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Initial Coverage Criteria

Actemra® Subcutaneous  
Orencia® Subcutaneous  
Xeljanz®

Rheumatoid Arthritis

Criteria based on 2012 Update of the 2008 ACR Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis and the 2010 EULAR Recommendations for the Management of Rheumatoid Arthritis with Synthetic and Biological Disease-modifying Antirheumatic Drugs.

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Rheumatology.
2. Patient has an FDA-approved diagnosis:
   a. For Actemra and Orencia, a diagnosis of moderate to severe rheumatoid arthritis or juvenile idiopathic arthritis.
   b. For Xeljanz, a diagnosis of moderate to severe rheumatoid arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of DMARD therapy including concurrent use of two or three of the regimens below for at least 3 months:
   a. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
   b. Hydroxychloroquine titrated to 200-400mg daily
   c. Sulfasalazine titrated to 2000mg to 3000mg daily
   d. Leflunomide 10-20mg daily
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. The requested medication is being prescribed according to the FDA-labeled regimen.
6. No other biologic agent will be used concurrently to treat this indication.
Initial Coverage Criteria

Cimzia® Subcutaneous

Ankylosing Spondylitis
Criteria based on ASAS/EULAR Recommendations for the Management of AS, 2010

Treatment goal: Maximize long term health-related quality of life through control of symptoms and inflammation, prevention of progressive structural damage, preservation/normalization of function and social participation.

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Rheumatology.
2. Patient has been diagnosed with ankylosing spondylitis.
3. Patient has had a trial and failure of an appropriate regimen or intolerance or contraindications to all the following first-line therapies:
   a. Continuous treatment with a NSAID at therapeutic doses for one month; and,
   b. For patients with only peripheral disease, local corticosteroid injections when the disease process permits; and,
   c. For patients with only peripheral disease, methotrexate 20mg for at least 3 months OR Sulfasalazine titrated to 2000mg to 3000mg daily for at least 3 months.
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Cimzia is being prescribed according to the FDA-labeled regimen.
6. No other biologic agent will be used concurrently to treat this indication.

Crohn’s Disease
Criteria based on 2014 AGA Institute Guidelines for the Identification, Assessment and Initial Medical Treatment in Crohn’s Disease and 2009 ACG Practice Guidelines for Management of Crohn’s Disease in Adults

Treatment Goal: low disease activity or disease remission

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Gastroenterology.
2. Patient has had ONE of the following:
   a. Treatment with any of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated:
      i. Prednisone 40-60 mg daily
      ii. Oral budesonide 9 mg daily
      iii. Budesonide rectal; OR
   b. Inability to taper off one of the corticosteroid regimens above; OR
   c. Breakthrough disease while stabilized for at least 3 months on one of the following therapies:
      i. Azathioprine 2-3 mg/kg daily
      ii. 6-mercaptopurine 1-1.5 mg/kg daily
      iii. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
3. Patient has tried and failed Humira using the FDA-approved regimen for a duration of at least 3 months.
4. Cimzia is being prescribed according to the FDA-labeled regimen.
5. No other biologic agent will be used concurrently to treat this indication.

Psoriatic Arthritis

*Criteria based on the 2011 Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis*

*Treatment Goal: low disease activity or remission*

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Dermatology or Rheumatology.
2. Patient has been diagnosed with psoriatic arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of each of the regimens below for at least 1 month:
   a. Continuous treatment with a NSAID at therapeutic doses; and,
   b. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Cimzia is being prescribed according to the FDA-labeled regimen.
6. No other biologic agent will be used concurrently to treat this indication.

