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Next Review Due By: 10/2024
Policy Number: C10410-A

Cosentyx (secukinumab)

PRODUCTS AFFECTED

Cosentyx (secukinumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderate to severe plaque psoriasis, Active psoriatic arthritis (PsA), Ankylosing spondylitis (AS), Non-radiographic axial spondyloarthritis, Enthesitis related arthritis, Hidradenitis suppurativa (HS)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing.
Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by- case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

Drug and Biologic Coverage Criteria

FOR ALL INDICATIONS:

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
   AND
2. Member is not on concurrent treatment or will be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
3. Prescriber attests member does not have an active infection, including clinically important localized infections
   AND
4. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

A. PSORIATIC ARTHRITIS (PsA):

1. Documentation of active psoriatic arthritis
   AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
3. (a) Documented treatment failure, serious side effects or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
   OR
   (b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]
   OR
   (c) Documentation member has severe psoriasis [PASI $\geq$ 12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]
   AND
4. Documentation of treatment failure, serious side effects or clinical contraindication to a trial (>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor NOTE: Contraindications to TNF treatment include congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease

B. CHRONIC PLAQUE PSORIASIS:

1. Documented diagnosis of moderate to severe psoriasis (BSA $\geq$ 3%) OR < 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that

would significantly impact daily function (e.g. face, neck, hands, feet, genitals)
AND

2. (a) Documentation of treatment failure serious side effects, or clinical contraindication to TWO of the following systemic therapies for ≥3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
   OR
   (b) Documentation of treatment failure to Phototherapy for ≥3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

C. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS:
1. Documented diagnosis of moderate to severe ankylosing spondylitis
   AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
   AND
3. FOR MEMBER WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to a trial (≥3 consecutive months) of methotrexate OR sulfasalazine
   AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
5. Documentation of treatment failure, serious side effects or clinical contraindication to a trial (>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor
   NOTE: Contraindications to TNF treatment include congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease

D. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS:
1. Prescriber attests to diagnosis of adult-onset axial spondyloarthritis
   AND
2. Documentation that C-reactive protein (CRP) levels are above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI), indicative of inflammatory disease
   AND
3. Documentation that there is no definitive radiographic evidence of structural damage on sacroiliac joints
   AND
4. Documentation member has active disease and prescriber provides baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
5. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
   AND
6. Documentation of treatment failure, serious side effects or clinical contraindication to a trial

(>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor for the given diagnosis
NOTE: Contraindications to TNF treatment include congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease

E. ENTHESITIS RELATED ARTHRITIS:
1. Documented diagnosis of Enthesitis related arthritis
AND
2. Documentation of trial (4 weeks) and failure of preferred formulary Nonsteroidal anti-inflammatory drugs (NSAIDs)
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

F. HIDRADENITIS SUPPURATIVA:
1. Documentation of Hurley stage II (moderate recurrent) or stage III (severe diffuse) disease
AND
2. Prescriber attestation that IF member is a smoker, the member has been counseled regarding the benefits of smoking cessation and/or connected with a program to support smoking cessation
AND
3. Documentation indicating the member has been counseled on the use of general supportive measures (e.g., education and support, avoidance of skin trauma, hygiene, dressings, smoking cessation, weight management, diet)
AND
4. (a) Documentation of treatment failure with or a clinical contraindication to a 3-month trial of the following:
   i. Oral tetracycline (e.g., minocycline, doxycycline AND
   ii. Topical antibiotic (Stage II disease ONLY) AND
   iii. Antiandrogen (e.g., finasteride) OR clindamycin/rifampin
AND
b) Documentation of treatment failure with or a clinical contraindication to intralesional corticosteroids
Note to reviewer – guideline recommended first line agents are as follows:
Hurley stage I disease: topical clindamycin, oral tetracycline, metformin and antiandrogenic agents; Hurley stage II or III disease: oral tetracycline, oral clindamycin, rifampin, metformin
AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure

or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
PSORIATIC ARTHRITIS (PsA): Prescribed by or in consultation with a board-certified rheumatologist or dermatologist
CHRONIC PLAQUE PSORIASIS, HIDRADENITIS SUPPURATIVA: Prescribed by or in consultation with a board-certified dermatologist
MODERATE TO SEVERE ANKYLOSING SPONDYLITIS and NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS, ENTHESITIS RELATED ARTHRITIS: Prescribed by or in consultation with a board-certified rheumatologist
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
Moderate to severe plaque psoriasis: 6 years of age and older
Active psoriatic arthritis (PsA): 2 years of age and older
Ankylosing spondylitis (AS), Non-Radiographic Axial Spondyloarthritis, Hidradenitis suppurativa: 18 years of age and older
Enthesitis related arthritis: 4 years of age and older

