REMEDY ONE
A HEALTHIER WAY TO DO BUSINESS

Autoimmune Products
Coverage Guidelines

Cimzia® (certolizumab pegol)	Enbrel® (etanercept)	Simponi Aria® (golimumab)
Remicade® (infliximab)	Humira® (adalimumab)	Stelara® (ustekinumab)
Actemra® (tocilizumab)	Orencia® (abatacept)	Xeljanz® (tofacitinib)

Policy Effective Date: January 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 DiseaseModifying 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

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.

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

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

Billing Code

HCPC	HCPC DESCRIPTION
J0717	Injection, certolizumab pegol, 1 mg
J1745	Injection, infliximab, 10 mg
J3262	Injection, tocilizumab, 1 mg
J1438	Injection, etanercept, 25 mg
J0135	Injection, adalimumab, 20 mg
J0129	Injection, abatacept, 10 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J3357	Injection, ustekinumab, 1 mg
J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

Covered Diagnosis Codes

Cimzia	
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
714.0	Rheumatoid arthritis

714.1	Felty's syndrome
714.2	Other rheumatoid arthritis with visceral or systemic involvement

Remicade	
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
720.0	Ankylosing spondylitis

Actemra	
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

Enbrel	
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

Humira	
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
696.0	Psoriatic arthropathy
696.1	Other psoriasis

705.83	Hidradenitis
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

Orencia	
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

Simponi Aria	
714.0	Rheumatoid arthritis
714.1	Felty's syndrome
714.2	Other rheumatoid arthritis with visceral or systemic involvement

Stelara	
696.1	Other psoriasis

Xeljanz	
714.0	Rheumatoid arthritis
714.1	Felty's syndrome
714.2	Other rheumatoid arthritis with visceral or systemic involvement

ADMINISTRATION CODES

Cimzia/Humira/Stelara

Code	Code Description
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

Remicade

Code	Code Description
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)

Actemra/Orencia

Code	Code Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

Enbrel

Code	Code Description
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

Simponi Aria

Code	Code Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug