



ND

Medical Policies



Policy Number: ME-I-31
Policy Name: Tocilizumab
Policy Type: Medical

Effective Date: 10-01-2025
Last Review Date: 09-04-2025

Policy Subtype: Injections
Review Date: 09-01-2026

Description

Tocilizumab (Actemra®), tocilizumab-bavi (Tofidence™) and tocilizumab-aazg (Tyenne®) are recombinant humanized anti-human interleukin 6 (IL-6) receptor monoclonal antibodies that work to inhibit IL-6 mediated actions at soluble and membrane bound IL-6 receptors. Inhibiting the signaling pathway can lead to inhibition of activated T- and B-cells, lymphocytes, monocytes, and fibroblasts.

Policy Application

All claims submitted for this policy will be processed according to the policy effective date and associated revision effective dates in effect on the date of service.

Criteria

Coverage is subject to the specific terms of the member's benefit plan.

Tocilizumab IV injection may be considered medically necessary when an individual meets the criteria for **ANY ONE** of the following:

- **Cytokine Release Syndrome (CRS):**
 - The individual must have grade 3 or 4 Cytokine Release Syndrome resulting in hypotension and/or hypoxia; **or**
- **Giant Cell Arteritis (GCA):**
 - The individual is 18 years of age and older for the treatment of GCA; **and**
 - The individual must meet one of the following conditions:
 - A minimum 7-day trial of high dose glucocorticoids; **or**

- At high risk of glucocorticoid side effects or complications, including osteoporosis, diabetes, hypertension, or glaucoma; **or**
- **Juvenile Idiopathic Arthritis, Polyarticular (PJIA):**
 - The individual is two (2) years of age and older with active PJIA; **and**
 - The individual has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs; **and**
 - clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review); **or**
- **Juvenile Idiopathic Arthritis, Systemic (SJIA):**
 - For individuals two (2) years of age and older with active SJIA; **and**
 - clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review); **or**
- **Rheumatoid Arthritis (RA):**
 - The individual is 18 years of age and older with moderately to severely active RA; **and**
 - The individual must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts;
 - TNF Inhibitor; **and**
 - T-cell Co-stimulation Blocker; **and**
 - Janus Kinase (JAK) Inhibitor; **and**
 - clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review); **or**
- **Other**
 - The individual has another FDA labeled indication for tocilizumab; **or**
 - The individual has another indication supported in compendia for the requested agent and route of administration with a current category 1, 2A, or 2B recommendation.

The use of tocilizumab for all other indications not listed in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness cannot be established by the available published peer-reviewed literature.

Procedure Code

J3262	Q5133	Q5135	Q5156
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NOTE: In addition to the above criteria, product specific dosage and/or frequency limits may apply in accordance with the United States Food and Drug Administration (U.S. FDA)-approved product prescribing information, national compendia, Centers for Medicare and Medicaid Services (CMS) and other peer reviewed resources or evidence-based guidelines.

Professional Statements and Societal Positions Guidelines

TNF Inhibitors

- Adalimumab
- Certolizumab
- Etanercept
- Golimumab
- Infliximab

Interleukin (IL) - 17 Inhibitors

- Ixekizumab
- Secukinumab

Interleukin (IL)-17A and IL-17F inhibitor

- Bimekizumab

T-cell Costimulation Blocker

- abatacept

Janus Kinase (JAK) Inhibitor

- baricitinib
- tofacitinib
- upadacitinib

Diagnosis Codes

Covered Diagnosis Codes for Procedure Code J3262, Q5156

D89.831	D89.832	D89.833	D89.834	D89.835	D89.839	G92.01
G92.02	G92.03	G92.04	G92.05	M05.00	M05.011	M05.012
M05.019	M05.021	M05.022	M05.029	M05.031	M05.032	M05.039
M05.041	M05.042	M05.049	M05.051	M05.052	M05.059	M05.061
M05.062	M05.069	M05.071	M05.072	M05.079	M05.09	M05.111
M05.112	M05.121	M05.122	M05.131	M05.132	M05.141	M05.142
M05.151	M05.152	M05.161	M05.162	M05.171	M05.172	M05.19
M05.20	M05.211	M05.212	M05.219	M05.221	M05.222	M05.229
M05.231	M05.232	M05.239	M05.241	M05.242	M05.249	M05.251
M05.252	M05.259	M05.261	M05.262	M05.269	M05.271	M05.272
M05.279	M05.29	M05.30	M05.311	M05.312	M05.319	M05.321
M05.322	M05.329	M05.331	M05.332	M05.339	M05.341	M05.342
M05.349	M05.351	M05.352	M05.359	M05.361	M05.362	M05.369
M05.371	M05.372	M05.379	M05.39	M05.40	M05.411	M05.412

M05.419	M05.421	M05.422	M05.429	M05.431	M05.432	M05.439
M05.441	M05.442	M05.449	M05.451	M05.452	M05.459	M05.461
M05.462	M05.469	M05.471	M05.472	M05.479	M05.49	M05.50
M05.511	M05.512	M05.519	M05.521	M05.522	M05.529	M05.531
M05.532	M05.539	M05.541	M05.542	M05.549	M05.551	M05.552
M05.559	M05.561	M05.562	M05.569	M05.571	M05.572	M05.579
M05.59	M05.60	M05.611	M05.612	M05.619	M05.621	M05.622
M05.629	M05.631	M05.632	M05.639	M05.641	M05.642	M05.649
M05.651	M05.652	M05.659	M05.661	M05.662	M05.669	M05.671
M05.672	M05.679	M05.69	M05.7A	M05.70	M05.711	M05.712
M05.719	M05.721	M05.722	M05.729	M05.731	M05.732	M05.739
M05.741	M05.742	M05.749	M05.751	M05.752	M05.759	M05.761
M05.762	M05.769	M05.771	M05.772	M05.779	M05.79	M05.8A
M05.80	M05.811	M05.812	M05.819	M05.821	M05.822	M05.829
M05.831	M05.832	M05.839	M05.841	M05.842	M05.849	M05.851
M05.852	M05.859	M05.861	M05.862	M05.869	M05.871	M05.872
M05.879	M05.89	M05.9	M06.0A	M06.00	M06.011	M06.012
M06.019	M06.021	M06.022	M06.029	M06.031	M06.032	M06.039
M06.041	M06.042	M06.049	M06.051	M06.052	M06.059	M06.061
M06.062	M06.069	M06.071	M06.072	M06.079	M06.08	M06.09
M06.1	M06.20	M06.211	M06.212	M06.219	M06.221	M06.222
M06.229	M06.231	M06.232	M06.239	M06.241	M06.242	M06.249
M06.251	M06.252	M06.259	M06.261	M06.262	M06.269	M06.271
M06.272	M06.279	M06.28	M06.29	M06.30	M06.311	M06.312

M06.319	M06.321	M06.322	M06.329	M06.331	M06.332	M06.339
M06.341	M06.342	M06.349	M06.351	M06.352	M06.359	M06.361
M06.362	M06.369	M06.371	M06.372	M06.379	M06.38	M06.39
M06.4	M06.8A	M06.80	M06.811	M06.812	M06.819	M06.821
M06.822	M06.829	M06.831	M06.832	M06.839	M06.841	M06.842
M06.849	M06.851	M06.852	M06.859	M06.861	M06.862	M06.869
M06.871	M06.872	M06.879	M06.88	M06.89	M06.9	M08.0A
M08.00	M08.011	M08.012	M08.019	M08.021	M08.022	M08.029
M08.031	M08.032	M08.039	M08.041	M08.042	M08.049	M08.051
M08.052	M08.059	M08.061	M08.062	M08.069	M08.071	M08.072
M08.079	M08.08	M08.09	M08.2A	M08.20	M08.211	M08.212
M08.219	M08.221	M08.222	M08.229	M08.231	M08.232	M08.239
M08.241	M08.242	M08.249	M08.251	M08.252	M08.259	M08.261
M08.262	M08.269	M08.271	M08.272	M08.279	M08.28	M08.29
M08.3	M08.4A	M08.40	M08.411	M08.412	M08.419	M08.421
M08.422	M08.429	M08.431	M08.432	M08.439	M08.441	M08.442
M08.449	M08.451	M08.452	M08.459	M08.461	M08.462	M08.469
M08.471	M08.472	M08.479	M08.48	M08.80	M08.811	M08.812
M08.819	M08.821	M08.822	M08.829	M08.831	M08.832	M08.839
M08.841	M08.842	M08.849	M08.851	M08.852	M08.859	M08.861
M08.862	M08.869	M08.871	M08.872	M08.879	M08.88	M08.89
M08.9A	M08.90	M08.911	M08.912	M08.919	M08.921	M08.922
M08.929	M08.931	M08.932	M08.939	M08.941	M08.942	M08.949
M08.951	M08.952	M08.959	M08.961	M08.962	M08.969	M08.971

