STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
   - 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.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to THREE of the preferred agents: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to FOUR of the following preferred agents: Taltz (ixekizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength and dosage form by NDC for a total of 6 months as follows:**
     FIRST APPROVAL
     - **75mg every week dosing: Approve for 1 month with a quantity limit of #2mL per 28 days. (PAC NOTE: Enter NDC 00078-1056-97 only)**
     - **150mg every week dosing: Approve for 1 month with a quantity limit of #4mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
     - **300mg every week dosing: Approve for 1 month with a quantity limit of #8mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 or 00078-1070-68 only)**

     SECOND APPROVAL
     - **75mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #0.5mL per 28 days. (PAC NOTE: Enter NDC 00078-1056-97 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**
     - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**
     - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 or 00078-1070-68 only. Start date is 3 DAYS BEFORE 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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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or a contraindication to ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #4.
   If no, continue to #7.

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Stelara (ustekinumab)
     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve the requested strength and dosage form by NDC for a total of 6 months as follows:**
   FIRST APPROVAL
   - **75mg every week dosing: Approve for 1 month with a quantity limit of #2mL per 28 days. (PAC NOTE: Enter NDC 00078-1056-97 only)**
   - **150mg every week dosing: Approve for 1 month with a quantity limit of #4mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

   SECOND APPROVAL
   - **75mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #0.5mL per 28 days. (PAC NOTE: Enter NDC 00078-1056-97 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**

   If no, continue to #5.

5. Is the patient 18 years of age or older **AND** meet the following criterion?
   - The patient had a trial of or contraindication to THREE of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

6. 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 for a total of 6 months as follows:**
   FIRST APPROVAL
   - **150mg every week dosing: Approve for 1 month with a quantity limit of #4mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every week dosing: Approve for 1 month with a quantity limit of #8mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 or 00078-1070-68 only)**

   SECOND APPROVAL
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**
   - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 or 00078-1070-68 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**

   If no, continue to #8.

7. 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 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), Taltz (ixekizumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #8.
   If no, continue to #13.

8. Does the patient require a loading dose?

   If yes, continue to #9.
   If no, continue to #11.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

9. Is the request for a maintenance dosage of 300mg?

   If yes, continue to #10.
   If no, **approve the 150mg dosage by NDC for a total of 6 months as follows:**
   FIRST APPROVAL
   - **150mg every week dosing: Approve for 1 month with a quantity limit of #4mL per 28 days. (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 per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**

10. Has the patient tried the 150mg maintenance dosing schedule **AND** continues to have active ankylosing spondylitis or active psoriatic arthritis?

    If yes, **approve by NDC for a total of 6 months as follows:**
    FIRST APPROVAL
    - **150mg every week dosing: Approve for 1 month with a quantity limit of #4mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

    SECOND APPROVAL
    - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 or 00078-1070-68 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.
    PAC NOTE: Enter proactive PAs for the 150mg dosage by NDC for a total of 6 months as follows:
    FIRST APPROVAL
    - **150mg every week dosing: Approve for 1 month with a quantity limit of #4mL per 28 days. (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 per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**

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INITIAL CRITERIA (CONTINUED)

11. Is the request for a maintenance dosage of 300mg?

    If yes, continue to #12.
    If no, **approve the 150mg dosage by NDC for 6 months with a quantity limit of #1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only).**

12. Has the patient tried the 150mg maintenance dosing schedule **AND** continues to have active ankylosing spondylitis or active psoriatic arthritis?

    If yes, **approve the 300mg dosage by NDC for 6 months with a quantity limit of #2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 or 00078-1070-68 only).**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.
    PAC NOTE: Enter a proactive PA for the 150mg maintenance dosage by NDC for 6 months with a quantity limit of #1mL per 28 days. Enter NDC 00078-0639-68 or 00078-0639-97 only.

13. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) 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 meets ONE of the following objective signs of inflammation:
      - C-reactive protein (CRP) levels above the upper limit of normal
      - Sacroiliitis on magnetic resonance imaging (MRI)
    - The patient had a trial of or contraindication to TWO of the following preferred agents: Taltz (ixekizumab), Cimzia (certolizumab), Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, continue to #14.
    If no, continue to #16.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

14. Is the request for the treatment of non-radiographic axial spondyloarthritis (nr-axSpA) with a loading dose?

    If yes, **approve the requested strength and dosage form by NDC for a total of 6 months as follows:**
    FIRST APPROVAL
    - **150mg every week dosing: Approve for 1 month with a quantity of #4mL per 28 days. (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 per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**

    If no, continue to #15.