Rheumatoid Arthritis

*Criteria based on 2012 Update of the 2008 ACR Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis and the 2010 EULAR Recommendations for the Management of Rheumatoid Arthritis with Synthetic and Biological Disease-modifying Antirheumatic Drugs.*

*Treatment Goal: low disease activity or remission*

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Rheumatology.
2. Patient has been diagnosed with moderate to severe rheumatoid arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of DMARD therapy including concurrent use of two or three of the regimens below for at least 3 months:
   a. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
   b. Hydroxychloroquine titrated to 200-400mg daily
   c. Sulfasalazine titrated to 2000mg to 3000mg daily
   d. Leflunomide 10-20mg daily
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Cimzia is being prescribed according to the FDA-labeled regimen.
6. No other biologic agent will be used concurrently to treat this indication.
**Initial Coverage Criteria**

**Cosentyx®**

**Ankylosing Spondylitis**
*Criteria based on ASAS/EULAR Recommendations for the Management of AS, 2010*

*Treatment goal: Maximize long term health-related quality of life through control of symptoms and inflammation, prevention of progressive structural damage, preservation/normalization of function and social participation.*

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Rheumatology.
2. Patient has been diagnosed with ankylosing spondylitis.
3. Patient has had a trial and failure of an appropriate regimen or intolerance or contraindications to all the following first-line therapies:
   a. Continuous treatment with a NSAID at therapeutic doses for one month; and,
   b. For patients with only peripheral disease, local corticosteroid injections when the disease process permits; and,
   c. For patients with only peripheral disease, methotrexate 20mg for at least 3 months OR Sulfasalazine titrated to 2000mg to 3000mg daily for at least 3 months.
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Cosentyx is being prescribed according to the FDA-labeled regimen.
6. No other biologic agent will be used concurrently to treat this indication.

**Plaque Psoriasis**
*Criteria based on 2012 Consensus Guidelines for the Management of Plaque Psoriasis and the 2011 Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis*

*Treatment Goal: low disease activity or remission*

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Dermatology.
2. Patient has been diagnosed with severe psoriasis defined as at least 10% body surface area (BSA) or palmar/plantar involvement.
3. Patient has had a trial and failure (BSA involvement is not improved) of an appropriate regimen or intolerance or contraindications to concurrent use of at least two of the regimens below for at least 12 weeks:
   a. Topical corticosteroid therapy
   b. Phototherapy: at least 20-30 treatments given 2-3 times weekly HP will purchase home units (See the Home Phototherapy medical policy)
   c. Methotrexate 5mg-15mg weekly (GI intolerance requires trial of SC/IM methotrexate at 5mg-15mg weekly) in combination with folic acid supplementation
   d. Cyclosporine at a dose of at least 2.5 – 5 mg/kg/day until disease control achieved
   e. Acitretin at a dose of at least 25 mg daily
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Cosentyx is being prescribed according to the FDA-labeled regimen.
6. The treatment goals and monitoring plan are documented in the medical record.
7. No other biologic agent will be used concurrently to treat this indication.

Psoriatic Arthritis

Criteria based on the 2011 Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Dermatology or Rheumatology.
2. Patient has been diagnosed with psoriatic arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of concurrent use of the regimens below for at least 1 month:
   a. Continuous treatment with a NSAID at therapeutic doses; and,
   b. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months, or there are concerns about immunosuppression for this patient.
5. Cosentyx is being prescribed according to the FDA-labeled regimen.
6. No biologic agent will be used concurrently to treat this indication.
Initial Coverage Criteria

Enbrel®

Ankylosing Spondylitis
Criteria based on ASAS/EULAR Recommendations for the Management of AS, 2010

Treatment goal: Maximize long term health-related quality of life through control of symptoms and inflammation, prevention of progressive structural damage, preservation/normalization of function and social participation.

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Rheumatology.
2. Patient has been diagnosed with ankylosing spondylitis.
3. Patient has had a trial and failure of an appropriate regimen or intolerance or contraindications to all the following first-line therapies:
   a. Continuous treatment with a NSAID at therapeutic doses for one month; and,
   b. For patients with only peripheral disease, local corticosteroid injections when the disease process permits; and,
   c. For patients with only peripheral disease, methotrexate 20mg for at least 3 months OR Sulfasalazine titrated to 2000mg to 3000mg daily for at least 3 months.
4. Enbrel is being prescribed according to the FDA-approved treatment regimen.
5. No other biologic agent will be used concurrently to treat this indication.

