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Policy Number: C10265-A

Actemra (tocilizumab)

PRODUCTS AFFECTED

Actemra (tocilizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderately to severely active rheumatoid arthritis (RA), Polyarticular juvenile idiopathic arthritis, Systemic juvenile idiopathic arthritis, Giant cell arteritis (GCA), Chimeric antigen receptor (CAR) T-cell-induced severe or life- threatening cytokine release syndrome (CRS), Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS (EXCEPT CRS):

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
   AND
2. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
   AND
3. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
4. Prescriber attests member does not have an active infection, including clinically important localized infections
   AND
5. Prescriber attests that member does NOT have an ANC less than 2000/mm3, platelets less than 100,000/mm3 or liver transaminases above 1.5 times ULN
   AND
6. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:

1. Documentation of moderate to severe rheumatoid arthritis diagnosis
   AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
3. (a) Member is currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity
   OR
   (b) Member has an FDA labeled contraindication or serious side effects to methotrexate, as determined by the prescribing physician AND member has tried one additional disease-modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months *(NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the Member has already had a 3-month trial of at least one biologic. These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD.)*

B. JUVENILE IDIOPATHIC ARTHRITIS (ACTIVE SYSTEMIC AND POLYARTICULAR):

1. Documented diagnosis of systemic juvenile idiopathic arthritis (SJIA) or polyarticular

juvenile idiopathic arthritis (PJIA) in a pediatric member
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) FOR ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (12 weeks) of one NSAID or glucocorticoid
OR
(b) FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (generally ≥12 weeks) of one or more of the following: Methotrexate, hydroxychloroquine, sulfasalazine, leflunomide

C. GIANT CELL ARTERITIS (GCA):
1. Documented diagnosis of Giant Cell Arteritis (GCA)
AND
2. Documented disease activity as evidenced by cranial symptoms of giant- cell arteritis or polymyalgia rheumatica and increased concentrations of serum acute-phase reactants (ESR > 30 mm/hour or CRP > 1 mg/dL)
AND
3. Member must have documented need for a glucocorticoid sparing agent use such as: presence of significant premorbid diseases, emergence of significant glucocorticoid-related side effects during the course of treatment, a relapsing course necessitating protracted glucocorticoid use, preexisting diabetes mellitus on treatment, osteoporosis, or significant obesity
AND
4. Documentation of treatment failure, serious side effects, or clinical contraindication to a trial (at least 3 months) of methotrexate
AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

D. CYTOKINE RELEASE SYNDROME (CAR-T THERAPY INDUCED):
APPROVED ONLY IF CART- T IS APPROVED BY TRANSPLANT TEAM. VERIFICATION OF CAR-T IS REQUIRED DOCUMENTATION.
1. Prescriber attests that member does NOT have an ANC less than 2000/mm3, platelets less than 100,000/mm3 or liver transaminases above 1.5 times ULN OR prescriber attests the benefit of treating CRS outweighs the risks of short-term treatment with Actemra
NOTE: Patients with severe or life-threatening CRS frequently have cytopenias or elevated ALT or AST due to the lymphodepleting chemotherapy or the CRS. The decision to administer ACTEMRA should take into account the potential benefit of treating the CRS versus the risks of short-term treatment with Actemra.

E. SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD) (Subcutaneous syringes only):
1. Documented diagnosis of systemic sclerosis-associated interstitial lung disease
AND
2. Documentation of chest high resolution computed tomography (HRCT) scan confirming diagnosis of interstitial lung disease [DOCUMENTATION REQUIRED]
AND
3. Documentation member has elevated acute-phase reactants as documented by at least one of the following [DOCUMENTATION REQUIRED]: CRP level ≥ 6 mg/L, erythrocyte sedimentation rate ≥ 28 mm/hour, platelet count ≥ 330 x 10^9/L
AND

4. Prescriber attests or clinical reviewer has found that tocilizumab is not being prescribed for use with nintedanib (Ofev)
   AND
5. Documentation of treatment failure, serious side effects or clinical contraindication to mycophenolate mofetil
   AND
6. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., respiratory symptoms, subjective exercise tolerance, physical exam, pulmonary function tests [spirometry, diffusing capacity for carbon monoxide (DLCO), six-minute walk test]) [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS (EXCEPT CRS):

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
   AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
   AND
5. Prescriber attests that ANC, platelets, and liver transaminases will be monitored as clinically indicated while the member is on treatment.

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months.

