HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

GOLIMUMAB (SIMPONI) SUBCUTANEOUS INJECTION

Generic	Brand	HICL	GCN	Exception/Other
GOLIMUMAB	SIMPONI		22533, 22536, 34697, 35001	ROUTE = SUBCUTANE.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with a diagnosis of moderate to severe rheumatoid arthritis (RA) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with **ONE** of the following:
     - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
     - Biologic agent approved for RA (e.g., Simponi, Enbrel, Humira)
   - Previous trial with **TWO** of the following: Enbrel, Humira, or Xeljanz

   If yes, continue to #5.
   If no, continue to #2.

2. Is the request for a patient with a diagnosis of psoriatic arthritis (PsA) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist or dermatologist
   - Trial with **ONE** of the following:
     - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
     - Biologic agent approved for PsA (e.g., Simponi, Enbrel, Humira)
   - Previous trial with **TWO** of the following: Enbrel, Humira, Stelara, or Xeljanz

   If yes, continue to #5.
   If no, continue to #3.

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GOLIMUMAB (SIMPONI) SUBCUTANEOUS INJECTION

INITIAL CRITERIA (CONTINUED)

3. Is the request for a patient with a diagnosis of ankylosing spondylitis (AS) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial with **ONE** of the following:
     - At least one prescription-strength NSAID (non-steroidal anti-inflammatory drug) such as: celecoxib, diclofenac, ibuprofen, naproxen, or meloxicam
     - Biologic agent approved for AS (e.g., Simponi, Enbrel, Humira)
   - Previous trial with Enbrel or Humira

   If yes, continue to #5.
   If no, continue to #4.

4. Is the request for a patient with a diagnosis of moderate to severe ulcerative colitis (UC) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a gastroenterologist
   - Trial with a biologic agent approved for UC (e.g., Simponi, Humira, Xeljanz) **OR** a trial with at least two of the following conventional therapies:
     - Corticosteroids (such as prednisone, prednisolone, methylprednisolone, budesonide)
     - 5-Aminosalicylates (such as sulfasalazine, mesalamine, olsalazine, balsalazide)
     - Immunosuppressants/Immunomodulators (such as 6-mercaptopurine, azathioprine, methotrexate)
   - Previous trial with Humira and Xeljanz

   If yes, continue to #5.
   If no, do not approve. Please use status code #238 and the denial text provided.

   DENIAL TEXT (if diagnosis not met): Per your health plan's Golimumab (Simponi) Subcutaneous Injection guideline, this medication is only covered for one of the following conditions: Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, or Ulcerative Colitis. Your provider did not indicate that you are being treated for any of these conditions and therefore your request was not approved.
   (Initial denial text continued on next page)

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GOLIMUMAB (SIMPONI) SUBCUTANEOUS INJECTION

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (RA): Per your health plan's Golimumab (Simponi) Subcutaneous Injection guideline, this medication is only covered for moderate to severe Rheumatoid Arthritis (RA) when you meet all of the following conditions:

- Patient is 18 years of age or older
- Prescribed by (or in consultation with) a rheumatologist
- Trial with one of the following:
  - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
  - Biologic agent approved for RA (e.g., Simponi, Enbrel, Humira), which also require prior authorization
- Previous trial with two of the following, which also require prior authorization: Enbrel, Humira, or Xeljanz

Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (PsA): Per your health plan's Golimumab (Simponi) Subcutaneous Injection guideline, this medication is only covered for Psoriatic Arthritis (PsA) when you meet all of the following conditions:

- Patient is 18 years of age or older
- Prescribed by (or in consultation with) a rheumatologist or dermatologist
- Trial with one of the following:
  - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
  - Biologic agent approved for PsA (e.g., Simponi, Enbrel, Humira), which also require prior authorization
- Previous trial with two of the following, which also require prior authorization: Enbrel, Humira, Stelara, or Xeljanz

Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

DENIAL TEXT (AS): Per your health plan's Golimumab (Simponi) Subcutaneous Injection guideline, this medication is only covered for Ankylosing Spondylitis when you meet all of the following conditions:

