



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

**GUSELKUMAB**

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GUSELKUMAB	TREMFYA	44418		GPI-10 (9025054200)	

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) 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 dermatologist
  - The patient had a trial of or contraindication to ONE or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine

If yes, continue to #2.

If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
  - The patient was previously stable on another biologic (e.g., Cimzia [certolizumab], Cosentyx [secukinumab]) and switching to the requested drug
  - The patient has psoriasis covering 3% or more of body surface area (BSA)
  - The patient has psoriatic lesions affecting the hands, feet, genital area, or face

If yes, **approve for 6 months by entering TWO approvals by HICL or GPI-10 as follows:**

- **FIRST APPROVAL: approve for 1 month with a quantity limit of #1mL per 28 days.**
- **SECOND APPROVAL: approve for 5 months with a quantity limit of #1mL per 56 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval)**

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

If yes, **approve for 6 months by entering TWO approvals by HICL or GPI-10 as follows:**

- **FIRST APPROVAL:** approve for 1 month with a quantity limit of #1mL per 28 days.
- **SECOND APPROVAL:** approve for 5 months with a quantity limit of #1mL per 56 days. (Please enter a start date of 3 WEEKS AFTER the START 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 **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
  2. Psoriatic arthritis (PsA: a type of skin and joint condition)
- B. **If you have moderate to severe plaque psoriasis, approval also requires:**
1. You are 18 years of age or older
  2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
  3. You had a trial of or contraindication (harmful for) to ONE or more forms of standard therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
  4. You meet ONE of the following criteria:
    - a. You were previously stable on another biologic (such as Cimzia [certolizumab], Cosentyx [secukinumab]) and switching to the requested drug
    - b. You have psoriasis covering 3% or more of body surface area (BSA)
    - c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

***(Initial denial text continued on next page)***

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INITIAL CRITERIA (CONTINUED)

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

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**  
If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**  
If no, do not approve.

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

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RENEWAL CRITERIA (CONTINUED)

**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 **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

- A. You have ONE of the following diagnoses:
  1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
  2. Psoriatic arthritis (PsA: a type of skin and joint condition)
- B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
  1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
- 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

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.

**RATIONALE**

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

**REFERENCES**

- Tremfya [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/23

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