

Department:	Pharmacy Management	Original Approval:	01/20/2016
Policy #:	PM129	Last Approval:	05/20/2019
Title:	Rituximab (Rituxan®)		
Approved By:	UM Committee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Rituximab (Rituxan): History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Prescribed by or in consultation with a rheumatologist, nephrologist, immunologist, oncologist, hematologist, neurologist or other specialist as indicated -Medication list (current and past) -Dosing and duration requested -Weight -Height -Labs/diagnostics as indicated.

BACKGROUND

Rituximab is a chimeric murine/human monoclonal antibody directed specifically against the CD20 antigen found on the surface of normal and malignant B lymphocytes.¹ The antigen CD20 is expressed on > 90% of B-cell non-Hodgkin's lymphomas (NHLs). B-cells are thought to play a role in the pathogenesis of rheumatoid arthritis (RA) and associated chronic synovitis.

Truxima was approved as biosimilar to Rituxan intravenous (IV), indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Rituxan IV. However, minor differences in clinically inactive components are allowed. At this time, Truxima has only demonstrated biosimilarity, not interchangeability.

Rituxan IV and Truxima are indicated for treatment of the following conditions:

1. Non-Hodgkin lymphoma (NHL), for previously untreated follicular, CD20-positive disease, in combination with first-line chemotherapy, and in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy; AND
2. NHL, for relapsed or refractory, low-grade or follicular, CD20-positive, B-cell, disease; AND
3. NHL, for non-progressing (including stable disease) low-grade, CD20-positive, B-cell disease as a single agent after first-line cyclophosphamide/vincristine/prednisone (CVP) chemotherapy.

In addition to the above indications, Rituxan IV is also indicated for treatment of the following conditions:

1. NHL, for previously untreated diffuse large B-cell, CD20-positive disease, in combination with cyclophosphamide/doxorubicin/vincristine/prednisone (CHOP) or other anthracycline-based chemotherapy regimens; AND
2. Chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC) for the treatment of patients with previously untreated and previously treated CD20-positive disease; AND

3. Rheumatoid arthritis (RA), in adult patients with moderately to severely active disease, in combination with methotrexate (MTX) for patients who have had an inadequate response to one or more tumor necrosis factor inhibitors (TNFis); AND
4. Granulomatosis with polyangiitis (GPA) [Wegener's granulomatosis {WG}] and microscopic polyangiitis (MPA) in adults, in combination with glucocorticoids; AND
5. Pemphigus vulgaris, for adults with moderate to severe.

Guidelines

- The use of rituximab is also supported in clinical guidelines in numerous other situations, both as first-line therapy and in patients who are refractory or have relapsed following treatment with other therapies.²⁻⁸Rituximab features prominently in the National Comprehensive Cancer Network (NCCN) guidelines for treatment of B-cell lymphomas and CLL/small lymphocytic lymphoma and is included in multiple treatment regimens across the spectrum of disease.^{6,11,36}
- Guidelines from the American College of Rheumatology (ACR) [2015] have tumor inhibitors and non-TNF biologics (including rituximab), equally positioned following a trial of a conventional synthetic DMARD.²
- EULAR/ERA-EDTA recommendations for ANCA-associated vasculitis mention rituximab in combination with low-dose corticosteroids as a potential treatment option for remission-maintenance therapy. Remission-maintenance therapy is recommended for at least 24 months following induction of sustained remission.⁷
- The British Committee for Standards in Hematology (BCSH) and the British Society for Bone Marrow Transplant recommendations for the management of chronic GVHD (2012) list rituximab as a potential second-line treatment for patients with refractory cutaneous or musculoskeletal chronic GVHD or third-line for treatment of GVHD involving other organs.²⁹
- Guidelines from the American Society of Hematology (ASH) for ITP (2011) mention rituximab as an appropriate agent for children and adolescents with ITP who have significant on-going bleeding despite treatment with intravenous immunoglobulin G (IVIg), anti-D, or corticosteroids.³ Rituximab is also appropriate as an alternative to splenectomy in children/adolescents with chronic ITP or in patient who do not respond to splenectomy. In adults, rituximab is recommended for patients with ITP who are at risk for bleeding and who have failed one other line of therapy (e.g., corticosteroids, IVIg, splenectomy).
- EULAR recommendations for the management of systemic lupus erythematosus with neuropsychiatric manifestations (2010) mention rituximab as a therapeutic option for patients with neuropsychiatric SLE refractory to standard immunosuppressive therapies.⁴ Rituximab is used in patients with a refractory acute confusional state or other psychiatric disorders (e.g., lupus psychosis), and in severe peripheral nervous system disorders (e.g., polyneuropathy, mononeuropathy, acute inflammatory demyelinating polyradiculoneuropathy, myasthenia gravis, plexopathy). EULAR in combination with the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) has recommendations for the management of adult and pediatric lupus nephritis (2012).¹⁹ Rituximab is an alternative for patients who do not respond to first-line therapies. ACR recommendations for management of lupus nephritis (2012)⁵ note that rituximab may be appropriate in certain patients with lupus nephritis who have tried mycophenolate mofetil and cyclophosphamide and in patients whose nephritis fails to improve or worsens following 6 months of one induction therapy.