- Patient is 18 years of age or older
- Prescribed by (or in consultation with) a rheumatologist
- Trial with one of the following:
  - At least one prescription-strength NSAID (non-steroidal anti-inflammatory drug) such as: celecoxib, diclofenac, ibuprofen, naproxen, or meloxicam
  - Biologic agent approved for AS (e.g., Simponi, Enbrel, Humira), which also require prior authorization
- Previous trial with Enbrel or Humira, each of which also require prior authorization

Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

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INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (UC): Per your health plan's Golimumab (Simponi) Subcutaneous Injection guideline, this medication is only covered for moderate to severe Ulcerative Colitis (UC) when you meet all of the following conditions:

- Patient is 18 years of age or older
- Prescribed by (or in consultation with) a gastroenterologist
- Trial with a biologic agent approved for UC (e.g., Simponi, Humira, Xeljanz), which also require prior authorization OR a trial with at least two of the following conventional therapies:
  - Corticosteroids (such as prednisone, prednisolone, methylprednisolone, budesonide)
  - 5-Aminosalicylates (such as sulfasalazine, mesalamine, olsalazine, balsalazide)
  - Immunosuppressants/Immunomodulators (such as 6-mercaptopurine, azathioprine, methotrexate)
- Previous trial with Humira and Xeljanz, both of which also require prior authorization

Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

5. **Approve for 12 months by GPID up to 13 fills.** (Simponi is hard-coded with a quantity of one syringe/pen per 30 days.) Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for Simponi subcutaneous **[____mg/mL syringe/pen]** has been approved for a 12-month period for a quantity of one syringe/pen per month.

   If the request is for ulcerative colitis and is a new start, approve the 100 mg pens and syringes for 12 months by GPID up to 13 fills with a force quantity of 3 for the first 28 days. Please enter an override with an 'F'. [The quantity limit is hard-coded]. Please use status code #056 and the approval text provided.
   APPROVAL TEXT (UC): Your request for Simponi has been approved for a 12-month period with a quantity of three 100 mg syringes or pens for the first month and then one 100 mg syringe or pen per month for the remaining 11 months.

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GOLIMUMAB (SIMPONI) SUBCUTANEOUS INJECTION

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the request meet **ALL** of the following criteria?
   - Prescribed for one of the following diagnoses: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, or ulcerative colitis
   - Prescribed by (or in consultation with) a dermatologist, rheumatologist, or gastroenterologist
   - Documentation that the patient experienced improvement while on therapy

   If yes, **approve for 12 months by GPID up to 13 fills.** (Simponi is hard-coded with a quantity of one syringe/pen per 30 days.) Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for Simponi subcutaneous injection **[____mg/mL syringe/pen]** has been approved for a 12-month period for a quantity of one syringe/pen per month.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Golimumab (Simponi) Subcutaneous Injection guideline, authorization for renewal requires that you meet **ALL** of the following conditions:
   - Prescribed for one of the following diagnoses: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, or ulcerative colitis
   - Prescribed by (or in consultation with) a dermatologist, rheumatologist, gastroenterologist
   - Documentation that the patient experienced improvement while on therapy

   Your provider did not indicate **[specific criteria not met]**, and therefore your request was not approved.

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RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of prior authorization requests for golimumab. Promote use of preferred products Humira and Enbrel when appropriate.

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)
- 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

Dosing:

- **Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis:** 50 mg administered by subcutaneous injection once a month
- **Ulcerative Colitis:** 200 mg initially administered by subcutaneous injection at week 0, followed by 100 mg at week 2 and then 100 mg every 4 weeks

REFERENCES

- Centocor Ortho Biotech, Inc. Simponi package insert. Horsham, PA. May 2018.
- Inman RD, Davis JC, Heijde D, et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis. Arthritis & Rheumatism. 2008; 58(11): 3402-3412.
- Kavanaugh A, McInnes I, Mease P, et al. Golimumab, a new human tumor necrosis factor α antibody administered every four weeks as a subcutaneous injection in psoriatic arthritis. Arthritis & Rheumatism. 2009; 60(4): 976-986.

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