SECUKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SECUKINUMAB	COSENTYX	41715		GPI-10 (9025057500)	

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) without psoriatic arthritis involvement 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 form of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
   FIRST APPROVAL
   - **150mg every week dosing: Approve 1 fill for a quantity of 5mL (5 syringes/pens) with an end date of 1 month. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every week dosing: Approve 1 fill for a quantity of 10mL (10 syringes/pens) with an end date of 1 month. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   SECOND APPROVAL
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 1mL (1 syringe/pen) per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 2mL (2 syringes/pens) per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis without psoriatic arthritis involvement 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 while on therapy.

   If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. 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 given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or a contraindication to at least **ONE** DMARD (disease-modifying anti-rheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #3.
   If no, continue to #6.

3. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)? (**Note:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.)

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
   FIRST APPROVAL
   - **150mg every week dosing: Approve 1 fill for a quantity of 5mL (5 syringes/pens) with an end date of 1 month. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every week dosing: Approve 1 fill for a quantity of 10mL (10 syringes/pens) with an end date of 1 month. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   SECOND APPROVAL
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 1mL (1 syringe/pen) per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 2mL (2 syringes/pens) per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   APPROVAL TEXT: Renewal requires that the patient has met **ONE** of the following criteria:
   - For the diagnosis of psoriatic arthritis (PsA), the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.
     OR
   - For the diagnosis of moderate to severe plaque psoriasis (PsO), 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 while on therapy.

   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Is the request for treatment of psoriatic arthritis (PsA) with a loading dose?

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
   FIRST APPROVAL
   - **150mg every week dosing: Approve 1 fill for a quantity of 5mL (5 syringes/pens) with an end date of 1 month. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

   SECOND APPROVAL
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 1mL (1 syringe/pen) per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 2mL (2 syringes/pens) per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #5.

5. Is the request for treatment of psoriatic arthritis (PsA) without a loading dose?

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
   - **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   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)

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) 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 rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the request for the treatment of ankylosing spondylitis (AS) with a loading dose?

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
   FIRST APPROVAL
   - **150mg every week dosing: Approve 1 fill for a quantity of 5mL (5 syringes/pens) with an end date of 1 month. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

   SECOND APPROVAL
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 1mL (1 syringe/pen) per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 2mL (2 syringes/pens) per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   APPROVAL TEXT: Renewal for ankylosing spondylitis requires 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) while on therapy.

   If no, continue to #8.

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INITIAL CRITERIA (CONTINUED)

8. Is the request for treatment of ankylosing spondylitis (AS) without a loading dose?

If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**

- **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
- **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

APPROVAL TEXT: Renewal for ankylosing spondylitis requires 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) while on therapy.

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 **SECUKINUMAB (Cosentyx)** 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 with red scaly skin patches)
3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)

B. If you have moderate to severe plaque psoriasis (PsO), approval also requires:
1. You are 18 years of age and older
2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
3. 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
4. You have previously tried at least ONE or more form of standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

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INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis (PsA), approval also requires:
1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
3. You have previously tried at least ONE DMARD (disease-modifying anti-rheumatic drugs), unless there is a medical reason why you cannot (contraindication): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. If you have ankylosing spondylitis (AS), approval also requires:
1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

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 has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy?

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for 12 months with the following quantity limits:**
   - **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   If no, continue to #2.

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RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for 12 months with the following quantity limits:**
   - **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and 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?

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for 12 months with the following quantity limits:**
   - **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   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 **SECUKINUMAB (Cosentyx)** 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 with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)

B. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires** that 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 while on therapy.

C. **If you have psoriatic arthritis (PsA), renewal also requires** that you have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

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RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis (AS), renewal also requires that 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 (BASDAI) 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 Cosentyx.

REFERENCES

- Cosentyx [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/16/20
Created: 02/15
Client Approval: 02/20
P&T Approval: 10/19