M08.972	M08.979	M08.98	M08.99	M31.5	M31.6	M34.81
R65.10	R65.11	T45.1X5A	T45.1X5D	T45.1X5S	T80.90XA	T80.90XD
T80.90XS						

Covered Diagnosis Codes for Procedure Code Q5133

M05.7A	M05.8A	M05.9	M05.00	M05.09	M05.19	M05.20
M05.29	M05.30	M05.39	M05.40	M05.49	M05.50	M05.59
M05.60	M05.69	M05.70	M05.79	M05.80	M05.89	M05.011
M05.012	M05.019	M05.021	M05.022	M05.029	M05.031	M05.032
M05.039	M05.041	M05.042	M05.049	M05.051	M05.052	M05.059
M05.061	M05.062	M05.069	M05.071	M05.072	M05.079	M05.111
M05.112	M05.121	M05.122	M05.131	M05.132	M05.141	M05.142
M05.151	M05.152	M05.161	M05.162	M05.171	M05.172	M05.211
M05.212	M05.219	M05.221	M05.222	M05.229	M05.231	M05.232
M05.239	M05.241	M05.242	M05.249	M05.251	M05.252	M05.259
M05.261	M05.262	M05.269	M05.271	M05.272	M05.279	M05.311
M05.312	M05.319	M05.321	M05.322	M05.329	M05.331	M05.332
M05.339	M05.341	M05.342	M05.349	M05.351	M05.352	M05.359
M05.361	M05.362	M05.369	M05.371	M05.372	M05.379	M05.411
M05.412	M05.419	M05.421	M05.422	M05.429	M05.431	M05.432
M05.439	M05.441	M05.442	M05.449	M05.451	M05.452	M05.459
M05.461	M05.462	M05.469	M05.471	M05.472	M05.479	M05.511
M05.512	M05.519	M05.521	M05.522	M05.529	M05.531	M05.532
M05.539	M05.541	M05.542	M05.549	M05.551	M05.552	M05.559
M05.561	M05.562	M05.569	M05.571	M05.572	M05.579	M05.611

M05.612	M05.619	M05.621	M05.622	M05.629	M05.631	M05.632
M05.639	M05.641	M05.642	M05.649	M05.651	M05.652	M05.659
M05.661	M05.662	M05.669	M05.671	M05.672	M05.679	M05.711
M05.712	M05.719	M05.721	M05.722	M05.729	M05.731	M05.732
M05.739	M05.741	M05.742	M05.749	M05.751	M05.752	M05.759
M05.761	M05.762	M05.769	M05.771	M05.772	M05.779	M05.811
M05.812	M05.819	M05.821	M05.822	M05.829	M05.831	M05.832
M05.839	M05.841	M05.842	M05.849	M05.851	M05.852	M05.859
M05.861	M05.862	M05.869	M05.871	M05.872	M05.879	M06.0A
M06.1	M06.4	M06.8A	M06.9	M06.00	M06.08	M06.09
M06.20	M06.28	M06.29	M06.30	M06.38	M06.39	M06.80
M06.88	M06.89	M06.011	M06.012	M06.019	M06.021	M06.022
M06.029	M06.031	M06.032	M06.039	M06.041	M06.042	M06.049
M06.051	M06.052	M06.059	M06.061	M06.062	M06.069	M06.071
M06.072	M06.079	M06.211	M06.212	M06.219	M06.221	M06.222
M06.229	M06.231	M06.232	M06.239	M06.241	M06.242	M06.249
M06.251	M06.252	M06.259	M06.261	M06.262	M06.269	M06.271
M06.272	M06.279	M06.311	M06.312	M06.319	M06.321	M06.322
M06.329	M06.331	M06.332	M06.339	M06.341	M06.342	M06.349
M06.351	M06.352	M06.359	M06.361	M06.362	M06.369	M06.371
M06.372	M06.379	M06.811	M06.812	M06.819	M06.821	M06.822
M06.829	M06.831	M06.832	M06.839	M06.841	M06.842	M06.849
M06.851	M06.852	M06.859	M06.861	M06.862	M06.869	M06.871
M06.872	M06.879	M08.0A	M08.2A	M08.3	M08.4A	M08.9A