15. Is the request for the treatment of non-radiographic axial spondyloarthritis (nr-axSpA) without a loading dose?

    If yes, **approve the requested strength and dosage form by NDC for a total of 6 months as follows:**
    - **150mg every 4 weeks dosing: #1mL per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

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

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

16. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) and meet **ALL** of the following criteria?
    - The patient is 4 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), sulfasalazine, OR methotrexate

    If yes, **approve the requested strength and dosage form by NDC for a total of 6 months as follow:**
    FIRST APPROVAL
    - **75mg every week dosing: Approve for 1 month with a quantity limit of #2mL per 28 days. (PAC NOTE: Enter NDC 00078-1056-97 only.)**
    - **150mg every week dosing: Approve for 1 month with a quantity limit of #4mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only.)**

    SECOND APPROVAL
    - **75mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #0.5mL per 28 days. (PAC NOTE: Enter NDC 00078-1056-97 only. Start date is 3 DAYS BEFORE the END date of the first approval.)**
    - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of #1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 DAYS BEFORE 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 **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: a type of skin condition)
        2. Psoriatic arthritis (PsA: a type of skin and joint condition)
        3. Ankylosing spondylitis (AS: a type of joint condition)
        4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
        5. Enthesitis-related arthritis (ERA: a type of joint condition)

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INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You had a trial of or contraindication (harmful) 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
   5. You meet ONE of the following:
      a. You are 6 to 17 years of age AND had a trial of or contraindication (harmful for) to THREE of the preferred medications: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)
      b. You are 18 years of age or older AND had a trial of or contraindication (harmful for) to FOUR of the following preferred medications: Taltz (ixekizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 2 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) to ONE DMARD (disease-modifying anti-rheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
   4. Request for 300mg dosage in psoriatic arthritis without coexisting plaque psoriasis requires you have tried the 150mg maintenance dosing schedule AND continue to have active psoriatic arthritis
   5. You meet ONE of the following:
      a. You are 2 to 5 years of age
      b. You are 6 to 17 years of age AND had a trial of or contraindication (harmful for) to the preferred medication: Stelara (ustekinumab)
      c. You are 18 years of age or older AND had a trial of or contraindication (harmful for) to THREE of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz IR/XR (tofacitinib immediate release or extended release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have 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 (such as ibuprofen, naproxen, meloxicam)
   4. Request for 300mg dosage requires you have tried the 150mg maintenance dosage schedule AND continue to have active ankylosing spondylitis
   5. You had a trial or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Taltz (ixekizumab), Xeljanz IR/XR (tofacitinib immediate release or extended release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

E. **If you have non-radiographic axial spondyloarthritis, 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 (such as ibuprofen, naproxen, meloxicam)
   4. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP: a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)
   5. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Taltz (ixekizumab), Cimzia (certolizumab), Rinvoq (upadacitinib)

F. **If you have enthesitis-related arthritis, approval also requires:**
   1. You are 4 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 (such as ibuprofen, naproxen, meloxicam), sulfasalazine, OR methotrexate

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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SECUKINUMAB

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 while on therapy

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

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to THREE of the preferred agents: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to FOUR of the following preferred agents: Taltz (ixekizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength and dosage form by NDC for 12 months with the following quantity limits:**
     - **75mg every 4 weeks dosing: #0.5mL per 28 days (PAC NOTE: Enter NDC 00078-1056-97 only).**
     - **150mg every 4 weeks dosing: #1mL per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only).**
     - **300mg every 4 weeks dosing: #2mL per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 or 00078-1070-68 only).**

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

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

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

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to the preferred agent: Stelara (ustekinumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to THREE of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength and dosage form by NDC for 12 months with the following quantity limits:**
     - **150mg every 4 weeks dosing: #1mL per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only).**
     - **300mg every 4 weeks dosing: #2mL per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 or 00078-1070-68 only).**

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

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of 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), Taltz (ixekizumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength and dosage form by NDC for 12 months with the following quantity limits:**
     - **150mg every 4 weeks dosing: #1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
     - **300mg every 4 weeks dosing: #2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 or 00078-1070-68 only)**

     If no, continue to #6.

6. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) 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: Taltz (ixekizumab), Cimzia (certolizumab), Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested dosage form by NDC for 12 months with the following quantity limit:**
     - **150mg every 4 weeks dosing: #1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

     If no, continue to #7.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion

   If yes, **approve the requested strength and dosage form by NDC for 12 months with the following quantity limits:**
   - **75mg every 4 weeks dosing: #0.5mL per 28 days. (PAC NOTE: Enter NDC 00078-1056-97 only).**
   - **150mg every 4 weeks dosing: #1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 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: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
      5. Enthesitis-related arthritis (ERA: a type of 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: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy
      2. You meet ONE of the following:
         a. You are 6 to 17 years of age AND had a trial of or contraindication (harmful for) to THREE of the preferred medications: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)
         b. You are 18 years of age or older AND had a trial of or contraindication (harmful for) to FOUR of the following preferred medications: Taltz (ixekizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

   (Renewal denial text continued on next page)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

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 meet ONE of the following:
      a. You are 2 to 5 years of age
      b. You are 6 to 17 years of age AND had a trial of or contraindication (harmful for) to the preferred medication: Stelara (ustekinumab)
      c. You are 18 years of age or older AND had a trial of or contraindication (harmful for) to THREE of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate release or extended release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

D. **If you have 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 (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You had a trial or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Taltz (ixekizumab), Xeljanz (tofacitinib immediate release or extended release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

E. **If you have non-radiographic axial spondyloarthritis, 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 (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Taltz (ixekizumab), Cimzia (certolizumab), Rinvoq (upadacitinib)

F. **If you have enthesitis-related arthritis, renewal also requires**:
   1. You have experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion

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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SECUKINUMAB

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. July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 02/15
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