POLICY Document for ACTEMRA (tocilizumab)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 3: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 4: Oncology Clinical Policy
- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
AUTOIMMUNE CONDITIONS

PRIMARY PREFERRED PRODUCTS: ENTYVIO, SIMPONI ARIA, SKYRIZI, STELARA

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the autoimmune drug products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Autoimmune Products

	Product(s)
Preferred	• **Entyvio** (vedolizumab) • **Simponi Aria** (golimumab, intravenous) • **Skyrizi** (risankizumab-rzaa) • **Stelara** (ustekinumab)

Targeted	• **Actemra** (tocilizumab) • **Cimzia** (certolizumab pegol) • **Cosentyx** (Secukinumab) • **Ilumya** (tildrakizumab-asmn) • **Orencia** (abatacept) • **Tofidence** (Tocilizumab-bavi) • **Tremfya** (guselkumab) • **Tyenne** (Tocilizumab-aazg) • **Tysabri** (natalizumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. For Actemra, Tofidence, or Tyenne when any of the following criteria is met:
   1. When the request is for Systemic Juvenile Idiopathic Arthritis
   2. When the request is for Giant Cell Arteritis
   3. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   4. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria.

B. For Cimzia, when any of the following criteria is met:
   1. When the request is for Axial Spondylarthritis
   2. Member is pregnant, breastfeeding, or of childbearing potential
   3. Member suffers from Trypanophobia (needle-phobic) and cannot self-inject
   4. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   5. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, Entyvio, and Skyrizi.

C. For Cosentyx, when any of the following criteria is met:
   1. When the request is for Axial Spondylarthritis
   2. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   3. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, and Skyrizi.

D. For Ilumya, when any of the following criteria is met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Stelara and Skyrizi

E. For Orencia, when any of the following criteria is met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.

2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, and Skyrizi.

F. For Tremfya, when any of the following criteria is met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, Entyvio, and Skyrizi.

G. For Tysabri, when any of the following criteria is met:
   1. When the request is for Multiple Sclerosis
   2. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   3. Member has a documented inadequate response, contraindication, or intolerable adverse event to Stelara, Entyvio, and Skyrizi.

Section 2: Site of Care

CareFirst Site of Care Criteria tocilizumab

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Actemra	tocilizumab	intravenous
Avtozma	tocilizumab-anoh	intravenous
Tofidence	tocilizumab-bavi	intravenous
Tyenne	tocilizumab-aazq	intravenous

Criteria For Approval For Administration In Outpatient Hospital Setting

This policy provides coverage for administration of tocilizumab in an outpatient hospital setting for 3 months when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of tocilizumab in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction that did not respond to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
- The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).
- The member has severe venous access issues that require the use of special interventions only available in the outpatient hospital setting.
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of tocilizumab does not meet the criteria for outpatient hospital infusion, coverage for tocilizumab is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
- Medical records supporting the member is medically unstable
- Medical records supporting the member has severe venous access issues that requires specialized interventions only available in the outpatient hospital setting
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Records supporting alternative infusion sites are greater than 30 miles from the member's home.
- Medical records supporting the member is new to therapy

Section 3: Clinical Criteria

Specialty Guideline Management
Actemra and Biosimilars

CVS/caremark

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Actemra	tocilizumab
Avtozma	tocilizumab-anoh
Tofidence	tocilizumab-bavi
Tyenne	tocilizumab-aazq

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1-4]

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs)
- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA)
- Patients 2 years of age and older with active systemic juvenile idiopathic arthritis (sJIA)
- Adult patients with giant cell arteritis (GCA)
- Adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) for slowing the rate of decline in pulmonary function
- 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)
- Hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)

Compendial Uses[5,18]

- Unicentric Castleman disease
- Multicentric Castleman disease
- Oligoarticular juvenile idiopathic arthritis
- Immune checkpoint inhibitor-related toxicity
- Acute graft versus host disease
- Cytokine release syndrome (other than severe or life-threatening CAR T cell-induced CRS)
- Polymyalgia rheumatica

Moderate to severe rheumatoid arthritis with no previous treatment failure

Note: The criteria outlined in this policy is only applicable to coverage in the outpatient setting. Hospitalized members receiving treatment for COVID-19 will be managed according to the member's inpatient benefit.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis (RA)

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Articular juvenile idiopathic arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Systemic juvenile idiopathic arthritis (sJIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Immune checkpoint inhibitor-related toxicity, and acute graft versus host disease (initial requests only)

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Giant cell arteritis (GCA)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Initial requests

Result of a chest high-resolution computed tomography (HRCT) study.