M08.00	M08.08	M08.09	M08.20	M08.28	M08.29	M08.40
M08.48	M08.80	M08.88	M08.89	M08.90	M08.98	M08.99
M08.011	M08.012	M08.019	M08.021	M08.022	M08.029	M08.031
M08.032	M08.039	M08.041	M08.042	M08.049	M08.051	M08.052
M08.059	M08.061	M08.062	M08.069	M08.071	M08.072	M08.079
M08.211	M08.212	M08.219	M08.221	M08.222	M08.229	M08.231
M08.232	M08.239	M08.241	M08.242	M08.249	M08.251	M08.252
M08.259	M08.261	M08.262	M08.269	M08.271	M08.272	M08.279
M08.411	M08.412	M08.419	M08.421	M08.422	M08.429	M08.431
M08.432	M08.439	M08.441	M08.442	M08.449	M08.451	M08.452
M08.459	M08.461	M08.462	M08.469	M08.471	M08.472	M08.479
M08.811	M08.812	M08.819	M08.821	M08.822	M08.829	M08.831
M08.832	M08.839	M08.841	M08.842	M08.849	M08.851	M08.852
M08.859	M08.861	M08.862	M08.869	M08.871	M08.872	M08.879
M08.911	M08.912	M08.919	M08.921	M08.922	M08.929	M08.931
M08.932	M08.939	M08.941	M08.942	M08.949	M08.951	M08.952
M08.959	M08.961	M08.962	M08.969	M08.971	M08.972	M08.979

Covered Diagnosis Codes for Procedure Code Q5135

M05.7A	M05.8A	M05.9	M05.00	M05.09	M05.19	M05.20
M05.29	M05.30	M05.39	M05.40	M05.49	M05.50	M05.59
M05.60	M05.69	M05.70	M05.79	M05.80	M05.89	M05.011
M05.012	M05.019	M05.021	M05.022	M05.029	M05.031	M05.032
M05.039	M05.041	M05.042	M05.049	M05.051	M05.052	M05.059
M05.061	M05.062	M05.069	M05.071	M05.072	M05.079	M05.111

M05.112	M05.121	M05.122	M05.131	M05.132	M05.141	M05.142
M05.151	M05.152	M05.161	M05.162	M05.171	M05.172	M05.211
M05.212	M05.219	M05.221	M05.222	M05.229	M05.231	M05.232
M05.239	M05.241	M05.242	M05.249	M05.251	M05.252	M05.259
M05.261	M05.262	M05.269	M05.271	M05.272	M05.279	M05.311
M05.312	M05.319	M05.321	M05.322	M05.329	M05.331	M05.332
M05.339	M05.341	M05.342	M05.349	M05.351	M05.352	M05.359
M05.361	M05.362	M05.369	M05.371	M05.372	M05.379	M05.411
M05.412	M05.419	M05.421	M05.422	M05.429	M05.431	M05.432
M05.439	M05.441	M05.442	M05.449	M05.451	M05.452	M05.459
M05.461	M05.462	M05.469	M05.471	M05.472	M05.479	M05.511
M05.512	M05.519	M05.521	M05.522	M05.529	M05.531	M05.532
M05.539	M05.541	M05.542	M05.549	M05.551	M05.552	M05.559
M05.561	M05.562	M05.569	M05.571	M05.572	M05.579	M05.611
M05.612	M05.619	M05.621	M05.622	M05.629	M05.631	M05.632
M05.639	M05.641	M05.642	M05.649	M05.651	M05.652	M05.659
M05.661	M05.662	M05.669	M05.671	M05.672	M05.679	M05.711
M05.712	M05.719	M05.721	M05.722	M05.729	M05.731	M05.732
M05.739	M05.741	M05.742	M05.749	M05.751	M05.752	M05.759
M05.761	M05.762	M05.769	M05.771	M05.772	M05.779	M05.811
M05.812	M05.819	M05.821	M05.822	M05.829	M05.831	M05.832
M05.839	M05.841	M05.842	M05.849	M05.851	M05.852	M05.859
M05.861	M05.862	M05.869	M05.871	M05.872	M05.879	M06.0A
M06.1	M06.4	M06.8A	M06.9	M06.00	M06.08	M06.09