Policy Statement

Prior authorization is recommended for medical benefit coverage of rituximab IV products. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by an Express Scripts clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Because of the specialized skills required for evaluation and diagnosis of patients treated with rituximab products as well as the monitoring required for adverse events (AEs) and long-term efficacy, initial approval requires rituximab to be prescribed by or in consultation with a physician who specializes in the condition being treated.

DEFINITIONS

None.

INDICATIONS/CRITERIA

Medicaid Members	<i>Continue to criteria for approval below.</i>
Medicare Members	<i>Step-utilization of Part D drugs not required.</i>

FDA-Approved Indications

1. **Antineutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis**. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Induction Treatment**. Approve for 1 month if the patient meets ALL of the following (i, ii, and iii):
 - i. Rituximab is prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist; AND
 - ii. The patient has an ANCA-associated vasculotide (e.g., granulomatosis with polyangiitis [GPA] {Wegener’s granulomatosis (WG)} or microscopic polyangiitis [MPA]); AND
 - iii. Rituximab IV (Rituxan IV, Truxima) is being administered in combination with glucocorticoids.
- B) Follow-Up Treatment of Patients Who Have Received Induction Treatment for ANCA-Associated Vasculitis** (e.g., induction treatment using rituximab infusion or other standard of

care immunosuppressants). Approve for 1 year if the patient meets BOTH of the following (i and ii):

- i. According to the prescribing physician, the patient achieved disease control with induction treatment; AND
- ii. If the patient previously received a course of rituximab, at least 16 weeks will elapse between courses of rituximab.

Dosing. Approve the following regimens:

- A) 375 mg/m² IV once weekly for 1 month (4 doses) for initial therapy; OR
- B) 500 mg on Days 1 and 15 followed by 500 mg every 6 months thereafter based on clinical evaluation.

Duration of Therapy.⁹⁻¹⁰ Extended approvals are allowed if the patient meets the conditions for coverage and dosing for follow-up treatment of patients who have received induction treatment (see Criteria above). Treatment is individualized. At the discretion of the prescriber, some patients who were treated with rituximab in the past may be retreated with induction treatment.

- EULAR/ERA-EDTA guidelines recommend that remission-maintenance therapy be continued for at least 24 months following induction of sustained remission.⁷

NOTE TO NURSE CLINICIAN: Approval duration should align with the criteria and requested dosing up to a maximum 1 year approval per review.

2. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL). Approve for 1 year if rituximab IV is prescribed by or in consultation with an oncologist or hematologist.

Dosing. Approve the following regimens:

- A) 375 mg/m² as an IV infusion, then 500 mg/m² on Day 1 of Cycles 2 through 6; OR
- B) 375 mg/m² as an IV infusion on Day 1 of each planned chemotherapy cycle.

Duration of Therapy. Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above). However, duration of treatment is usually as needed to complete six to eight doses.

NOTE TO NURSE CLINICIAN: Approval duration should align with the criteria and requested dosing up to a maximum 1 year approval per review.

