Medical Drug Clinical Criteria

Subject:	Monoclonal Antibodies to Interleukin-6		
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Overview

This document addresses the use of monoclonal antibodies which bind to interleukin-6 (IL-6) receptors and inhibit release of proinflammatory cytokines. Indications are drug-specific but IL-6 inhibitors are approved for the treatment of rheumatoid arthritis, giant cell arteritis, polyarticular and systemic juvenile idiopathic arthritis, chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome, and other conditions as applicable. Agents addressed in this clinical guideline include:

- Tocilizumab Agents (Actemra, Tofidence, Tyenne)
- Kevzara (sarilumab)

Actemra is available in intravenous and subcutaneous injection formulations and Kevzara is available in a subcutaneous formulation.

Rheumatoid Arthritis: The American College of Rheumatology (ACR) guidelines recommend disease-modifying antirheumatic drug (DMARD) monotherapy as first-line treatment in individuals with RA with moderate to high disease activity. Methotrexate (MTX) monotherapy, titrated to a dose of at least 15 mg, is recommended over hydroxychloroquine, sulfasalazine, and leflunomide. Methotrexate monotherapy is also recommended over monotherapy with biologics (tumor necrosis factor inhibitors [TNFi], IL-6 inhibitors, abatacept) or JAK inhibitors. For individuals taking maximally tolerated doses MTX who are not at target, the addition of a biologic or JAK inhibitor is recommended. Non-TNFi biologics or JAK inhibitors are conditionally recommended over TNFi in individuals with heart failure.

Juvenile Idiopathic Arthritis: The American College of Rheumatology (ACR) guidelines provide recommendations for juvenile idiopathic arthritis, including systemic disease (SJIA) and JIA with polyarthritis (PJIA). SJIA is an autoinflammatory condition marked by intermittent fever, rash, and arthritis. PJIA is marked by the presence of more than four affected joints in the first six months of illness. For SJIA, NSAIDs or glucocorticoids are conditionally recommended as initial monotherapy, depending on whether macrophage activation syndrome (MAS) is present or not. IL-1 inhibitors (anakinra or canakinumab), or tocilizumab are also conditionally recommended as initial therapy or to achieve inactive disease, with no preferred agent. For SJIA without MAS, IL-1 inhibitors (anakinra or canakinumab) and tocilizumab are strongly recommended for inadequate response to or intolerance of NSAIDs and/or glucocorticoids (ACR 2021). For children with active polyarthritis, biologic therapy including TNFi, abatacept, or tocilizumab +/- DMARD is recommended following initial DMARD therapy (preferably methotrexate) (ACR 2019). Adult-onset Still's Disease (AOSD) describes SJIA when the condition begins after the patient's 16th birthday. Though only canakinumab has been specifically FDA approved for AOSD, other agents used for SJIA may be useful in clinical practice.

Chronic Antibody-Mediated Renal Transplant Rejection: Antibody-mediated rejection is caused by anti-donor-specific antibodies, mostly anti-HLA antibodies. Treatment for acute antibody-mediated rejection (AMR) generally consists of IVIG and rituximab, with or without plasma exchange. Although success has been reported with these therapies, chronic AMR (cAMR) and transplant glomerulopathy remain significant problems that are often unresponsive to current therapies. There is literature (Choi 2017) to support tocilizumab as a treatment option for cAMR and transplant glomerulopathy in human leucocyte antigen (HLA)-sensitive renal allograft recipients. Given limited alternative treatment options and supporting literature, tocilizumab may be an option for cAMR and transplant glomerulopathy who have failed standard therapy.

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD): Interstitial lung disease (ILD) is a common pulmonary manifestation of systemic sclerosis (SSc) and is a leading cause of systemic sclerosis-related death. SSc-ILD presents with fatigue, shortness of breath and dry cough. Diagnosis is based on the presence of characteristic findings of ILD on chest high resolution computed tomography (HRCT) in an individual with SSc and exclusion of other causes of ILD. Actemra was approved for preventing the decline of pulmonary function in adult patients with SSc-ILD. Approval was based on a post-hoc analysis of a randomized, double-blind, placebo-controlled trial of patients with SSc (Khanna 2020). Although primary efficacy endpoint in difference in change from baseline in skin fibrosis was not met, patients in the Actemra arm with ILD at baseline were observed to have less decline in baseline forced vital capacity (FVC) compared to placebo (-255 mL vs -14mL in observed FVC; -6.40% vs 0.07% in percent predicted FVC). The subgroup with ILD had early, mild disease confirmed by HRCT with ppFVC greater than 55% (mean baseline 82%). The American Thoracic Society (ATS) clinical practice guideline on the treatment of systemic sclerosis-associated interstitial lung disease provides

recommendations for the use of mycophenolate (strong recommendation), cyclophosphamide (conditional recommendation), and tocilizumab (conditional recommendation). Recommendations are based on low or very low-quality evidence.

Giant Cell Arteritis (GCA) and Polymyalgia Rheumatica (PMR): GCA is an inflammatory disease marked by vasculitis of large- and medium-sized vessels with common systemic symptoms including fatigue, fever, and weight loss. It is associated with PMR, a more common inflammatory condition characterized by aching and morning stiffness around the shoulders, hip, and neck. Both conditions occur in individuals over the age of 50 and are primarily treated with corticosteroids. Approximately half of individuals with GCA have PMR. Actemra is approved for GCA while Kevzara is approved for PMR; both are initiated with a tapering course of corticosteroids and then continued as monotherapy.

Biosimilar Agents: Biosimilar products must be highly similar to the reference product and there must be no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. Biosimilars must utilize the same mechanism of action (MOA), route of administration, dosage form and strength as the reference product; and the indications proposed must have been previously approved for the reference product. The potential exists for a biosimilar product to be approved for one or more indications for which the reference product is licensed based on extrapolation of data intended to demonstrate biosimilarity in one indication. Sufficient scientific justification for extrapolating data is necessary for FDA approval. Factors and issues that should be considered for extrapolation include the MOA for each indication, the pharmacokinetics, bio-distribution, and immunogenicity of the product in different patient populations, and differences in expected toxicities in each indication and patient population. As biosimilar agents must demonstrate similarity to the reference product in FDA indications, it is reasonable that biosimilarity can be extrapolated to off-label indications as well. There are currently two FDA approved tocilizumab biosimilar agents, Tofidence (tocilizumab-bavi) and Tyenne (tocilizumab-aazg). Tofidence is only available as a single-dose vial; so it can be used in indications where intravenous Actemra is used. In addition, Tofidence only carries the indications for RA, SJIA, and PJIA. The intravenous dosage form of Actemra is additionally approved for cytokine release syndrome (CRS), Coronavirus Disease 2019 (COVID-19), and Giant cell arteritis (GCA). Tyenne is available in the same dosage forms as Actemra (vial and syringe/autoinjector), and is approved for the same indications except for CRS and COVID-19. Off-label indications, including antibody-mediated rejection, graft-versus host disease, Castleman disease, and immunotherapy-related toxicities have primarily used the intravenous form of Actemra. The approval of biosimilars was based on pharmacokinetic data, clinical comparative efficacy data, and extrapolation to selected indications of the reference product. Data support the efficacy and safety of a single switch between reference and biosimilar products (NCT03830203; Zubrzycka-Sienkiewicz 2024).

IL-6 inhibitors have a black box warning for serious infections. Individuals treated with IL-6 inhibitors are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. IL-6 inhibitors should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before IL-6 inhibitor use and during therapy. Treatment for latent TB should be initiated prior to use. Risks and benefits of Il-6 inhibitors should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tocilizumab Agents (Actemra, Tofidence, Tyenne)

Initial requests for Actemra (tocilizumab), Tofidence (tocilizumab-bavi), or Tyenne (tocilizumab-aazg) may be approved for the following:

I. Giant cell arteritis (GCA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with GCA; **AND**
   B. Tocilizumab is used in combination with a tapering course of corticosteroids (such as prednisone); **OR**
   C. Tocilizumab is used as a single agent following discontinuation of corticosteroids;

OR

II. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**
   B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to, or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
   D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

III. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**
   B. Individual has had an inadequate response to, or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate)]; **OR**

C. Individual has a contraindication to methotrexate;

OR

IV. Still's disease (Adult-onset Still's Disease [AOSD] or Systemic juvenile idiopathic arthritis (SJIA) when the following is met:
A. Individual is 2 years of age or older with Still's Disease as either AOSD or SJIA;

OR

V. Multicentric Castleman Disease when each of the following criteria are met (NCCN 2A):
A. Individual with a diagnosis of multicentric Castleman disease; **AND**
B. Disease has progressed following treatment of relapsed/refractory or progressive disease;

OR

VI. Unicentric Castleman Disease when each of the following criteria are met (NCCN 2A):
A. Individual with a diagnosis of relapsed/refractory unicentric Castleman Disease; **AND**
B. Used as a single agent; **AND**
C. Human immunodeficiency virus negative; **AND**
D. Human herpes-8 negative; **AND**

OR

VII. Cytokine Release Syndrome when the following criteria are met:
A. Individual is 2 years of age or older with chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (Label, NCCN 2A); **OR**
B. Individual has acute lymphocytic leukemia and is using tocilizumab for severe blinatumomab- induced CRS;

OR

VIII. Chronic Antibody-Mediated Renal Transplant Rejection when the following criteria are met (Choi 2017):
A. Individual has chronic active antibody-mediated rejection plus donor-specific antibodies and transplant glomerulopathy;
AND
B. Individual has failed to respond to intravenous immune globulin (IVIG) plus rituximab therapy (with or without plasma exchange);

OR

IX. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) when each of the following criteria is met:
A. Individual has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD); **AND**
B. Diagnosis has been demonstrated through chest high resolution computed tomography (HRCT) scan showing ground glass opacification or fibrosis; **AND**
C. Documentation is provided that individual has pulmonary function tests showing Forced Vital Capacity (% FVC) greater than 55% of predicted (Khanna 2020);

OR

X. Coronavirus Disease 2019 (COVID-19) when each of the following criteria are met:
A. Individual is 18 years of age or older; **AND**
B. Individual is currently hospitalized with COVID-19; **AND**
Individual is currently receiving systemic corticosteroids and requires supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO);

OR

XI. Acute Graft-versus-host disease (GVHD) when each of the following criteria are met (NCCN 2A)
A. Individual has a diagnosis of steroid-refractory acute GVHD; **AND**
B. Individual is initiating tocilizumab in combination with systemic corticosteroids;

XII. Immunotherapy-related toxicities when each of the following criteria are met (NCCN 2A):
A. Individual is undergoing immune checkpoint inhibitor therapy for a cancer diagnosis; **AND**
B. Individual is using for one of the following toxicities related immune checkpoint inhibitor therapy:
1. Giant cell arteritis; **OR**
2. Moderate to Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs; **OR**
3. Steroid-refractory polymyalgia rheumatica.

Continuation requests for Actemra (tocilizumab), Tofidence (tocilizumab-bavi), or Tyenne (tocilizumab-aazg) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of Actemra/Tofidence; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Actemra (tocilizumab), Tofidence (tocilizumab-bavi), or Tyenne (tocilizumab-aazg) may not be approved for the following:

I. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, deucravacitinib, nintedanib, pirfenidone, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, other IL-6 inhibitors, rituximab, or natalizumab; **OR**
II. If initiating therapy for a diagnosis other than COVID-19 or CRS, individual has an absolute neutrophil count less than 2000/mm3, platelet count less than 100,000/mm3, or alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limit of normal; **OR**

III. Tuberculosis, other active serious infections or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
IV. If initiating therapy for a diagnosis other than COVID-19 or CRS, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. Individual with SSc-ILD and concomitant class II or higher pulmonary arterial hypertension (Khanna 2020); **OR**
VI. When the above criteria are not met and for all other indications.

