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 given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to at least **ONE** or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   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 #2mL (#2 100mg/mL syringes)**
   - **SECOND APPROVAL: approve for 5 months with a quantity limit of #1mL (#1 100mg/mL syringe) per 56 days (Please enter a start date of 1 WEEK AFTER the END date of the first approval)**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that 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 no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   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 #2mL (#2 100mg/mL syringes)**
   - **SECOND APPROVAL: approve for 5 months with a quantity limit of #1mL (#1 100mg/mL syringe) per 56 days (Please enter a start date of 1 WEEK AFTER the END 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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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

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; dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA; joint pain and swelling)

B. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   4. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   5. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older

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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GUSELKUMAB

GUIDELINES FOR USE (CONTINUED)

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 (#1 100mg/mL syringe) per 56 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL (#1 100mg/mL syringe) per 56 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 **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; dry, itchy skin patches with scales)
      2. Psoriatic arthritis (PsA; joint pain and swelling)
   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

   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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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: 08/24/20

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P&T Approval: 10/20