Polymyalgia rheumatica and immune checkpoint inhibitor-related inflammatory arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, articular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, giant cell arteritis, and polymyalgia rheumatica: rheumatologist
- Systemic sclerosis-associated interstitial lung disease: rheumatologist or pulmonologist
- Immune checkpoint inhibitor-related inflammatory arthritis: oncologist, hematologist, or rheumatologist
- Cytokine release syndrome, unicentric Castleman disease, multicentric Castleman disease, acute graft versus host disease, and immune checkpoint inhibitor-related toxicity: oncologist or hematologist

CVS/caremark

Coverage Criteria

Rheumatoid arthritis (RA)[1-4,6,7,14,16-18]

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when either of the following criteria is met:

- Member has been tested for either of the following biomarkers and the test was positive:
  - Rheumatoid factor (RF)
  - Anti-cyclic citrullinated peptide (anti-CCP)
- Member has been tested for ALL of the following biomarkers:
  - RF
  - Anti-CCP
  - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

Articular juvenile idiopathic arthritis[1-4,10,19]

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for active articular juvenile idiopathic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active articular juvenile idiopathic arthritis when any of the following criteria is met:

Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.

Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:

Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
Presence of erosive disease or enthesitis
Delay in diagnosis
Elevated levels of inflammation markers
Symmetric disease

Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and the member also meets one of the following:

High-risk joints are involved (e.g., cervical spine, wrist, or hip)
High disease activity
Is judged to be at high risk for disabling joint disease

Systemic juvenile idiopathic arthritis (sJIA)[1-4,9,19]

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic indicated for active sJIA.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active sJIA when the member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).

Giant cell arteritis (GCA)[1,2,4,5,11]

Authorization of 12 months may be granted for adult members for treatment of giant cell arteritis when the member's diagnosis was confirmed by either of the following:

- Temporal artery biopsy or cross-sectional imaging
- Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP]).

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)[1,15,21,22]

Authorization of 12 months may be granted for adult members for treatment of sclerosis-associated interstitial lung disease when the diagnosis was confirmed by a high-resolution computed tomography (HRCT) study of the chest.

Cytokine release syndrome[1,5]

Authorization of 1 month may be granted for the prophylaxis or treatment of cytokine release syndrome (CRS).

Unicentric Castleman disease[5]

Authorization of 12 months may be granted for treatment of unicentric Castleman disease when all of the following criteria are met:

- The member is human immunodeficiency virus (HIV)-negative.
- The member is human herpesvirus-8-negative.
- The requested medication will be used as a single agent.
- The disease has progressed following treatment of relapsed/refractory disease or has surgically unresectable disease.

Multicentric Castleman disease[5]

Authorization of 12 months may be granted for treatment of multicentric Castleman disease when either of the following criteria is met:

- The member meets both of the following:
  - The requested medication will be used as a single agent.

The disease has progressed following treatment of relapsed/refractory or progressive disease.

The requested medication is being used as a substitute for siltuximab when there is a shortage of siltuximab or it is not available.

Immune checkpoint inhibitor-related toxicity[5]

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and either of the following criteria is met:

Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

Acute graft versus host disease[5]

Authorization of 12 months may be granted for treatment of acute graft versus host disease when either of the following criteria is met:

Member has had an inadequate response to systemic corticosteroids.

Member has an intolerance or contraindication to corticosteroids.

Polymyalgia rheumatica (PMR)[5]

Authorization of 12 months may be granted for treatment of polymyalgia rheumatica (PMR) when any of the following criteria is met:

Member has had an inadequate response to systemic corticosteroids.

Member has had a disease flare during a taper with systemic corticosteroids.

Member has had an inadequate response to methotrexate.

Member has had an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix A).