Plaque Psoriasis

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Dermatology.
2. Patient has been diagnosed with severe psoriasis defined as at least 10% body surface area (BSA) or palmar/plantar involvement.
3. Patient has had a trial and failure (BSA involvement is not improved) of an appropriate regimen or intolerance or contraindications to concurrent use of at least two of the regimens below for at least 12 weeks:
   a. Topical corticosteroid therapy
   b. Phototherapy: at least 20-30 treatments given 2-3 times weekly
      HP will purchase home units (See the Home Phototherapy medical policy)
   c. Methotrexate 5mg-15mg weekly (GI intolerance requires trial of SC/IM methotrexate at 5mg-15mg weekly) in combination with folic acid supplementation
   d. Cyclosporine at a dose of at least 2.5 – 5 mg/kg/day until disease control achieved
   e. Acitretin at a dose of at least 25 mg daily
4. Enbrel is being prescribed according to the FDA-approved treatment regimen of a maintenance dose of 50mg once weekly.
5. The treatment goals and monitoring plan are documented in the medical record.
6. No other biologic agent will be used concurrently to treat this indication.
Psoriatic Arthritis

Criteria based on the 2011 Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Dermatology or Rheumatology.
2. Patient has been diagnosed with psoriatic arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of each of the regimens below for at least 1 month:
   a. Continuous treatment with a NSAID at therapeutic doses; and,
   b. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
4. Enbrel is being prescribed according to the FDA-approved treatment regimen of a maintenance dose of 50mg once weekly.
5. No other biologic agent will be used concurrently to treat this indication.

Rheumatoid Arthritis

Criteria based on 2012 Update of the 2008 ACR Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis and the 2010 EULAR Recommendations for the Management of Rheumatoid Arthritis with Synthetic and Biological Disease-modifying Antirheumatic Drugs.

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Rheumatology.
2. Patient has been diagnosed with moderate to severe rheumatoid arthritis or polyarticular juvenile idiopathic arthritis.
3. Enbrel is being used first-line in a patient who has high disease activity and features of poor prognosis (per the ACR guidelines), OR
4. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of DMARD therapy including concurrent use of two or three of the regimens below for at least 3 months:
   a. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
   b. Hydroxychloroquine titrated to 200-400mg daily
   c. Sulfasalazine titrated to 2000mg to 3000mg daily
   d. Leflunomide 10-20mg daily
5. Enbrel is being prescribed according to the FDA-approved treatment regimen.
6. No other biologic agent will be used concurrently to treat this indication.
Initial Coverage Criteria

Humira®

Ankylosing Spondylitis
Criteria based on ASAS/EULAR Recommendations for the Management of AS, 2010

Treatment goal: Maximize long term health-related quality of life through control of symptoms and inflammation, prevention of progressive structural damage, preservation/normalization of function and social participation.

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Rheumatology.
2. Patient has been diagnosed with ankylosing spondylitis.
3. Patient has had a trial and failure of an appropriate regimen or intolerance or contraindications to all the following first-line therapies:
   a. Continuous treatment with a NSAID at therapeutic doses for one month; and,
   b. For patients with only peripheral disease, local corticosteroid injections when the disease process permits; and,
   c. For patients with only peripheral disease, methotrexate 20mg for at least 3 months OR Sulfasalazine titrated to 2000mg to 3000mg daily for at least 3 months.
4. Humira is being prescribed according to the FDA-approved treatment regimen.
5. No other biologic agent will be used concurrently to treat this indication.

