REMEDY ONE
A HEALTHIER WAY TO DO BUSINESS

Autoimmune Medical Infused and Injectable Products
Coverage Guidelines

Actemra® (tocilizumab)	*Orencia® (abatacept)*
Cimzia® (certolizumab pegol)	*Simponi Aria® (golimumab)*
Remicade® (infliximab)	*Stelara® (ustekinumab)*

Policy Effective Date: January 1, 2016

Revised: April 1, 2016

Approval Criteria:

ACTEMRA® (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:

Rheumatoid Arthritis (RA)
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).

Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.

Systemic Juvenile Idiopathic Arthritis (SJIA)
Patients 2 years of age and older with active systemic juvenile idiopathic arthritis.

Dosage
Rheumatoid Arthritis

Recommended Adult Intravenous (IV) Dosage:
When used in combination with DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response.

Recommended Adult Subcutaneous (SC) Dosage:

- Patients less than 100 kg weight 162 mg administered subcutaneously every other week, followed by an increase to every week based on clinical response

- Patients at or above 100 kg weight 162 mg administered subcutaneously every week
  Polyarticular Juvenile Idiopathic Arthritis

Recommended Intravenous PJIA Dosage Every 4 Weeks
- Patients less than 30 kg weight 10 mg per kg
- Patients at or above 30 kg weight 8 mg per kg

Systemic Juvenile Idiopathic Arthritis Recommended Intravenous SJIA Dosage Every 2 Weeks
- Patients less than 30 kg weight 12 mg per kg
- Patients at or above 30 kg weight 8 mg per kg

CIMZIA is a tumor necrosis factor (TNF) blocker indicated for:
Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
Treatment of adults with moderately to severely active rheumatoid arthritis
Treatment of adult patients with active psoriatic arthritis.
Treatment of adults with active ankylosing spondylitis

Dosage
CIMZIA is administered by subcutaneous injection. The initial dose of CIMZIA is 400 mg (given as two subcutaneous injections of 200 mg)

Crohn's Disease
400 mg initially and at Weeks 2 and 4. If response occurs, follow with 400 mg every four weeks

Rheumatoid Arthritis
400 mg initially and at Weeks 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4 weeks can be considered.

Psoriatic Arthritis
400 mg initially and at week 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4 weeks can be considered.

ORENCIA is a selective T cell costimulation modulator indicated for:

Adult Rheumatoid Arthritis (RA) - moderately to severely active RA in adults. ORENCIA may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.

Juvenile Idiopathic Arthritis - moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older. ORENCIA may be used as monotherapy or concomitantly with methotrexate

Important Limitations of Use - should not be given concomitantly with TNF antagonists

Dosage
Intravenous Administration for Adult RA

Body Weight of Patient	Dose Number of Vials
Less than 60 kg 500 mg	2
60 to 100 kg 750 mg	3
More than 100 kg 1000 mg	4

Subcutaneous Administration for Adult RA
Administer by subcutaneous injection once weekly with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, administer a single intravenous infusion (as per body weight categories above), followed by the first 125 mg subcutaneous injection given within a day of the intravenous infusion.

Patients transitioning from ORENCIA intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

Intravenous Administration for Juvenile Idiopathic Arthritis
Pediatric patients weighing less than 75 kg receive 10 mg/kg intravenously based on the patient's body weight. Pediatric patients weighing 75 kg or more should be administered ORENCIA following the adult intravenous dosing regimen, not to exceed a maximum dose of 1000 mg.

REMICADE is a tumor necrosis factor (TNF) blocker indicated for:

Crohn's disease
Adult patient (18 years or older)

Pediatric Crohn's disease
Patient at least 6 years of age; AND
Documented moderate to severe disease; AND
Documented trial and failure on ONE conventional oral agent for at least 3 months, unless use is contraindicated, such as mesalamine, corticosteroids, 6-mercaptopurine or azathioprine

Ulcerative colitis
Adult patient (18 years or older); AND
Documented moderate to severe disease; AND
Documented trial and failure on ONE conventional oral therapy such as corticosteroids, 6-mercaptopurine or azathioprine

Pediatric Ulcerative colitis
Patient at least 6 years of age; AND
Documented moderate to severe disease; AND
Documented trial and failure on ONE conventional oral therapy such as corticosteroids, 6-mercaptopurine or azathioprine

Fistulizing Crohn's disease
Adult patient (18 years or older); AND
Documented trial and failure on ONE conventional oral therapy such as corticosteroids, 6-mercaptopurine or azathioprine

Rheumatoid Arthritis (RA)
Adult patient (18 years or older); AND
Documented moderate to severe disease; AND
Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, Imuran, Ridaura, Plaquenil, Cuprimine, Azulfidine, or Arava; AND
Used in combination with methotrexate (MTX) unless contraindicated

Psoriatic Arthritis
Adult patient (18 years or older); AND
Documented moderate to severe active disease; AND