Kevzara (sarilumab)

Initial requests for Kevzara (sarilumab) may be approved for the following:

I. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate~~ly~~ to severe RA; **AND**
   B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to, or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
   D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

II. Polymyalgia Rheumatica (PMR) when each of the following criteria are met:
   A. Individual is 18 years of age or older with PMR; **AND**
   B. Individual has had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper; **AND**
   C. Individual has had at least one episode of unequivocal PMR flare (unequivocal symptoms include shoulder and/or hip girdle pain associated with inflammatory stiffness) while on corticosteroid therapy (NCT03600818); **AND**
   E. Kevzara (sarilumab) is used in combination with a tapering course of corticosteroids; **OR**
   F. Kevzara (sarilumab) is used as a single agent following discontinuation of corticosteroids.

Continuation requests for Kevzara (sarilumab) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of Kevzara; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Kevzara (sarilumab) may not be approved for the following:

I. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, other IL-6 inhibitors, rituximab, or natalizumab; **OR**
II. If initiating therapy, individual has an absolute neutrophil count less than 2000/mm3, platelet count less than 150,000/mm3, or alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limits of normal; **OR**
III. Tuberculosis, other active serious infections or a history of recurrent infections [Repeat TB testing not required for ongoing therapy]; **OR**
IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); OR
V. When the above criteria are not met and for all other indications.

Quantity Limits

Tocilizumab Agents Quantity Limit

Drug	Limit
Actemra (tocilizumab) 80 mg, 200 mg, & 400 mg vial for intravenous infusion	8 mg/kg* as frequently as every 4 weeks
Tofidence (tocilizumab-bavi) 80 mg, 200 mg, & 400 mg vial for intravenous infusion	8 mg/kg* as frequently as every 4 weeks
Tyenne (tocilizumab-aazg) 80 mg, 200 mg, & 400 mg vial for intravenous infusion	8 mg/kg* as frequently as every 4 weeks
Override Criteria	
I. For polyarticular juvenile idiopathic arthritis (PJIA), may approve up to 10 mg/kg every 4 weeks for individuals weighing less than 30 kg II. For systemic juvenile idiopathic arthritis (SJIA), may approve up to 12 mg/kg every 2 weeks for patients weighing less than 30 kg and up to 8 mg/kg every 2 weeks for patients at or above 30 kg.	

III. For cytokine release syndrome (CRS), may approve a total of up to four intravenous doses at least 8 hours apart; each dose up to 8 mg/kg for individuals weighing at or above 30 kg and up to 12 mg/kg in individuals weighing less than 30 kg;
IV. For Coronavirus Disease 2019 (COVID-19), may approve a total of up to two intravenous doses at least 8 hours apart; each dose up to 8 mg/kg*.

*For rheumatoid arthritis, CRS, and COVID-19, each dose should not exceed 800mg total; For giant cell arteritis, each dose should not exceed 600 mg total.

Drug	Limit
Actemra (tocilizumab) 162 mg/0.9 mL ACTPen prefilled autoinjector	4 autoinjectors per 28 days
Actemra (tocilizumab) 162 mg/0.9 mL prefilled syringe	4 syringes per 28 days
Tyenne (tocilizumab-aazg) 162 mg/0.9 mL prefilled autoinjector	4 autoinjectors per 28 days
Tyenne (tocilizumab-aazg) 162 mg/0.9 mL prefilled syringe	4 syringes per 28 days

Kevzara (sarilumab) Quantity Limit

Drug	Limit
Kevzara (sarilumab) 150 mg, 200 mg prefilled pen/syringe	2 pens/syringes per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3262	Injection, tocilizumab, 1 mg [Actemra]
C9399	Unclassified drugs or biologicals (Hospital Outpatient Use ONLY) [when specified as sarilumab (Kevzara), (Tyenne)]
J3490	Unclassified drug [when specified as sarilumab (Kevzara)]
J3590	Unclassified biologics [when specified as sarilumab (Kevzara), (Tyenne)]
Q5133	Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg
Q0249	Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, 1 mg.