3. B-Cell Lymphoma (e.g., Follicular Lymphoma, Diffuse Large B-Cell Lymphoma [DLBCL], Acquired Immune Deficiency [AIDS]-Related B-Cell Lymphoma, Burkitt Lymphoma, Castleman's Disease, Marginal Zone Lymphoma [e.g., extranodal or MALT {gastric or nongastric}, nodal, or splenic marginal zone lymphoma], Primary Mediastinal Large B-Cell Lymphoma, Mantle Cell Lymphoma, Post-Transplant Lymphoproliferative Disorders, Gray Zone Lymphoma). Approve for 1 year if rituximab is prescribed by or in consultation with an oncologist or hematologist.

Dosing. Approve the following dosing regimens (A or B):

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- A)** One 375 mg/m² intravenous infusion administered using one of the following treatment schedules:
- i.** Once weekly for up to 8 doses; OR
 - ii.** Day 1 of each chemotherapy cycle for up to 8 doses; OR
 - iii.** Once every 4 to 12 weeks (e.g., as part of a maintenance regimen); OR
 - iv.** Once weekly for 4 weeks (repeated at 6-month intervals).
- B)** If administered with Zevalin, 250 mg/m² as an IV infusion on Day 1 with the dose repeated on Day 7, 8, or 9 (i.e., two doses).

Duration of Therapy. Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).

- Duration of treatment is usually for four to eight doses unless administered with Zevalin when the duration of treatment is two doses (which are generally separated by 7 to 9 days).
- Some patients will continue on rituximab for maintenance therapy, based on the opinion of the prescribing physician.

NOTE TO NURSE CLINICIAN: Approval duration should align with the criteria and requested dosing up to a maximum 1 year approval per review.

4. Pemphigus Vulgaris. Approve for duration noted if the patient meets ONE of the following (A or B):

- A) Initial Treatment.** Approve for 1 month (two infusions given 2 weeks apart) if the patient meets BOTH of the following (i and ii):
- i.** Rituximab is prescribed by or in consultation with a dermatologist; AND
 - ii.** Rituximab is initiated in combination with a corticosteroid (e.g., prednisone), unless contraindicated; OR
- B) Patient is Being Treated of a Relapse or for Maintenance of Pemphigus Vulgaris.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i.** Rituximab is prescribed by or in consultation with a dermatologist; AND
 - ii.** Subsequent infusions of rituximab will be administered no sooner than 16 weeks following the previous rituximab infusion.

Dosing. Approve the following dosing regimens:

- A)** Two 1,000 mg IV infusions separated by 2 weeks given as initial therapy or treatment of relapse; AND
- B)** Subsequent 500 mg maintenance doses are given every 6 months (minimum of 16 weeks between doses) beginning 12 months following the initial dose.

Duration of Therapy. Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).

NOTE TO NURSE CLINICIAN: Approval duration should align with the criteria and requested dosing up to a maximum 1 year approval per review.

5. **Rheumatoid Arthritis (RA)**. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy**. Approve for 4 months (two infusions given 2 weeks apart) if the patient meets BOTH of the following conditions (i and ii):
- i. History of failure, contraindication or intolerance to at least one tumor necrosis factor (TNF) inhibitors [e.g., adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)]
 - ii. Rituximab IV (Rituxan IV, Truxima) is prescribed by or in consultation with a rheumatologist.
- B) Patient has already Received One or More Courses of Rituximab for Rheumatoid Arthritis (RA)**. Approve for 4 months (two infusions given 2 weeks apart) if the patient meets BOTH of the following conditions (i and ii):
- i. 16 weeks or greater will elapse between treatment courses (i.e., there will be a minimum of 16 weeks since the first dose of the previous rituximab course and the first dose of the next course of rituximab); AND
 - ii. If the patient has already received two or more courses of therapy, the patient has responded to therapy (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids), as determined by the prescribing physician.

Dosing. Approve the following dosing regimen:
Two 500 or 1,000 mg IV infusions separated by 2 weeks.

Duration of Therapy. Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).

- Some patients who do not respond to the initial course will respond to a second course of treatment.^{9,16} Additional courses in a patient with a partial response can lead to an improved response.

The approved dose of rituximab in RA is two 1,000-mg doses separated by 2 weeks; however, two 500-mg doses have also been used and provide a relatively equivalent clinical response.² The higher dose is associated with an earlier response, higher degrees of clinical response, and less radiographic progression compared to the lower dose. Subsequent courses should be administered every 24 weeks based on a clinical evaluation, but not before 16 weeks have elapsed.

