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) agent such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - concurrent use of methotrexate (unless contraindicated)
   - 18 years of age or older
   - patient will not be on concurrent therapy with Orencia or Kineret
   - previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

   If yes, approve for 4 months by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.
   APPROVAL TEXT: Renewal requires that the patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count.
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets all of the following criteria?
   - therapy initiated by 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) agent such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - concurrent use of methotrexate (unless contraindicated)
   - 18 years of age or older
   - patient will not be on concurrent therapy with Orencia or Kineret
   - previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

   If yes, approve for 4 months for by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.
   APPROVAL TEXT: Renewal requires that the patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count.
   If no, continue to #3.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe 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 Orencia or Kineret
   - previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

   If yes, approve for 4 months by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.
   APPROVAL TEXT: Renewal requires documentation that he 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 no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meets all of the following criteria?
   - therapy initiated by or in consultation with a gastroenterologist
   - previous trial with 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 Orencia or Kineret
   - previous trial with the preferred TNF (tumor necrosis factor) inhibitor: Humira

   If yes, approve for 12 months and enter two authorizations by GPID as follows:
   - Approve 1 fill of 2mL of the 100mg prefilled SmartJect autoinjectors or syringes.
   - Approve 12 fills of 1mL of the 100mg prefilled SmartJect autoinjectors or syringes.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline for GOLIMUMAB - SQ requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe ankylosing spondylitis, or moderate to severe ulcerative colitis. Additional guideline requirements apply.

For patients with moderate to severe rheumatoid arthritis, approval requires all of the following:
- therapy initiated by or in consultation with a rheumatologist
- previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agent such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- concurrent use of methotrexate (unless contraindicated)
- 18 years of age or older
- patient will not be on concurrent therapy with Orencia or Kineret
- previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

For patients with psoriatic arthritis, approval requires all of the following:
- 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) agent such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- concurrent use of methotrexate (unless contraindicated)
- 18 years of age or older
- patient will not be on concurrent therapy with Orencia or Kineret
- previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

For patients with moderate to severe ankylosing spondylitis, approval requires all of the following:
- therapy initiated by or in consultation with a rheumatologist
- 18 years of age or older
- patient will not be on concurrent therapy with Orencia or Kineret
- previous trial with the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

For patients with moderate to severe ulcerative colitis, approval requires all of the following:
- therapy initiated by or in consultation with a gastroenterologist
- previous trial with 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 Orencia or Kineret
- previous trial with the preferred TNF (tumor necrosis factor) inhibitor: Humira

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RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets all of 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
   - concurrent use of methotrexate (unless contraindicated)

   If yes, approve for 12 months by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets all of 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
   - concurrent use of methotrexate (unless contraindicated)

   If yes, approve for 12 months by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe 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 by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.
   If no, continue to #4.

4. Does the patient have moderate to severe ulcerative colitis (UC)?

   If yes, approve for 12 months by GPID for 1mL of the 100mg prefilled SmartJect autoinjector or syringe per 28 days.
   If no, do not approve.

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

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline for GOLIMUMAB - SQ renewal requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe ankylosing spondylitis, or moderate to severe ulcerative colitis. Additional guideline requirements apply.

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires all of the following:
- documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy
- concurrent use of methotrexate (unless contraindicated)

Renewal for the diagnosis of psoriatic arthritis requires all of the following:
- documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy
- concurrent use of methotrexate (unless contraindicated)

Renewal for the diagnosis of moderate to severe ankylosing spondylitis requires the following:
- 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)

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

DOSAGE
RA, PsA, and AS: 50 mg administered by subcutaneous injection once a month
UC: 200 mg initially administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2 and then 100 mg every 4 weeks

FDA APPROVED INDICATIONS
Simponi 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
- Active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Active ankylosing spondylitis (AS)

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FDA APPROVED INDICATIONS (CONTINUED)

- Moderate to severe Ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy
  - Inducing and maintaining clinical response
  - Improving endoscopic appearance of the mucosa during induction
  - Inducing clinical remission
  - Achieving and sustaining clinical remission in induction responders

REFERENCES


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