ICD-10 Diagnosis

C90.00-C95.92	Leukemias
D47.Z2	Castleman disease
M05.00-M05.9	Rheumatoid arthritis with rheumatoid factor
M06.00-M06.09	Rheumatoid arthritis without rheumatoid factor
M06.4	Inflammatory polyarthropathy
M06.80-M06.89	Other specified rheumatoid arthritis
M06.9	Rheumatoid arthritis, unspecified
M08.20-M08.29	Juvenile rheumatoid arthritis with systemic onset
M08.80-M08.89	Other juvenile arthritis
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M31.5	Giant cell arteritis with polymyalgia rheumatica
M31.6	Other giant cell arteritis
M34.81	Systemic sclerosis with lung involvement
M35.3	Polymyalgia rheumatica
R65.10-R65.11	Systemic inflammatory response syndrome (SIRS) of non-infectious origin [cytokine release syndrome]
T86.11	Kidney transplant rejection

T86.12	Kidney transplant failure
T86.19	Other complication of kidney transplant
U07.1	COVID-19
Z94.0	Kidney transplant status

Document History

Revised: 05/17/2024
Document History:

- 05/17/2024 – Annual Review: Add new tocilizumab biosimilar Tyenne to clinical criteria and quantity limit. Coding Reviewed: Added Tyenne to HCPCS C9399, J3590.
- 03/01/2024 – Administrative update to add documentation.
- 11/17/2023 – Annual Review: Add new tocilizumab biosimilar to clinical criteria and add quantity limit for tocilizumab biosimilar; update tocilizumab criteria to include NCCN recommendations in Castleman disease, graft-versus-host disease, cytokine release syndrome and immunotherapy-related toxicities; clarify prior trial requirements regarding contraindications; add continuation of use language; include etrasimod in combination exclusion; clarify ongoing TB testing requirements. Coding Reviewed: Added Tofidence to HCPCS J3490, J3590. Effective 4/1/24 Added HCPCS Q5133 for Tofidence. Removed HCPCS J3490, J3590 for Tofidence.
- 03/13/2023 – Select Review: Update sarilumab criteria to include new FDA approved use in polymyalgia rheumatica; wording and formatting updates. Coding Reviewed: Added ICD-10-CM M35.3.
- 02/24/2023 – Select Review: Update tocilizumab criteria and quantity limit to include new FDA approved us in COVID-19 and clarify may not be approved section per diagnosis. Coding Reviewed: Added ICD-10-CM U07.1.
- 11/18/2022 – Annual Review: Update tocilizumab use in cytokine release syndrome to allow for all severity grades per NCCN, allow use in adult onset stills disease, remove prior trial requirements for systemic juvenile idiopathic arthritis, and update may not approve criteria for pulmonary arterial hypertension per trial exclusion criteria; update tocilizumab intravenous quantity limit to include max dose in giant cell arteritis; update combination exclusion list to include immunomodulator drugs; wording and formatting updates. Coding Reviewed: Added ICD-10-CM M08.80-M08.89.
- 11/19/2021 – Annual Review: Update rheumatoid arthritis criteria to align with guidelines; remove option of TNF failure for consistency; clarify tuberculosis testing language; update references; wording and formatting changes for clarity. Coding Reviewed: No changes.
- 08/01/2021 – Administrative update to add documentation.
- 05/21/2021: Select review: Update Actemra criteria for new indication in systemic sclerosis-associated interstitial lung disease. Coding Reviewed: Added ICD-10-CM M34.81.
- 11/20/2020 – Annual Review: Add continuation of use section; update tuberculosis testing language. Coding Reviewed: No changes.
- 11/15/2019 – Annual Review: Wording and formatting changes; update combination therapy criteria for consistency with other agents. Coding Reviewed: No Changes.
- 09/23/2019 - Administrative update to add drug specific quantity limit.
- 12/10/2018 – Select Review: Add new QL for Actemra ACTPen autoinjector per label.
- 11/16/2018 – Annual Review: Initial P&T review of Monoclonal Antibodies to Interleukin-6 Clinical Guideline - combined Actemra (tocilizumab) and Kevzara (sarilumab) policies. Update clinical criteria to delete “active” disease wording. Update criteria to delete requirement agent is being used “to reduce signs and symptoms, maintain clinical response”, etc. Add examples of conventional therapy to approval criteria for clarity. Update sarilumab QL for clarity. Wording and formatting changes to criteria for consistency. HCPCS coding updated: Added C9399. No ICD-10 changes.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.