Other Uses with Supportive Evidence

6. **Graft-Versus-Host Disease (GVHD)**. Approve for 1 year if the patient meets BOTH of the following (A and B):

- A)** Rituximab IV is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center; AND
- B)** The patient meets ONE of the following conditions (i or ii):

- i. The patient has tried one immunosuppressant for graft-versus-host disease (GVHD) [e.g., one corticosteroid such as methylprednisolone, antithymocyte globulin, cyclosporine, Thalomid® {thalidomide tablets}, tacrolimus, mycophenolate mofetil, sirolimus {Rapamune®, generic}, Nipent® {pentostatin infusion}, imatinib {Gleevec®, generic}, methotrexate, or infliximab {e.g., Remicade, Inflectra}]; OR
- ii. The patient is concurrently receiving at least one of these medications (e.g., one corticosteroid such as methylprednisolone, antithymocyte globulin, cyclosporine, Thalomid, tacrolimus, mycophenolate mofetil, sirolimus, Nipent, imatinib, or methotrexate) in combination with rituximab.

Dosing. Approve the following dosing regimens:

- A) 375 mg/m² IV once weekly for up to four doses; OR
- B) 375 mg/m² IV once weekly for 4 doses followed by a similar infusion once monthly or once every 3 months; OR
- C) 50 mg/m² once weekly for up to four doses.

Duration of Therapy. Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above). Although some cases of GVHD will only receive treatment for up to four doses, some patients with chronic disease may require repeat authorizations.³⁰

NOTE TO NURSE CLINICIAN: Approval duration should align with the criteria and requested dosing up to a maximum 1 year approval per review.

7. Immune Thrombocytopenia (ITP). Approve if the patient meets ONE of the following (A or B):

- A) Initial Therapy. Approve for 1 month if the patient meets BOTH of the following (i and ii):
 - i. Rituximab is prescribed by or in consultation with a hematologist; AND
 - ii. The patient has tried one other therapy (e.g., intravenous immunoglobulin [IVIG], anti-D [RHO] immunoglobulin, corticosteroids, splenectomy).
- B) Patient has Already Received a Course of Rituximab for ITP. Approve for 1 month if the patient meets ALL of the following (i, ii, and iii):
 - i. At least 6 months will elapse between treatment courses (i.e., there will be a minimum of 6 months separating the first dose of the previous rituximab course and the first dose of the requested course of rituximab); AND
 - ii. The patient responded to therapy (e.g., platelet count increased from baseline following treatment with rituximab), as determined by the prescribing physician; AND
 - iii. The prescribing physician has determined that the patient has relapsed (e.g., the patient experiences thrombocytopenia after achievement of a remission).

Dosing. Approve the following dosing regimen: 375 mg/m² IV once weekly for 4 doses.^{3,17}

Duration of Therapy. Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).

- Patients are generally treated with one course of therapy. Retreatment, if necessary, is based on clinical need.

The dose of rituximab IV mentioned in the ASH guidelines for ITP is 375 mg/m² IV once weekly for four doses.³ This dose was also evaluated in a Phase III study that treated patients with ITP with rituximab and dexamethasone.¹⁷ **NOTE:** Low-dose treatment with rituximab IV 100 mg weekly for 4 weeks has been used in a limited number of patients with ITP but clinical efficacy and patient population for this dosing has not been established in a randomized clinical trial.¹⁸ In adults with ITP, studies have found similar efficacy with standard dosing of rituximab IV (375 mg/m² once weekly for 4 weeks) vs. 1,000 mg on Days 1 and 15 (i.e., the RA regimen).²⁶⁻²⁷

8. Multiple Sclerosis. Approve for 1 year if the patient meets BOTH of the following (A and B):

- A)** The patient has had an inadequate response or was unable to tolerate at least ONE other disease-modifying agent for MS (e.g., Ocrevus™ [ocrelizumab IV infusion], Avonex [interferon beta-1a for intramuscular {IM} injection], Rebif [interferon beta-1a SC injection], Betaseron [interferon beta-1b SC injection], Extavia [interferon beta-1b SC injection], Copaxone [glatiramer acetate SC injection], Glatopa [glatiramer acetate SC injection], Plegridy [peginterferon beta-1a SC injection], Gilenya [fingolimod capsules], Aubagio [teriflunomide tablets], Tecfidera [dimethyl fumarate delayed-release capsules], or Lemtrada [alemtuzumab IV injection]); AND
- B)** Rituximab (Rituxan IV, Truxima) is prescribed by or in consultation with a physician who specializes in the treatment of MS and/or a neurologist.

