	1	0	Actemra ^a Avtozma ^a
tocilizumab 80 mg/4 mL injection, 4 mL vial	9671B	1	1	0	Actemra ^a Avtozma ^a
tocilizumab 200 mg/10 mL injection, 10 mL vial	9672C	1	1	0	Actemra ^a Avtozma ^a
tocilizumab 400 mg/20 mL injection, 20 mL vial	9673D	1	1	0	Actemra ^a Avtozma ^a

Recommended listings for Biosimilar (Avtozma)

First continuing treatment and First continuing treatment – balance of supply

(Max Quantities and Max Repeats to align with the current Subsequent Continuing listings (Streamlined) for Originator (Actemra))

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
tocilizumab 80 mg/4 mL injection, 4 mL vial	New Public	2	2	5	Avtozma
tocilizumab 200 mg/10 mL injection, 10 mL vial	New Public	1	1	5	Avtozma
tocilizumab 400 mg/20 mL injection, 20 mL vial	New Public	1	1	5	Avtozma
tocilizumab 80 mg/4 mL injection, 4 mL vial	New Private	2	2	5	Avtozma
tocilizumab 200 mg/10 mL injection, 10 mL vial	New Private	1	1	5	Avtozma
tocilizumab 400 mg/20 mL injection, 20 mL vial	New Private	1	1	5	Avtozma
tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes	New	1	4	5	Avtozma
tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices	New	1	4	5	Avtozma

** New item codes for Avtozma (biosimilar); no 'a' flag as substitution cannot occur between the streamlined and written authority level item codes to get Actemra on streamline for this treatment phase; PFS & PFP will also need new item codes for first continuing treatment phase.*

Add biosimilar (Avtozma) to current Subsequent Continuing listings (Streamlined) for Originator (Actemra)

(Max Quantities and Max Repeats to align with the current Subsequent Continuing listings (Streamlined) for Originator (Actemra))

tocilizumab 200 mg/10 mL injection, 10 mL vial	13684F	1	1	5	Actemra ^a Avtozma ^a
tocilizumab 80 mg/4 mL injection, 4 mL vial	13690M	2	2	5	Actemra ^a Avtozma ^a
tocilizumab 80 mg/4 mL injection, 4 mL vial	13696W	2	2	5	Actemra ^a Avtozma ^a
tocilizumab 400 mg/20 mL injection, 20 mL vial	13715W	1	1	5	Actemra ^a Avtozma ^a
tocilizumab 200 mg/10 mL injection, 10 mL vial	13716X	1	1	5	Actemra ^a Avtozma ^a
tocilizumab 400 mg/20 mL injection, 20 mL vial	13731Q	1	1	5	Actemra ^a Avtozma ^a

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

The sponsor had no comment.