Actemra® (tocilizumab)
(Intravenous)

Document Number: MH-0002

Last Review Date: 10/18/2023,

Date of Origin: 09/21/2010

Dates Reviewed: 12/2010, 03/2011, 05/2011, 06/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 09/2012, 11/2012, 12/2012, 03/2013, 06/2013, 09/2013, 11/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 09/2015, 12/0215, 03/2016, 06/2016, 09/2016, 12/2016, 03/2017, 05/2017, 09/2017, 12/2017, 03/2018, 06/2018, 10/2018, 10/2019, 10/2020, 11/2020, 10/2021, 04/2022, 10/2022, 03/2023, 10/2023

I. Length of Authorization [1,17,29]

Initial coverage will be provided as follows:

- **RA, PJIA** Initial authorization for a maximum of 6 infusions in a 6 month period.
- **SJIA** Initial authorization for a maximum of 12 infusions in a 6 month period.
- **CRS** Authorization will be approved for 4 doses only and may NOT be renewed
- **Castleman Disease** – 4 months and may be renewed
- **Immune Checkpoint Inhibitor Related toxicities** – 1 dose only and may NOT be renewed
- **Acute graft versus host disease** – 6 months and may be renewed
- **Giant Cell Arteritis** Authorization will be approved for up to one (1) year of therapy.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Actemra 80 mg/4 mL vial: 1 vial per 14 days
- Actemra 200 mg/10 mL vial: 3 vials per 28 days
- Actemra 400 mg/20 mL vial: 2 vials per 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

Diagnosis	Billable Units	Interval (days)
Giant Cell Arteritis	600	28
Rheumatoid Arthritis & Polyarticular Juvenile Idiopathic Arthritis	800	28
Systemic Juvenile Idiopathic Arthritis, Castleman's Disease (B-Cell Lymphomas) & Acute Graft Versus Host Disease (aGVHD)	800	14
Cytokine Release Syndrome (CRS)	3200	1 course of therapy only
Immune Checkpoint Inhibitor Related Toxicities	800	1 course of therapy only

III. Initial Approval Criteria

ACTEMRA (tocilizumab) is considered medically appropriate for:

- Adult members with moderately to severely active rheumatoid arthritis (RA) who have had failed a trial (at least one month each) or were intolerant of infliximab or an adalimumab product; **OR**
- Members 2 years of age and older with active polyarticular juvenile idiopathic arthritis (PJIA) Members must have failed a trial (at least one month each) or were intolerant of an infliximab product or an adalimumab product; **OR**
- Members 2 years of age and older with active systemic juvenile idiopathic arthritis (SJIA); OR
- Members 2 years of age and older with chimeric antigen receptor (CAR) T cell- induced severe or life-threatening cytokine release syndrome (CRS)
    - Prescribed by, or in consultation of an oncologist; OR
- **Systemic sclerosis-associated interstitial lung disease**
    - Aged 18 years or older; AND
    - Prescribed by a pulmonologist or rheumatologist; AND
    - Diagnosis with documentation of both a high-resolution computed tomography (HRCT) scan and Pulmonary function tests (PFT), including forced vital capacity (FVC) and diffusing capacity for carbon monoxide (DLCO)
    - Trial of mycophenolate was ineffective, contraindicated, or not tolerated
- **Adult-onset Still's disease**
    - Prescribed by a rheumatologist, AND
    - Trial of anakinra (Kineret) was ineffective, contraindicated, or not tolerated
- **Castleman Disease (B-cell lymphomas)**
    - Used as a single agent; AND
        - Patient has unicentric disease; AND
            - Patient is human immunodeficiency virus (HIV)-negative and human herpres-8 (HHV-8)-negative; AND
            - Used as second-line therapy for relapsed or refractory disease; OR
        - Patient has multicentric disease; AND
            - Used as subsequent therapy for relapsed, refractory, or progressive disease

- **Management of Immune Checkpoint Inhibitor Related Toxicities**
    - Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, dostarlimab etc.); AND
        - Used as additional therapy for management of giant cell arteritis; OR
        - Patient has severe immunotherapy-related inflammatory arthritis; AND
            - Used as additional disease modifying antirheumatic therapy; AND
                - Patient's symptoms have not improved within 1 week after starting high-dose corticosteroids; OR
                - Patient is unable to taper corticosteroids by week 2
- **Acute Graft versus Host Disease**
    - Patient has received a hematopoietic stem cell transplant; AND
    - Used for steroid-refractory acute GVHD; AND
    - Used in combination with systemic corticosteroids as additional therapy following no response to first-line therapies
- **Adult patients with giant cell arteritis (GCA)**
    - Prescribed by, or in consultation with, a Rheumatologist
    - Diagnosis confirmed by confirmation of one (1) of the following:
        - Temporal artery biopsy; OR Doppler ultrasound; **OR** Magnetic resonance angiography (MRA); OR Positron emission tomography (PET);