Dosing. Approve the following dosing regimens:

- A)** Initial dose of 500 mg to 2,000 mg (may be divided into two infusions within 1 month).
- B)** Repeat doses of 500 mg to 2,000 mg IV (may be divided into two infusions within 1 month) if at least 6 months has elapsed since the previous dose.

Duration of Therapy. Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).

NOTE TO NURSE CLINICIAN: Approval duration should align with the criteria and requested dosing up to a maximum 1 year approval per review.

9. Neuromyelitis Optica (NMO). Approve for 1 year if rituximab IV is prescribed by or in consultation with a neurologist.

Duration of Therapy. Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).

- There is documentation in the literature of patients using rituximab IV for NMO for up to 7 years.³⁴

NOTE TO NURSE CLINICIAN: Approval duration should align with the criteria and requested dosing up to a maximum 1 year approval per review.

Common practice is to administer a single course of rituximab IV (375 mg/m²) for 4 weeks or 1,000 mg infused twice within 2 weeks for induction. Protocols for maintenance therapy differ and may be selected based on the circulating B-cell repopulation.³⁷

NMO is an autoimmune inflammatory disease on the central nervous system which is characterized by severe attacks of optic neuritis and longitudinally extensive transverse myelitis.³² Guidelines for the treatment of transverse myelitis note that rituximab should be considered to decrease the number of relapses in patients with transverse myelitis due to NMO.³³

10. Systemic Lupus Erythematosus (SLE) [Lupus]. Approve for the duration noted if the patients meets ONE of the following (A or B):

- A) Initial Therapy.** Approve for 1 month (adequate duration to receive one course) if the patient meets BOTH of the following (i and ii):
- i. Rituximab is prescribed by or in consultation with a rheumatologist, nephrologist, or neurologist; AND
 - ii. The patient meets ONE of the following conditions (a or b):
 - a. The patient has neuropsychiatric manifestations of SLE AND has tried at least ONE other therapy (e.g., at least one antidepressant, antipsychotic, corticosteroid, immunosuppressant, or plasma exchange); OR
 - b. The patient has lupus nephritis AND has tried at least ONE immunosuppressant (e.g., mycophenolate mofetil, cyclophosphamide, azathioprine).
- B) Patient has Already Received a Course of rituximab IV for SLE.** Approve for 1 month (adequate duration to receive one course) if 6 months or greater will elapse between treatment courses (i.e., there will be a minimum of 6 months separating the first dose of the previous rituximab course and the first dose of the requested course of rituximab).

Dosing. Approve the requested dose. There are limited data evaluating rituximab in patients with various forms of SLE.

Duration of Therapy. Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).

In one Phase III study that included patients with active proliferative lupus nephritis, the dose used was 1,000 mg administered as an IV infusion on Days 1, 15, 168, and 182.²⁰ In a limited number of pediatric patients, alternative dosages based on body surface area (BSA) [dosed in mg/m²] have been evaluated (e.g., 187.5 mg/m² for one dose followed by 375 mg/m² for three weekly doses) and should also be considered for approval.²¹

11. Patient has been Established on Rituxan. Approve if the patient meets the conditions for coverage required for **Dosing, Extended Approval, Duration of Therapy,** and **Labs/Diagnostics** for an approved use in this *Rituxan Utilization Review* policy.

12. Other Cancer-Related Indications. Forward to the Medical Director for review on a case-by-case basis. Examples of other indications supported in the *NCCN Compendium*, mainly with category 2A or 2B recommendations, include: acute lymphoblastic leukemia (ALL), central nervous system (CNS) cancers (leptomeningeal metastases, primary CNS lymphoma), Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, and Hodgkin's lymphoma (e.g., nodular lymph predominant Hodgkin's disease).⁶

Conditions Not Recommended for Approval.