Continuation of Therapy

Rheumatoid arthritis (RA)[1-4,6,7,14,16-17]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive

clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Articular juvenile idiopathic arthritis[1-4,10,19]

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability

Systemic juvenile idiopathic arthritis (sJIA)[1-4,9,19]

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for sJIA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability
- Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

Giant cell arteritis (GCA)[1,12]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for GCA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Headaches
- Scalp tenderness
- Tenderness and/or thickening of superficial temporal arteries
- Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
- Jaw and/or tongue claudication
- Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
- Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
- Limb claudication

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)[1]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for SSc-ILD when the member is currently receiving treatment with Actemra or Tyenne.

Immune checkpoint inhibitor-related inflammatory arthritis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Cytokine release syndrome, acute graft versus host disease, and immune checkpoint inhibitor-related toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Unicentric Castleman disease and Multicentric Castleman disease

Authorization of 12 months may be granted for continued treatment in members (including new members) who are using the requested medication for Unicentric Castleman disease or Multicentric Castleman disease when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Polymyalgia rheumatica (PMR)

Authorization of 12 months may be granted for continued treatment in members who are using the requested medication for PMR and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Morning stiffness
- Hip or shoulder pain
- Hip or shoulder range of motion
- C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

Other[1-4,13]

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate[20]

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis[19]

- Positive rheumatoid factor
- Positive anti-cyclic citrullinated peptide antibodies
- Pre-existing joint damage

Section 4: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

PROGRAM DESCRIPTION

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness, and efficiency of cancer care so patients can live better lives.[1] It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN Templates® are based on NCCN Guidelines® and NCCN Compendium®. The NCCN Compendium lists the appropriate drugs and biologics as treatment options for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus[2]

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

POLICY

Policy for Regimen Prior Authorization

A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

PROCEDURE

This policy provides coverage of a regimen review when all of the following criteria are met:
1. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal.
   - If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.
2. The prior authorization review is requested for an oncology drug or biologic.
3. The member is eligible for regimen review.
4. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include the following:
   - Ampullary Adenocarcinoma
   - Anal Carcinoma
   - B-Cell Lymphomas
   - Basal Cell Skin Cancer
   - Biliary Tract Cancers
   - Bone Cancer
   - Breast Cancer
   - Bladder Cancer
   - Central Nervous System Cancers
   - Cervical Cancer
   - Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
   - Chronic Myeloid leukemia
   - Colon Cancer
   - Dermatofibrosarcoma Protuberans
   - Esophageal Cancer
   - Gastric Cancer
   - Gastrointestinal Stromal Tumors
   - Gestational Trophoblastic Neoplasms
   - Hairy Cell Leukemia
   - Head and Neck Cancers
   - Histiocytic Neoplasms
   - Hodgkin Lymphoma
   - Hepatocellular Carcinoma
   - Kaposi Sarcoma
   - Kidney Cancer
   - Melanoma: Cutaneous
   - Melanoma: Uveal
   - Merkel Cell Carcinoma

- Mesothelioma: Peritoneal
- Mesothelioma: Pleural
- Multiple Myeloma
- Myelodysplastic Syndromes
- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
- Myeloproliferative Neoplasms
- Neuroendocrine and Adrenal Tumors
- Non-Small Cell Lung Cancer
- Occult Primary
- Ovarian Cancer
- Pancreatic Cancer
- Penile Cancer
- Primary Cutaneous Lymphomas
- Prostate Cancer
- Rectal Cancer
- Small Bowl Adenocarcinoma
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
- Squamous Cell Skin Cancer
- Systemic Mastocytosis
- Systemic Light Chain Amyloidosis
- T-Cell Lymphomas
- Testicular Cancer
- Thymomas and Thymic Carcinomas
- Thyroid Carcinoma
- Uterine Neoplasms
- Vaginal Cancer
- Vulvar Cancer
- Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
- Wilms Tumor (Nephroblastoma)

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Further review may be indicated when the above criteria are not met.

Authorizations may be granted for 12 months or as medically required, based on the member's condition and provider's assessment.

Supportive Care: Myeloid Growth Factor Therapy
Granulocyte colony stimulating factors are recommended for primary prophylaxis based on the febrile neutropenia risk of the chemotherapy regimen. Febrile neutropenia risk levels vary by NCCN Chemotherapy Order template and are listed at the top of the template. Regimens associated with a high or intermediate risk of febrile neutropenia may include a granulocyte colony stimulating factor as part of the prior authorization.

Continuation of Therapy
To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

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SECTION 4

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