STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLIMUMAB - SQ	SIMPONI		22533 22536 34697 35001	GPI-14 (6627004000D540) (6627004000E540) (6627004000D520) (6627004000E520)	

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 meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient is currently using or has a contraindication to methotrexate

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   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)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

     If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

     If no, continue to #5.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had a trial of or contraindication to the preferred agent Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for a total of 6 months by GPID or GPI-14 and enter two authorizations as follows:**
     - **FIRST APPROVAL: Approve 1 month of the 100 mg/mL prefilled syringe OR SmartJect autoinjector with a quantity limit of #3 mL per 28 days.**
     - **SECOND APPROVAL: Approve 5 months of the 100 mg/mL prefilled syringe OR SmartJect autoinjector with a quantity limit of #1 mL per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

     If no, do not approve.
     INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for approval:
     A. You have ONE of the following diagnoses:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Psoriatic arthritis (PsA: a type of skin and joint condition)
        3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
        4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You are currently using or have a contraindication (harmful for) to methotrexate
   5. You meet ONE of the following:
      a. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancerous), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You had a trial of or contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

D. **If you have moderate to severe ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   4. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You had a trial of or contraindication (harmful for) to ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
4. You had a trial of or contraindication (harmful for) to the preferred medication Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GOLIMUMAB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient is currently using or has a contraindication to methotrexate

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, continue to #4.

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RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - 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) while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

     If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to the preferred agent Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months of the 100 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #1 mL per 28 days.**

     If no, do not approve.
     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for renewal:
     A. You have ONE of the following diagnoses:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Psoriatic arthritis (PsA: a type of skin and joint condition)
        3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
        4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication (harmful for) to methotrexate
   3. You meet ONE of the following:
      a. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancerous), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

D. **If you have moderate to severe ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (diagnostic test to determine the effectiveness of drug therapy) while on therapy
   2. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You had a trial of or contraindication (harmful for) to the preferred medication Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GOLIMUMAB - SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi.

REFERENCES

- Simponi [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 06/09
Client Approval: 07/23
P&T Approval: 04/23