ACTEMRA (tocilizumab) may NOT be approved for an individual with ANY of the following:

- In combination with other biologic DMARDs such as anti-CD20 monoclonal antibodies, IL-1R antagonists, Janus kinase inhibitors (e.g. tofacitinib), selective co-stimulation modulators, or TNF antagonists; **AND**
- Tuberculosis, invasive fungal infection, or other active serious infections or a history of recurrent infections; **AND**
- Individual has not had a tuberculin skin test or CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating tocilizumab

IV. Renewal Criteria [1]

RA, PJIA

- Continued authorizations or re-authorizations can be approved for a period of up to 1 year and require clinical documentation indicating medication effectiveness and absence of treatment of limiting toxicity. Maximum of 13 infusions in a 1 year period based on recommended infusion interval of every 4 weeks.

SJIA

- Continued authorizations or re-authorizations can be approved for a period of up to 1 year and require clinical documentation indicating medication effectiveness and absence of treatment limiting toxicity. Maximum of 13 infusions in a 1 year period based on recommended infusion interval of every 4 weeks, or 26 infusions in a 1 year period based on recommended infusion internal of every 2 weeks.

Giant Cell Arteritis

- Continued authorization or re-authorizations can be approved for a period up to 1 year and require clinical documentation indicating medication effectiveness and absence of treatment of limiting toxicity. Dose is 6mg per KG every 4 weeks.

Comments:

- A maximum of 7616 combined units every 26 weeks are allowed for JIA or systemic sclerosis.
- Documentation is expected to be maintained in the member's medical record and to be available to the plan. Every page of the record is expected to be legible and include both the appropriate member identification information (e.g., complete name dates of service(s)), and information identifying the physician or non-physician practitioner responsible for and providing the care of the member. The member's medical record must contain documentation that fully supports the medical necessity for services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

- The medical record must include the following information
    - A physician's order
    - The name of the drug or biological administered
    - The route of administration
    - The dosage (e.g., mgs, mcgs, cc's or IU's)
- When a portion of the drug or biological is discarded, the medical record must clearly document the amount administered and the amount wasted or discarded.
- Codes and descriptors listed in this document are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with the plan. Inclusion of a code in the table does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

V. Dosage/Administration [1,8,17,20-22,25,28]

Doses exceeding 800 mg per infusion are not recommended (unless otherwise specified).

Indication	Dose
Adult Rheumatoid Arthritis	Administer 4 mg/kg intravenously every 4 weeks • May increase to 8 mg/kg every 4 weeks based on clinical response, up to a maximum of 800 mg per dose.
Indication	Dose
Polyarticular Juvenile Idiopathic Arthritis	Weight ≥ 30 kg • Administer 8 mg/kg intravenously every 4 weeks Weight < 30 kg • Administer 10 mg/kg intravenously every 4 weeks
Systemic Juvenile Idiopathic Arthritis	Weight ≥ 30 kg • Administer 8 mg/kg intravenously every 2 weeks Weight < 30 kg • Administer 12 mg/kg intravenously every 2 weeks
Castleman Disease (B-Cell Lymphomas)	Administer 8 mg/kg intravenously every 2 weeks for 16 weeks (8 doses total)
Cytokine Release Syndrome (CRS)	Weight ≥ 30 kg • Administer 8 mg/kg intravenously every 8 hours, if needed, up to a maximum of 4 total doses* Weight < 30 kg • Administer 12 mg/kg intravenously every 8 hours, if needed, up to a maximum of 4 total doses* *If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses may be administered. The interval between consecutive doses should be at least 8 hours. May be used with or without corticosteroids. Doses exceeding 800 mg per infusion are not recommended in CRS patients.
Immune-Checkpoint Inhibitor Related Toxicities	Administer 4 mg/kg intravenously one time only
Acute GVHD	Administer 8 mg/kg intravenously, every 2-4 weeks until disease progression or unacceptable toxicity.
Giant Cell Arteritis	Administer 6 mg/kg intravenously, every 4 weeks • Doses exceeding 600 mg per infusion are not recommended in GCA patients.

VI. Billing Code/Availability Information

HCPCS Code:

- J3262 – Injection, tocilizumab, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Actemra 80 mg/4 mL single-dose vial: 50242-0135-xx
- Actemra 200 mg/10 mL single-dose vial: 50242-0136-xx
- Actemra 400 mg/20 mL single-dose vial: 50242-0137-xx

VII. References

1. Actemra [package insert]. South San Francisco, CA; Genentech, Inc; June 2022. Accessed September 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tocilizumab. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2022.
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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC