GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist
   - previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 18 years of age or older
   - patient will not be on concurrent therapy with another TNF inhibitors (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agents (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Ocrevus, or Rituxan)
   - previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

If yes, approve for a total of 4 months. Please enter two authorizations as follows:
   - Approve for 1 fill for #1 Starter kit (enter quantity 3 for a starter kit of 6 prefilled syringes) OR for #3 kits (enter quantity 3 for a package of 6 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) for the first month then,
   - Approve for 3 months for #1 kit (enter quantity 1 for a package of 2 vials or prefilled syringes) per month.

APPROVAL TEXT: Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. If no, continue to #2.
INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist or dermatologist
   - previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 18 years of age or older
   - patient will not be on concurrent therapy with another TNF inhibitors (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agents (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Orencia, or Rituxan)
   - previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

If yes, approve for a total of 4 months. Please enter two authorizations as follows:
- Approve for 1 fill for #1 Starter kit (enter quantity 3 for a starter kit of 6 prefilled syringes) OR for #3 kits (enter quantity 3 for a package of 6 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) for the first month then,
- Approve for 3 months for #1 kit (enter quantity 1 for a package of 2 vials or prefilled syringes) per month.

APPROVAL TEXT: Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. If no, continue to #3.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meets all of the following criteria?
   • therapy initiated by or in consultation with a rheumatologist
   • 18 years of age or older
   • patient will not be on concurrent therapy with another TNF inhibitors (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agents (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Ocrevus, or Rituxan)
   • previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

   If yes, approve for a total of 4 months. Please enter two authorizations as follows:
   • Approve for 1 fill for #1 Starter kit (enter quantity 3 for a starter kit of 6 prefilled syringes) OR for #3 kits (enter quantity 3 for a package of 6 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) for the first month then,
   • Approve for 3 months for #1 kit (enter quantity 1 for a package of 2 vials or prefilled syringes) per month.

   APPROVAL TEXT: Renewal requires that the patient experienced or maintained an improvement of at least 50% or 2 units in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).
   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meets all of the following criteria?
   - therapy initiated by or in consultation with a gastroenterologist
   - previous trial or contraindication to one or more of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - 18 years of age or older
   - patient will not be on concurrent therapy with another TNF inhibitors (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agents (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Ocrevus, or Rituxan)
   - previous trial with the preferred TNF (tumor necrosis factor) inhibitor: Humira

If yes, approve for a total of 3 months. Please enter two authorizations as follows:
   - Approve for 1 fill for #1 Starter kit (enter quantity 3 for a starter kit of 6 prefilled syringes) OR for #3 kits (enter quantity 3 for a package of 6 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) for the first month then,
   - Approve for 2 months for #1 kit (enter quantity 1 for a package of 2 vials or prefilled syringes) per month.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT: Our guideline for CERTOLIZUMAB PEGOL requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, or moderate to severe Crohn's disease. Additional guideline requirements apply.

For patients with moderate to severe rheumatoid arthritis, all of the following criteria are required:

- therapy initiated by or in consultation with a rheumatologist
- previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- 18 years of age or older
- patient will not be on concurrent therapy with another TNF inhibitors (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agents (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Ocrevus, or Rituxan)
- previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Humira and Enbrel

For patients with psoriatic arthritis, all of the following criteria are required:

- therapy initiated by or in consultation with a rheumatologist or dermatologist
- previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- 18 years of age or older
- patient will not be on concurrent therapy with another TNF inhibitors (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agents (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Ocrevus, or Rituxan)
- previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Humira and Enbrel

For patients with ankylosing spondylitis, all of the following criteria are required:

- therapy initiated by or in consultation with a rheumatologist
- 18 years of age or older
- patient will not be on concurrent therapy with another TNF inhibitors (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agents (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Ocrevus, or Rituxan)
- previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Humira and Enbrel

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe Crohn's disease, all of the following criteria are required:

- therapy initiated by or in consultation with a gastroenterologist
- previous trial or contraindication to one or more of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- 18 years of age or older
- patient will not be on concurrent therapy with another TNF inhibitors (Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria) or any other biologic DMARD (disease-modifying antirheumatic drug) agents (Actemra, Kineret, Stelara, Cosentyx, Entyvio, Tysabri, Orecia, or Rituxan)
- previous trial with the preferred formulary TNF (tumor necrosis factor) inhibitor: Humira

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets the following criteria?
   - documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy
   
   If yes, approve for 12 months for #1 kit per month (enter quantity 1 for a package of 2 vials or prefilled syringes).
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets the following criteria?
   - documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

   If yes, approve for 12 months for #1 kit per month (enter quantity 1 for a package of 2 vials or prefilled syringes).
   If no, continue to #3.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meets the following criteria?
   • documentation that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

   If yes, approve for 12 months for #1 kit per 28 days (enter quantity 1 for a package of 2 vials or prefilled syringes).
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn’s disease (CD)?

   If yes, approve for 12 months for #1 kit per month (enter quantity 1 for a package of 2 vials or prefilled syringes).
   If no, do not approve.

DENIAL TEXT: Our guideline for CERTOLIZUMAB PEGOL renewal requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, or moderate to severe Crohn's disease. Additional guideline requirements apply.

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:
   • documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy.

Renewal for the diagnosis of psoriatic arthritis requires:
   • documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy.

Renewal for the diagnosis of ankylosing spondylitis requires:
   • documentation of at least a 50% improvement or increase of 2 units from baseline on the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index).

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of prior authorization requests for Cimzia.

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CERTOLIZUMAB PEGOL

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.

**Ankylosing Spondylitis:** 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.

FDA APPROVED INDICATIONS
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.

REFERENCES

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