Rituximab products have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

- 1. Concurrent Use with A Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD.** Rituximab should not be administered in combination with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see [APPENDIX](#) for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of additive efficacy.⁵⁻⁶ Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with rituximab.
- 2. Current Use with Disease-Modifying Agents Used for Multiple Sclerosis (MS).** Rituximab has not been evaluated in combination with other disease-modifying agents used for MS (e.g., Ocrevus, Avonex, Betaseron, Extavia, Rebif, Plegridy, Copaxone, Glatopa, Gilenya, Aubagio, Tecfidera, Tysabri, or Lemtrada); therefore, safety and efficacy have not been adequately established. The concomitant use of rituximab IV with other immune-modulating or immunosuppressive therapies is anticipated to increase the risk of immunosuppression.

SPECIAL CONSIDERATIONS

None.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

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CFR	
WAC	WAC 284-43-2050
RCW	
Contract Citation	<input checked="" type="checkbox"/> WAH <input checked="" type="checkbox"/> IMC <input checked="" type="checkbox"/> MA
Other Requirements	
NCQA Elements	

APPENDIX

Brand (generic name)	Mechanism of Action
Cimzia ® (certolizumab pegol for SC injection)	Inhibition of TNF
Enbrel ® (etanercept for SC injection)	Inhibition of TNF
Erelzi ™ (etanercept-szszs for SC injection)	Inhibition of TNF
Humira ® (adalimumab for SC injection)	Inhibition of TNF
Amjevita ® (adalimumab-atto for SC injection)	Inhibition of TNF
Cyltezo ® (adalimumab-adbm for SC injection)	Inhibition of TNF
Simponi ® (golimumab for SC injection)	Inhibition of TNF
Simponi Aria ™ (golimumab for IV infusion)	Inhibition of TNF
Remicade ® (infliximab for IV infusion)	Inhibition of TNF
Inflectra ™ (infliximab-dyyb for IV infusion)	Inhibition of TNF
Renflexis ® (infliximab-abda for IV infusion)	Inhibition of TNF
Actemra ® (tocilizumab for IV infusion)	Inhibition of IL-6
Actemra ® (tocilizumab for SC injection)	Inhibition of IL-6
Kevzara ® (sarilumab for SC injection)	Inhibition of IL-6
Orencia ® (abatacept for IV infusion)	T-cell costimulation modulator
Orencia ® (abatacept for SC injection)	T-cell costimulation modulator
Rituxan ® (rituximab for IV infusion)	CD20-directed cytolytic antibody
Truxima ® (rituximab-abbs for IV infusion)	CD20-directed cytolytic antibody
Kineret ® (anakinra for subcutaneous SC injection)	Inhibition of IL-1
Stelara ® (ustekinumab for SC injection)	Inhibition of IL-12/23
Stelara ® (ustekinumab for IV infusion)	Inhibition of IL-12/23
Siliq ™ (brodalumab SC injection)	Inhibition of IL-17
Cosentyx ™ (secukinumab for SC injection)	Inhibition of IL-17A
Taltz ® (ixekizumab for SC injection)	Inhibition of IL-17A
Ilumya ™ (tildrakizumab-asmn for SC injection)	Inhibition of IL-23
Tremfya ™ (guselkumab for SC injection)	Inhibition of IL-23
Otezla ® (apremilast tablets)	Inhibition of PDE4
Olumiant ® (baricitinib tablets)	Inhibition of the JAK pathways
Xeljanz ®, Xeljanz XR (tofacitinib tablets, tofacitinib extended-release tablets)	Inhibition of the JAK pathways

SC – Subcutaneous; TNF – Tumor necrosis factor; IV – Intravenous, IL – Interleukin;PDE4 – Phosphodiesterase 4;
JAK – Janus kinase.

Revision History

Revision Date	Revision Description	Revision Made By
01/13/2016	New	Kelly Force; Yusuf Rashid, RPh
01/20/2016	Approval	MMLT
01/12/2017	No revisions	Fran McGaugh
01/13/2017	Approval	MMLT
07/24/2017	Criteria completely updated and revised	Michael Sporck, Pharmacy Intern Sophia Yun, PharmD
07/25/2017	Approved	MMLT
03/09/2018	Reassigned from UM140 to PM129	Cindy Bush
04/27/2018	Transferred to new template	Cindy Bush
05/22/2018	Revised	Jennifer Farley, PharmD
06/14/2018	Approval	UM Committee
04/12/2019	Revised	Ivan Figueira, PharmD
05/20/2019	Approval	UM Pharmacy Subcommittee