Crohn’s Disease
Criteria based on 2014 AGA Institute Guidelines for the Identification, Assessment and Initial Medical Treatment in Crohn’s Disease and 2009 ACG Practice Guidelines for Management of Crohn’s Disease in Adults

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Gastroenterology.
2. Patient is using Humira as first line therapy for fistulizing and severe disease (as defined by the ACG guidelines), OR
3. Patient has had ONE of the following:
   a. Treatment with any of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated:
      i. Prednisone 40-60 mg daily
      ii. Oral budesonide 9 mg daily
      iii. Budesonide rectal; OR
   b. Inability to taper off one of the corticosteroid regimens above; OR
   c. Breakthrough disease while stabilized for at least 3 months on one of the following therapies:
      i. Azathioprine 2-3 mg/kg daily
      ii. 6-mercaptopurine 1-1.5 mg/kg daily
      iii. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
4. Humira is being prescribed according to the FDA-approved treatment regimen of a maintenance dose of 40 mg every other week.
5. No other biologic agent will be used concurrently to treat this indication.
**Hidradenitis Suppurativa**
Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Dermatology.
2. Patient has been diagnosed with moderate to severe hidradenitis suppurativa.
3. Humira is being prescribed according to the FDA-approved treatment regimen of a maintenance dose of 40 mg every week.
4. No other biologic agent will be used concurrently to treat this indication.

**Plaque Psoriasis**
*Criteria based on 2012 Consensus Guidelines for the Management of Plaque Psoriasis and the 2011 Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis*

*Treatment Goal: low disease activity or remission*

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Dermatology.
2. Patient has been diagnosed with severe psoriasis defined as at least 10% body surface area (BSA) or palmar/plantar involvement.
3. Patient has had a trial and failure (BSA involvement is not improved) of an appropriate regimen or intolerance or contraindications to concurrent use of at least two of the regimens below for at least 12 weeks:
   a. Topical corticosteroid therapy
   b. Phototherapy: at least 20-30 treatments given 2-3 times weekly  
      HP will purchase home units (See the Home Phototherapy medical policy)
   c. Methotrexate 5mg-15mg weekly (GI intolerance requires trial of SC/IM methotrexate at 5mg-15mg weekly) in combination with folic acid supplementation
   d. Cyclosporine at a dose of at least 2.5 – 5 mg/kg/day until disease control achieved
   e. Acitretin at a dose of at least 25 mg daily
4. Humira is being prescribed according to the FDA-approved treatment regimen of a maintenance dose of 40 mg every other week.
5. The treatment goals and monitoring plan are documented in the medical record.
6. No other biologic agent will be used concurrently to treat this indication.

**Psoriatic Arthritis**
*Criteria based on the 2011 Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis*

*Treatment Goal: low disease activity or remission*

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Dermatology or Rheumatology.
2. Patient has been diagnosed with psoriatic arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of each of the regimens below for at least 1 month:
   a. Continuous treatment with a NSAID at therapeutic doses; and,
   b. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
4. Humira is being prescribed according to the FDA-approved treatment regimen of a maintenance dose of 40 mg every other week.
5. No other biologic agent will be used concurrently to treat this indication.
Rheumatoid Arthritis

*Criteria based on 2012 Update of the 2008 ACR Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis and the 2010 EULAR Recommendations for the Management of Rheumatoid Arthritis with Synthetic and Biological Disease-modifying Antirheumatic Drugs.*

*Treatment Goal: low disease activity or remission*

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Rheumatology.
2. Patient has been diagnosed with moderate to severe rheumatoid arthritis or juvenile idiopathic arthritis.
3. Patient is using Humira as first line therapy due to high disease activity and features of poor prognosis (per the ACR guidelines), OR
4. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of DMARD therapy including concurrent use of two or three of the regimens below for at least 3 months:
   a. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
   b. Hydroxychloroquine titrated to 200-400mg daily
   c. Sulfasalazine titrated to 2000mg to 3000mg daily
   d. Leflunomide 10-20mg daily
5. Humira is being prescribed according to the FDA-approved treatment regimen.
6. No other biologic agent will be used concurrently to treat this indication.

Ulcerative Colitis

*Criteria based on 2009 Ulcerative Colitis Practice Guidelines in Adults: ACG Practice Parameters Committee*

*Treatment Goal: low disease activity or remission*

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Gastroenterology.
2. Patient is using Humira as first line therapy for severe disease (as defined by the ACG guidelines), OR
3. Patient has breakthrough disease or trial and failure or intolerance or contraindications to use of at least two of the systemic regimens below for at least 12 weeks:
   a. Sulfasalazine 4-6 gram daily
   b. Mesalamine 2-4.8 gram daily
   c. Balsalazide 6.75 grams
   d. Corticosteroid regimens:
      i. Prednisone 40-60 mg daily
      ii. Oral budesonide 9 mg daily
      iii. Budesonide rectal; OR
   e. Azathioprine 1.5-2.5 mg/kg daily
   f. 6-mercaptopurine 1-1.5 mg/kg daily
4. Humira is being prescribed according to the FDA-approved treatment regimen of a maintenance dose of 40 mg every other week.
5. The treatment goals and monitoring plan are documented in the medical record.
6. No other biologic agent will be used concurrently to treat this indication.
Uveitis

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Ophthalmology, other retinal specialist, Rheumatology, or another specialist in consultation with a retinal specialist.
2. Patient has been diagnosed with non-infectious intermediate, posterior or panuveitis
3. Humira is being prescribed according to the FDA-approved treatment regimen of a maintenance dose of 40 mg every week.
4. No other biologic agent will be used concurrently to treat this indication.
Initial Coverage Criteria

Kineret®

Cryopyrin-Associated Periodic Syndromes (CAPS)

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed by a specialist.
2. Patient has been diagnosed with Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndromes (FCAS) and Muckle-Wells Syndrome (MWS).
3. Patient is 4 years of age or older.
4. Kineret is being prescribed according to the FDA-approved treatment regimen.
5. No other biologic agent will be used concurrently to treat this indication.

Rheumatoid Arthritis

Criteria based on 2012 Update of the 2008 ACR Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis and the 2010 EULAR Recommendations for the Management of Rheumatoid Arthritis with Synthetic and Biological Disease-modifying Antirheumatic Drugs.

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Rheumatology.
2. Patient has a diagnosis of moderate to severe rheumatoid arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of DMARD therapy including concurrent use of two or three of the regimens below for at least 3 months:
   a. Methotrexate 20mgweekly (GI intolerance requires trial of SC/IM methotrexate at 20mgweekly)
   b. Hydroxychloroquine titrated to 200-400mg daily
   c. Sulfasalazine titrated to 2000mg to 3000mg daily
   d. Leflunomide 10-20mg daily
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. The requested medication is being prescribed according to the FDA-labeled regimen.
6. No other biologic agent will be used concurrently to treat this indication.


Initial Coverage Criteria

Otezla®

Plaque Psoriasis


Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Dermatology.
2. Patient has been diagnosed with severe psoriasis defined as at least 10% body surface area (BSA) or palmar/plantar involvement.
3. Patient has had a trial and failure (BSA involvement is not improved) of an appropriate regimen or intolerance or contraindications to concurrent use of at least two of the regimens below for at least 12 weeks:
   a. Topical corticosteroid therapy
   b. Phototherapy: at least 20-30 treatments given 2-3 times weekly
      HP will purchase home units (See the Home Phototherapy medical policy)
   c. Methotrexate 5mg-15mg weekly (GI intolerance requires trial of SC/IM methotrexate at 5mg-15mg weekly) in combination with folic acid supplementation
   d. Cyclosporine at a dose of at least 2.5 – 5 mg/kg/day until disease control achieved
   e. Acitretin at a dose of at least 25 mg daily
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months, or there are concerns about immunosuppression for this patient.
5. Otezla is being prescribed according to the FDA-labeled regimen.
6. The treatment goals and monitoring plan are documented in the medical record.
7. No biologic agent will be used concurrently to treat this indication.