PRESCRIBER REQUIREMENTS:

CYTOKINE RELEASE SYNDROME (CAR-T THERAPY INDUCED): Prescribed by or in consultation with a board-certified oncologist.
SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD): Prescribed by or in consultation with a board-certified rheumatologist or pulmonologist.
ALL OTHER INDICATIONS: Prescribed by or in consultation with a board-certified rheumatologist.
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
PJIA, SJIA and CAR T-cell-induced cytokine release syndrome: 2 years of age and older
All other indications: 18 years of age and older

QUANTITY:
CYTOKINE RELEASE SYNDROME (CAR-T THERAPY INDUCED): max 8 single dose vials per lifetime, not to exceed 800 mg. NOTE: PLEASE REVIEW FOR AUTHORIZATION CONCURRENTLY WITH CAR-T THERAPY

ALL OTHER INDICATIONS:
Subcutaneous:
Rheumatoid arthritis: Up to 162 mg every week
Giant cell arteritis: Up to 162 mg every week
SSc- ILD: 162 mg every week
PJIA: < 30 kg – 162 mg every 3 weeks; 30 kg or greater – 162 mg every 2 weeks
SJIA: <30 kg – 162 mg every 2 weeks; 30 kg or greater – 162 mg every week

Intravenous:
Rheumatoid arthritis: 4 mg/kg every 4 weeks, may increase to 8 mg/kg every 4 weeks, not to exceed 800 mg per infusion
Giant cell arteritis: 6 mg/kg every 4 weeks, not to exceed 600 mg per infusion
PJIA: < 30 kg – 10 mg/kg every 4 weeks; 30 kg or greater – 8 mg/kg every 4 weeks
SJIA: < 30 kg – 12 mg/kg every 2 weeks; 30 kg or greater – 8 mg/kg every 2 weeks
CRS: < 30 kg – 12 mg/kg; 30 kg or greater – 8 mg/kg, not to exceed 800 mg per infusion

Maximum Quantity Limits –
SC: 4 packages (4 syringes) per 28 days
IV: 80 mg/4 mL vial: 1 vial per 14 days, 200 mg/10 mL vial: 1 vial per 14 days, 400 mg/20 mL vial: 2 vials per 14 days

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.
Note: Site of Care Utilization Management Policy applies for Actemra (tocilizumab) IV. For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous, Subcutaneous

DRUG CLASS:
Interleukin-6 Receptor Inhibitors

FDA-APPROVED USES:
Actemra IV and SQ:
- Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti- Rheumatic Drugs (DMARDs).
- Indicated for the treatment of adult patients with giant cell arteritis (GCA).

Drug and Biologic Coverage Criteria

- Indicated for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.
- Indicated for the treatment of patients 2 years of age and older with active systemic juvenile idiopathic arthritis.

Actemra SQ (only): Indicated for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis- associated interstitial lung disease (SSc-ILD).

Actemra IV (only):

- Indicated for the treatment of adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T-cell-induced severe or life-threatening cytokine release syndrome (CRS).
- Indicated for treatment of hospitalized adult patient with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and required supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
OBJECTIVE MEASURES FOR RA:
[Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Member Activity Scale (PAS or PAS- II), Routine Assessment of Member Index Data with 3 measures, Simplified Disease Activity Index (SDAI)] OBJECTIVE MEASURES FOR PJIA:
Global Arthritis Score (GAS), Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS), Disease Activity Score based on 28-joint evaluation (DAS28), Simple Disease Activity Index (SDAI), Health Assessment Questionnaire disability index (HAQ-DI), Visual Analogue Scale (VAS), Likert scales of global response or pain by the member or global response by the physician, Joint tenderness and/or swelling counts, Laboratory data

Table 1. The American College of Rheumatology/European League Against Rheumatism criteria for the classification of systemic sclerosis (SSc)*

Item	Sub-item(s)	Weight/score†
Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints *(sufficient criterion)*	–	9
Skin thickening of the fingers *(only count the higher score)*	Puffy fingers	2
	Sclerodactyly of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints)	4
Fingertip lesions *(only count the higher score)*	Digital tip ulcers	2
	Fingertip pitting scars	3
Telangiectasia	–	2
Abnormal nailfold capillaries	–	2
Pulmonary arterial hypertension and/or interstitial lung disease *(maximum score is 2)*	Pulmonary arterial hypertension	2
	Interstitial lung disease	2
Raynaud's phenomenon	–	3
SSc-related autoantibodies (anticentromere, anti–topoisomerase I [anti–Scl-70], anti–RNA polymerase III) *(maximum score is 3)*	Anticentromere	3
	Anti–topoisomerase I	
	Anti–RNA polymerase III	