M06.20	M06.28	M06.29	M06.30	M06.38	M06.39	M06.80
M06.88	M06.89	M06.011	M06.012	M06.019	M06.021	M06.022
M06.029	M06.031	M06.032	M06.039	M06.041	M06.042	M06.049
M06.051	M06.052	M06.059	M06.061	M06.062	M06.069	M06.071
M06.072	M06.079	M06.211	M06.212	M06.219	M06.221	M06.222
M06.229	M06.231	M06.232	M06.239	M06.241	M06.242	M06.249
M06.251	M06.252	M06.259	M06.261	M06.262	M06.269	M06.271
M06.272	M06.279	M06.311	M06.312	M06.319	M06.321	M06.322
M06.329	M06.331	M06.332	M06.339	M06.341	M06.342	M06.349
M06.351	M06.352	M06.359	M06.361	M06.362	M06.369	M06.371
M06.372	M06.379	M06.811	M06.812	M06.819	M06.821	M06.822
M06.829	M06.831	M06.832	M06.839	M06.841	M06.842	M06.849
M06.851	M06.852	M06.859	M06.861	M06.862	M06.869	M06.871
M06.872	M06.879	M08.0A	M08.2A	M08.3	M08.4A	M08.9A
M08.00	M08.08	M08.09	M08.20	M08.28	M08.29	M08.40
M08.48	M08.80	M08.88	M08.89	M08.90	M08.98	M08.99
M08.011	M08.012	M08.019	M08.021	M08.022	M08.029	M08.031
M08.032	M08.039	M08.041	M08.042	M08.049	M08.051	M08.052
M08.059	M08.061	M08.062	M08.069	M08.071	M08.072	M08.079
M08.211	M08.212	M08.219	M08.221	M08.222	M08.229	M08.231
M08.232	M08.239	M08.241	M08.242	M08.249	M08.251	M08.252
M08.259	M08.261	M08.262	M08.269	M08.271	M08.272	M08.279
M08.411	M08.412	M08.419	M08.421	M08.422	M08.429	M08.431
M08.432	M08.439	M08.441	M08.442	M08.449	M08.451	M08.452

M08.459	M08.461	M08.462	M08.469	M08.471	M08.472	M08.479
M08.811	M08.812	M08.819	M08.821	M08.822	M08.829	M08.831
M08.832	M08.839	M08.841	M08.842	M08.849	M08.851	M08.852
M08.859	M08.861	M08.862	M08.869	M08.871	M08.872	M08.879
M08.911	M08.912	M08.919	M08.921	M08.922	M08.929	M08.931
M08.932	M08.939	M08.941	M08.942	M08.949	M08.951	M08.952
M08.959	M08.961	M08.962	M08.969	M08.971	M08.972	M08.979
M31.5	M31.6					

CURRENT CODING

HCPCS:

J3262	Tocilizumab injection	Medicaid Expansion
Q5133	Inj, tofidence, 1 mg	Medicaid Expansion
Q5135	Inj, tyenne, 1 mg	Medicaid Expansion

References

I-31

1. Actemra (tocilizumab) injection, for intravenous or subcutaneous use [package insert]. Genentech, Inc. South San Francisco, CA. Revised 12/2022.
2. Tyenne® (tocilizumab-aazg) injection, for intravenous or subcutaneous use. [package insert] Fresenius Kabi USA, LLC., Lake Zurich, IL. Revised 03/2024.
3. Tofidence™ (tocilizumab-bavi) injection, for intravenous use. [package insert] Biogen MA Inc.,Cambridge MA. Revised 09/2023.
4. Preferred Drug List (PDL) Prior Authorization Criteria. North Dakota Department of Human Services. Medical Services Division. <https://ndmedicaid.acentra.com/preferred-drug-list-pdl/#pd>

ND Committee Review

Internal Medical Policy Committee 11-19-2024 *Effective January 01, 2025*

- **Adopted** Medicaid Expansion specific policy

Internal Medical Policy Committee 07-08-2025 **Effective August 01, 2025**

- **Updated** initial criteria required based on the DHHS PDL Version 2025.5

Internal Medical Policy Committee 09-04-2025 **Effective October 01, 2025**

- **Added** new code, Q5156, to the policy

Disclaimer

Current medical policy is to be used in determining a Member's contract benefits on the date that services are rendered. Contract language, including definitions and specific inclusions/exclusions, as well as state and federal law, must be considered in determining eligibility for coverage. Members must consult their applicable benefit plans or contact a Member Services representative for specific coverage information. Likewise, medical policy, which addresses the issue(s) in any specific case, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and the Company reserves the right to review and update medical policy periodically.