Psoriatic Arthritis

Criteria based on the 2011 Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Dermatology or Rheumatology.
2. Patient has been diagnosed with psoriatic arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of each of the regimens below for at least 1 month:
   a. Continuous treatment with a NSAID at therapeutic doses; and,
   b. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months, or there are concerns about immunosuppression for this patient.
5. Otezla is being prescribed according to the FDA-labeled regimen.
6. No biologic agent will be used concurrently to treat this indication.
Initial Coverage Criteria

Simponi® Subcutaneous

Ankylosing Spondylitis
Criteria based on ASAS/EULAR Recommendations for the Management of AS, 2010

Treatment goal: Maximize long term health-related quality of life through control of symptoms and inflammation, prevention of progressive structural damage, preservation/normalization of function and social participation.

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Rheumatology.
2. Patient has been diagnosed with ankylosing spondylitis.
3. Patient has had a trial and failure of an appropriate regimen or intolerance or contraindications to all the following first-line therapies:
   a. Continuous treatment with a NSAID at therapeutic doses for one month; and,
   b. For patients with only peripheral disease, local corticosteroid injections when the disease process permits; and,
   c. For patients with only peripheral disease, methotrexate 20mg for at least 3 months OR Sulfasalazine titrated to 2000mg to 3000mg daily for at least 3 months.
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Simponi is being prescribed according to the FDA-labeled regimen.
6. No other biologic agent will be used concurrently to treat this indication.

Psoriatic Arthritis
Criteria based on the 2011 Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:
1. Prescribed and followed by Dermatology or Rheumatology.
2. Patient has been diagnosed with psoriatic arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of each of the regimens below for at least 1 month:
   a. Continuous treatment with a NSAID at therapeutic doses; and,
   b. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Simponi is being prescribed according to the FDA-labeled regimen.
6. No other biologic agent will be used concurrently to treat this indication.

Rheumatoid Arthritis
Criteria based on 2012 Update of the 2008 ACR Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis and the 2010 EULAR Recommendations for the Management of Rheumatoid Arthritis with Synthetic and Biological Disease-modifying Antirheumatic Drugs.
**Treatment Goal: low disease activity or remission**

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Rheumatology.
2. Patient has been diagnosed with moderate to severe rheumatoid arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of DMARD therapy including concurrent use of two or three of the regimens below for at least 3 months:
   a. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
   b. Hydroxychloroquine titrated to 200-400mg daily
   c. Sulfasalazine titrated to 2000mg to 3000mg daily
   d. Leflunomide 10-20mg daily
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Simponi is being prescribed according to the FDA-labeled regimen.
6. No other biologic agent will be used concurrently to treat this indication.

**Ulcerative Colitis**

*Criteria based on 2009 Ulcerative Colitis Practice Guidelines in Adults: ACG Practice Parameters Committee*

**Treatment Goal: low disease activity or remission**

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Gastroenterology.
2. Patient has breakthrough disease or trial and failure or intolerance or contraindications to use of at least two of the systemic regimens below for at least 12 weeks:
   a. Sulfasalazine 4-6 gram daily
   b. Mesalamine 2-4.8 gram daily
   c. Balsalazide 6.75 grams
   d. Corticosteroid regimens:
      i. Prednisone 40-60 mg daily
      ii. Oral budesonide 9 mg daily
      iii. Budesonide rectal; OR
   e. Azathioprine 1.5-2.5 mg/kg daily
   f. 6-mercaptopurine 1-1.5 mg/kg daily
3. Patient has tried and failed Humira using the FDA-approved regimen for a duration of at least 3 months.
4. Simponi is being prescribed according to the FDA-labeled regimen.
5. The treatment goals and monitoring plan are documented in the medical record.
6. No other biologic agent will be used concurrently to treat this indication.
Initial Coverage
Criteria