* These criteria are applicable to any patient considered for inclusion in an SSc study. The criteria are not applicable to patients with skin thickening sparing the fingers or to patients who have a scleroderma-like disorder that better explains their manifestations (e.g., nephrogenic sclerosing fibrosis, generalized morphea, eosinophilic fasciitis, scleredema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft-versus-host disease, diabetic cheiroarthropathy).
† The total score is determined by adding the maximum weight (score) in each category. Patients with a total score of ≥9 are classified as having definite SSc.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Tocilizumab (Actemra) is a recombinant humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody (IgG1κ). The drug binds to membrane-bound (mIL-6R) and soluble (sIL- 6R) forms of the interleukin-6 receptor, thereby reducing the inflammatory process by inhibiting signaling through these receptors. Interleukin-6 is a pleiotropic pro-inflammatory cytokine involved in multiple phases of the inflammatory response, including T-cell activation and induction of immunoglobulin secretion. Actemra SC has demonstrated efficacy and is indicated for the treatment of rheumatoid arthritis (RA) in adults with moderate to severe active RA who have had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Actemra SC has been shown to inhibit and slow structural joint damage, improve physical function, and achieve a major clinical response in patients taking methotrexate (MTX). In addition to RA, Actemra SC is also indicated in adults with giant cell arteritis (GCA). It is recommended to be given once weekly and may be given in combination with a tapering course of glucocorticoids. Actemra SC can be used alone following the discontinuation of glucocorticoids. The subcutaneous formulation is also indicated for SSc-ILD and has been shown slow the rate of decline in pulmonary function in adult patients. Actemra is also available as an intravenous (IV) formulation which, in addition to RA, is indicated in patients 2 years of age and older for the treatment of active systemic juvenile idiopathic arthritis (SJIA) or polyarticular juvenile idiopathic arthritis (PJIA). The IV formulation is not indicated in GCA or SSc-ILD.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Actemra (tocilizumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Actemra (tocilizumab) include: patients with known hypersensitivity to Actemra, administration during an active infection including localized infections, use with live vaccines.

OTHER SPECIAL CONSIDERATIONS:
Actemra has a Black Box Warning for risk of serious infections. Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections have occurred in patients receiving Actemra.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J3262	Injection, tocilizumab, 1 mg

AVAILABLE DOSAGE FORMS:
Actemra SOLN 80MG/4ML single-dose vial
Actemra SOLN 200MG/10ML single-dose vial
Actemra SOLN 400MG/20ML single-dose vial
Actemra ACT Pen SOAJ 162MG/0.9ML
Actemra SOSY Prefilled Syringe162MG/0.9ML

REFERENCES

1. Actemra Prescribing Information. South San Francisco, CA; Genentech, Inc. December 2022.
2. American College of Rheumatology 2008 Recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum.2008;59(6):762-784.
3. Jones G, Sebba A, Gu J, et al. Comparison of tocilizumab monotherapy versus methotrexate monotherapy in patients with moderate to severe rheumatoid arthritis: the AMBITION study. AnnRheum Dis. 2010;69(1):88-96.
4. Smolen JS, Beaulieu A, Rubbert-Roth A, et al. for the OPTION Investigators. Effect of interleukin-6 receptor inhibition with tocilizumab in patients with rheumatoid arthritis (OPTION study): a double-blind, placebo-controlled, randomized trial. Lancet. 2008;371:987-97.
5. Genovese MC, McKay JD, Nasonov EL, et al. Interleukin-6 receptor inhibition with tocilizumab reduces disease activity in rheumatoid arthritis with inadequate response to disease- modifying antirheumatic drugs: The tocilizumab in combination with traditional disease- modifying antirheumatic drug therapy study. Arthritis Rheum. 2008;58(10):2968-80.
6. Emery P, Keystone E, Tony HP, et al. IL-6 receptor inhibition with tocilizumab improves treatment outcomes in patients with rheumatoid arthritis refractory to anti-tumor necrosis factor biologicals: results from a 24-hour week multicenter randomized placebo-controlled trial. Ann Rheum Dis. 2008;67:1516-1523.
7. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013;65(10):2499-512.
8. De Benedetti F, Brunner H, Ruperto N, et al. Tocilizumab in patients with systemic juvenile idiopathic arthritis: efficacy data from the placebo-controlled 12-week part of the phase 3 TENDER trial. Arthritis Rheum. 2010; 62. Presented at the ACR Annual Meeting; November 6- 7, 2010; Atlanta, GA. Abstract #1434.
9. Gabay C, Emery P, van Vollenhoven R, et al. Tocilizumab monotherapy versus adalimumab monotherapy for treatment of rheumatoid arthritis (ADACTA): a randomized, double-blind, controlled phase 4 trial. Lancet. 2013;381(9877):1541-1550.
10. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. 2011;63(4):465-82.
11. Roofeh, D., Lin, C. J., Goldin, J., et al. (2021). Tocilizumab prevents progression of Early systemic Sclerosis–associated Interstitial lung disease. Arthritis & Rheumatology, 73(7), 1301–1310. https://doi.org/10.1002/art.41668.
12. Roofeh, D., Jaafar, S., Vummidi, D., & Khanna, D. (2019). Management of systemic sclerosis-associated interstitial lung disease. Current opinion in rheumatology, 31(3), 241–249. https://doi.org/10.1097/BOR.0000000000000592
13. van den Hoogen, F., Khanna, D., Fransen, J., Johnson, et al. (2013). 2013 classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative. Arthritis and rheumatism, 65(11), 2737–2747. https://doi.org/10.1002/art.38098
14. Onel, K., Horton, D., Lovell, D., Shenoi, S., Cuello, C., & Angeles-Han, S. et al. (2022). 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis & Rheumatology, 74(4), 553-569. doi: 10.1002/art.42037
15. Ringold, S., Angeles-Han, S., Beukelman, T., Lovell, D., Cuello, C., & Becker, M. et al. (2019). 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis,