- For patients with predominantly axial disease or severe enthesitis, an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; OR
- Without predominantly axial disease or severe enthesitis: Patient has tried and failed at least a 3 month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine,sulfasalazine, or hydroxychloroquine

Ankylosing Spondylitis

Adult patient (18 years or older); AND

Documented active disease; AND

Patient had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated

Plaque psoriasis
Documented moderate to severe chronic disease (for at least 6 months); AND
Adult patient (18 years or older); AND
Patient must have plaques covering ≥ 10% of their body surface area or <10% of BSA, but with involvement of palms, soles, head and neck, or genitalia which causes disruption of normal activities; AND
Topical therapy is no longer tolerated or effective with agents such as corticosteroids, anthralin, calcipotriene, or tazarotene; AND
Previous treatment failure with phototherapy: (Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol; AND
Patient is a candidate for systemic therapy (i.e., Acitretin, methotrexate, or cyclosporine) with adequate trial and failure or intolerance to treatment

Dosage
REMICADE is administered by intravenous infusion over a period of not less than 2 hours.

Indication	Dose
Rheumatoid Arthritis	Up to 10mg/kg every 4 weeks
Crohn's Disease	Up to 10mg/kg every 8 weeks
Ankylosing Spondylitis	Up to 5mg/kg every 6 weeks
All other indications	Up to 5mg/kg every 8 weeks

SIMPONI ARIA® is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate

Dosage
2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, then every 8 weeks
Dilution of supplied SIMPONI ARIA solution with 0.9% w/v sodium chloride is required prior to administration. Alternatively, 0.45% w/v sodium chloride can also be used.

STELARA® is a human interleukin-12 and -23 antagonist indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy or active psoriatic arthritis (PsA), alone or in combination with methotrexate.

Dosage

STELARA® is administered by subcutaneous injection.

Psoriasis

For patients weighing ≤100 kg (220 lbs.), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.

For patients weighing >100 kg (220 lbs.), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

Psoriatic Arthritis

The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.

For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg (220 lbs.), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

Billing Code

HCPC	HCPC DESCRIPTION
J0717	Injection, certolizumab pegol, 1 mg
J1745	Injection, infliximab, 10 mg
J3262	Injection, tocilizumab, 1 mg
J0129	Injection, abatacept, 10 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J3357	Injection, ustekinumab, 1 mg

Covered Diagnosis Codes

ICD10	DESCRIPTION	ACTEMRA	CIMZIA	ORENCIA	REMICADE	SIMPONI ARIA	STELARA
D36.0	Benign neoplasm of lymph nodes	✓					
D86.0 – D86.9	Sarcoidosis				✓		
E10.10 – E10.9	Type 1 diabetes mellitus			✓			
E10.65	Type 1 diabetes mellitus with hyperglycemia						✓
E10.9	Type 1 diabetes mellitus without complications						✓
H20.041 – H20.049	Secondary noninfectious iridocyclitis (should be billed in conjunction with M35.2)				✓		
H44.111 – H44.119	Panuveitis (should be billed in conjunction with M35.2)				✓		
H44.131 – H44.139	Sympathetic uveitis (should be billed in conjunction with M35.2)				✓		
K31.6	Fistula of stomach and duodenum				✓		

K50.00 – K50.919	Crohn's disease		✓		✓		
K51.00 – K51.919	Ulcerative colitis				✓		
K60.3	Anal fistula				✓		
K60.4	Rectal fistula				✓		
K60.5	Anorectal fistula				✓		
K63.2	Fistula of intestine				✓		
L40.0	Psoriasis vulgaris				✓		✓
L40.50 – L40.59	Arthropathic psoriasis		✓		✓		✓
L40.8	Other psoriasis				✓		✓
M05.00 – M05.09	Felty's syndrome	✓	✓	✓	✓	✓	
M05.10 – M05.19	Rheumatoid lung disease with rheumatoid arthritis	✓	✓	✓	✓	✓	
M05.20 – M05.29	Rheumatoid vasculitis with rheumatoid arthritis	✓	✓	✓	✓	✓	
M05.30 – M05.39	Rheumatoid heart disease with rheumatoid arthritis	✓	✓	✓	✓	✓	
M05.40 – M05.49	Rheumatoid myopathy with rheumatoid arthritis	✓	✓	✓	✓	✓	
M05.50 – M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis	✓	✓	✓	✓	✓	
M05.60 – M05.69	Rheumatoid arthritis with involvement of other organs and systems	✓	✓	✓	✓	✓	
M05.70 – M05.79	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement	✓	✓	✓	✓	✓	
M05.80 – M05.89	Other rheumatoid arthritis with	✓	✓	✓	✓	✓	

	rheumatoid factor						
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified	✓	✓	✓	✓	✓	
M06.00 – M06.09	Rheumatoid arthritis without rheumatoid factor	✓	✓	✓	✓	✓	
M06.20 – M06.29	Rheumatoid bursitis	✓	✓	✓	✓	✓	
M06.30 – M06.39	Rheumatoid nodule	✓	✓	✓	✓	✓	
M06.4	Inflammatory polyarthropathy	✓	✓	✓	✓	✓	
M06.80 – M06.89	Other specified rheumatoid arthritis	✓	✓	✓	✓	✓	
M06.9	Rheumatoid arthritis, unspecified	✓	✓	✓	✓	✓	
M08.00 – M08.09	Unspecified juvenile rheumatoid arthritis	✓		✓	✓		
M08.20 – M08.29	Juvenile rheumatoid arthritis with systemic onset				✓		
M08.3	Juvenile rheumatoid polyarthritis (seronegative)	✓		✓	✓		
M08.40 – M08.48	Pauciarticular juvenile rheumatoid arthritis	✓		✓	✓		
M08.80 – M08.89	Other juvenile arthritis	✓		✓	✓		
M08.80 – M08.99	Juvenile arthritis, unspecified	✓			✓		
M08980 – M08.99	Juvenile arthritis, unspecified			✓			
M12.00 – M12.09	Chronic postrheumatic arthropathy [Jaccoud]	✓	✓	✓	✓	✓	

M31.30 – M31.31	Wegener's granulomatosis				✓		
M34.0 – M34.9	Systemic sclerosis [scleroderma]	✓					
M35.2	Behçet's disease (should be billed in conjunction with H20.041 – H20.049, H44.131 – H44.139 or H44.111 H44.119)				✓		
M45.0 – M45.9	Ankylosing spondylitis		✓		✓		
N82.2	Fistula of vagina to small intestine				✓		
N82.3	Fistula of vagina to large intestine				✓		
N82.4	Other female intestinal-genital tract fistulae				✓		
R59.0	Localized enlarged lymph nodes	✓					
R59.1	Generalized enlarged lymph nodes	✓					

ICD9	DESCRIPTION	ACTEMRA	CIMZIA	ORENCIA	REMICADE	SIMPONI ARIA	STELARA
555.0	Regional enteritis of small intestine		✓		✓		
555.1	Regional enteritis of large intestine		✓		✓		
555.2	Regional enteritis of small intestine with large intestine		✓		✓		
555.9	Regional enteritis of unspecified site		✓		✓		
556.0	Ulcerative (chronic) enterocolitis				✓		
556.1	Ulcerative (chronic) ileocolitis				✓		
556.2	Ulcerative (chronic) proctitis				✓		
556.3	Ulcerative (chronic) proctosigmoiditis				✓		

556.4	Pseudopolyposis of colon				✓		
556.5	Left sided ulcerative (chronic) colitis				✓		
556.6	Universal ulcerative (chronic) colitis				✓		
556.8	Other ulcerative colitis				✓		
556.9	Unspecified ulcerative colitis				✓		
569.81	Fistula of intestine, excluding rectum and anus				✓		
619.1	Digestive-genital tract fistula, female				✓		
696.0	Psoriatic arthropathy				✓		
696.1	Other psoriasis				✓		✓
714.0	Rheumatoid arthritis	✓	✓	✓	✓	✓	
714.1	Felty's syndrome	✓	✓	✓	✓	✓	
714.2	Other rheumatoid arthritis with visceral or systemic involvement	✓	✓	✓	✓	✓	
714.30	Polyarticular juvenile rheumatoid arthritis, chronic or unspecified	✓		✓			
714.31	Polyarticular juvenile rheumatoid arthritis, acute	✓		✓			
714.32	Pauciarticular juvenile rheumatoid arthritis	✓		✓			
714.33	Monoarticular juvenile rheumatoid arthritis	✓		✓			
720.0	Ankylosing spondylitis				✓		

ADMINISTRATION CODES

Code	Code Description	ACTEMRA	CIMZIA	ORENCIA	REMICADE	SIMPONI ARIA	STELARA
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	✓	✓	✓			✓
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic		✓				✓

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	✓		✓	✓	✓	
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure) (Use 96366 in conjunction with 96365, 96367)				✓		
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	✓		✓	✓	✓	
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure) (Use 96415 in conjunction with 96413)				✓		

References

1. Actemra [package insert]. South San Francisco, CA; Genentech, Inc.; November 2014. Accessed April 2016.
2. Cimzia [package insert]. Smyrna, GA; UCB, Inc.; February 2016. Accessed April 2016.
3. Orencia [package insert]. Princeton, NJ; Bristol-Myers Squibb Company. June 2015. Accessed April 2016.
4. Remicade [package insert]. Horsham, PA; Janssen Biotech, Inc.; October 2015. Accessed April 2016.
5. Simponi Aria [package insert]. Horsham, PA; Janssen Biotech, Inc.; March 2016. Accessed April 2016.
6. Stelara [package insert]. Horsham, PA; Janssen Biotech, Inc.; March 2014. Accessed April 2016.