Stelara®
Subcutaneous

Plaque Psoriasis

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Dermatology.
2. Patient has been diagnosed with severe psoriasis defined as at least 10% body surface area (BSA) or palmar/plantar involvement.
3. Patient has had a trial and failure (BSA involvement is not improved) of an appropriate regimen or intolerance or contraindications to concurrent use of at least two of the regimens below for at least 12 weeks:
   a. Topical corticosteroid therapy
   b. Phototherapy: at least 20-30 treatments given 2-3 times weekly
      HP will purchase home units (See the Home Phototherapy medical policy)
   c. Methotrexate 5mg-15mg weekly (GI intolerance requires trial of SC/IM methotrexate at 5mg-15mg weekly) in combination with folic acid supplementation
   d. Cyclosporine at a dose of at least 2.5 – 5 mg/kg/day until disease control achieved
   e. Acitretin at a dose of at least 25 mg daily
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Stelara prescribing and administration is in accordance with the following:
   a. Dosing: 45 mg for patients weighing </= 100kg, 90 mg for patients weighing > 100kg every 12 weeks (submission of weight is required)
   b. Professional administration is preferred for quarterly monitoring of disease control by specialist
   c. In addition to all of the above criteria, self-administration also requires demonstrated medical necessity due to the cost of each dose of the medication
      i. Hardship of traveling to provider/office scheduling
      ii. Medical chart documentation of the monitoring plan
      iii. Pharmacy personnel will contact patient to educate and ensure proper storage/administration/adherence to drug and monitoring plan.
6. The treatment goals and monitoring plan are documented in the medical record.
7. No other biologic agent will be used concurrently to treat this indication.
Psoriatic Arthritis

Criteria based on the 2011 Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis

Treatment Goal: low disease activity or remission

Initial requests meeting the following criteria will be approved for one year:

1. Prescribed and followed by Dermatology or Rheumatology.
2. Patient has been diagnosed with psoriatic arthritis.
3. Patient has had a trial and failure or intolerance or contraindications to an appropriate regimen of each of the regimens below for at least 1 month:
   a. Continuous treatment with a NSAID at therapeutic doses; and,
   b. Methotrexate 20mg weekly (GI intolerance requires trial of SC/IM methotrexate at 20mg weekly)
4. Patient has tried and failed both Humira AND Enbrel using the FDA-approved regimens for each for a duration of at least 3 months.
5. Stelara prescribing and administration is in accordance with the following:
   a. Prescribed according to the FDA-approved regimen of a maintenance dose of 45 mg every 12 weeks.
      i. For patients with concurrent plaque psoriasis weighing > 100kg a maintenance dose of 90mg every 12 weeks may be used (submission of weight is required)
   b. Professional administration is preferred for quarterly monitoring of disease control by specialist
   c. In addition to all of the above criteria, self-administration also requires demonstrated medical necessity due to the cost of each dose of the medication
      i. Hardship of traveling to provider/office scheduling
      ii. Medical chart documentation of the monitoring plan
      iii. Pharmacy personnel will contact patient to educate and ensure proper storage/administration/adherence to drug and monitoring plan
6. No other biologic agent will be used concurrently to treat this indication.
Renewal/Reauthorization Criteria
Applies to all drugs with their associated diagnoses listed in this document

Regimens up to FDA-approved doses and frequencies
Renewals will be provided annually when the following questions are answered:
1. The patient has been examined by this office within the last fourteen months. Y/N
2. Check one of the following:
   a. This patient has achieved low disease activity or remission.
   b. This patient has achieved sufficient disease control to continue this agent.
   c. If neither of the above, please indicate why the drug should be continued.

Regimens more intense (dose or interval) than the FDA-approved regimen
All requests will require provider attestation of the following each year that the regimen remains higher than an FDA-approved regimen:
1. I attest that the use of DMARD therapy in combination with this biologic has been tried and failed to provide an acceptable level of disease control or it is contraindicated or unacceptable toxicity resulted.
2. I attest that there is clinical rationale for why dosing for this drug should be increased beyond the FDA-approved regimen rather than switching to an alternative agent.
3. The patient will be seen and disease control assessed at least annually.
4. I attest that prior to escalating the dose, I assessed this patient’s compliance to therapy at the FDA-approved dosing regimen.