Sacroiliitis, and Enthesitis. Arthritis Care & Research, 71(6), 717-734. doi: 10.1002/acr.23870
16. Maz, M., Chung, S., Abril, A., Langford, C., Gorelik, M., & Guyatt, G. et al. (2021). 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Giant Cell Arteritis and Takayasu Arteritis. Arthritis & Rheumatology, 73(8), 1349-1365. doi: 10.1002/art.41774
17. Fraenkel, L., Bathon, J., England, B., St. Clair, E., Arayssi, T., & Carandang, K. et al. (2021). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research, 73(7), 924-939. doi: 10.1002/acr.24596
18. Menter, A., Strober, B., Kaplan, D., Kivelevitch, D., Prater, E., & Stoff, B. et al. (2019). Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal Of The American Academy Of Dermatology, 80(4), 1029-1072. doi: 10.1016/j.jaad.2018.11.057
19. Menter, A., Gelfand, J., Connor, C., Armstrong, A., Cordoro, K., & Davis, D. et al. (2020). Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. Journal Of The American Academy Of Dermatology, 82(6), 1445-1486. doi: 10.1016/j.jaad.2020.02.044
20. Elmets, C., Lim, H., Stoff, B., Connor, C., Cordoro, K., & Lebwohl, M. et al. (2019). Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. Journal Of The American Academy Of Dermatology, 81(3), 775-804. doi: 10.1016/j.jaad.2019.04.042
21. Singh, J., Guyatt, G., Ogdie, A., Gladman, D., Deal, C., & Deodhar, A. et al. (2018). 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology, 71(1), 5-32. doi: 10.1002/art.40726
22. National Comprehensive Cancer Network. 2022. Management of Immunotherapy-Related Toxicities (Version 1.2022). [online] Available at: <https://www.nccn.org/professionals/physician_gls/pdf/immunotherapy.pdf> [Accessed 11 August 2022].
23. Katzen, J., Raparia, K., Agrawal, R., Patel, J., Rademaker, A., Varga, J., & Dematte, J. (2015). Early Stage Lung Cancer Detection in Systemic Sclerosis Does Not Portend Survival Benefit: A Cross Sectional Study. PLOS ONE, 10(2), e0117829. doi: 10.1371/journal.pone.0117829
24. Hellmich, B., Agueda, A., Monti, S., Buttgereit, F., de Boysson, H., Brouwer, E., … Tomasson, G. (2019). 2018 Update of the EULAR recommendations for the management of large vessel vasculitis. Annals of the Rheumatic Diseases, 79(1), 19–30. https://doi.org/10.1136/annrheumdis-2019-215672
25. Maz, M., Chung, S. A., Abril, A., Langford, C. A., Gorelik, M., Guyatt, G., … Vitobaldi, O. I. (2021). 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Giant Cell Arteritis and Takayasu Arteritis. Arthritis Care & Research, 73(8), 1071–1087. https://doi.org/10.1002/acr.24632

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity FDA-Approved Uses Other Special Considerations References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file