QUANTITY:
Plaque Psoriasis:
Adults (≥18 years of age) - Recommended dosage is 300 mg by subcutaneous injection at Weeks 0, 1, 2,3, and 4 followed by 300 mg every 4 weeks. For some patients, a dose of 150 mg may be acceptable.
Pediatric patients (6 years to <18 years of age)
For patients weighing less than 50kg the dose is 75mg at weeks 0, 1,2, 3, and 4, followed by dosing every 4 weeks
For patients weighing greater than or equal to 50 kg the dose is 150mg at weeks 0, 1,2, 3, and 4, followed by dosing every 4 weeks

Psoriatic Arthritis:
Subcutaneous Dosage
Adults –
For adult psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis use the dosage and administration for plaque psoriasis
For other psoriatic arthritis patients, administer with or without a loading dosage.
With a loading dosage: 150 mg at Weeks 0,1, 2, 3, and 4 and every 4 weeks thereafter
Without a loading dosage: 150 mg every 4 weeks.
If a member continues to have active psoriatic arthritis, consider a dosage of 300 mg every 4weeks.
Pediatric Patients 2 years of age and older-
For patients weighing ≥ 15 kg and < 50 kg the dose is 75 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

For patients weighing ≥ 50 kg the dose is 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

Intravenous Dosage
Adults –
Administer with or without a loading dosage
With a loading dosage: 6 mg/kg at week 0, followed by 1.75 mg/kg every 4 weeks thereafter (max 300mg per maintenance infusion)
Without a loading dosage: 1.75 mg/kg every 4 weeks (max 300mg per maintenance infusion)

Ankylosing Spondylitis:
Subcutaneous Dosage
Administer with or without a loading dose.
With a loading dosage: 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
Without a loading dosage: 150 mg every 4 weeks
If a member continues to have active ankylosing spondylitis, consider a dosage of 300 mg every 4 weeks.

Intravenous Dosage
Administer with or without a loading dose
With a loading dosage: 6 mg/kg at week 0, followed by 1.75 mg/kg every 4 weeks thereafter (max 300mg per maintenance infusion)
Without a loading dosage: 1.75 mg/kg every 4 weeks (max 300mg per maintenance infusion)

Non-radiographic Axial Spondyloarthritis:
Subcutaneous Dosage
Administer with or without a loading dose.
With a loading dosage: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
Without a loading dosage: 150 mg every 4 weeks

Intravenous Dosage
Administer with or without a loading dose
With a loading dosage: 6 mg/kg at week 0, followed by 1.75 mg/kg every 4 weeks thereafter (max 300mg per maintenance infusion)
Without a loading dosage: 1.75 mg/kg every 4 weeks (max 300mg per maintenance infusion)

Enthesitis related arthritis:
For patients weighing ≥ 15 kg and < 50 kg the dose is 75 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks
For patients weighing ≥ 50 kg the dose is 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks

Hidradenitis Suppurativa:
Recommended dosage is 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. If a patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks.

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous, Intravenous

DRUG CLASS:
Antipsoriatics – Systemic

FDA-APPROVED USES:
Indicated for the treatment of:

- moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy
- active psoriatic arthritis (PsA) in patients 2 years of age and older
- adults with active ankylosing spondylitis (AS)
- adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- active enthesitis-related arthritis (ERA) in patients 4 years of age and older
- adults with moderate to severe hidradenitis suppurativa (HS)

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

To meet the CASPAR criteria, a patient must have inflammatory articular disease (joint, spine, or entheseal) with ≥3 points from any of the following five categories:
1. Evidence of current psoriasis,[b,c] a personal history of psoriasis, or a family history of psoriasis[d]
2. Typical psoriatic nail dystrophy[e] observed on current physical examination
3. A negative test result for rheumatoid factor
4. Either current dactylitis[f] or a history of dactylitis recorded by a rheumatologist
5. Radiographic evidence of juxtaarticular new bone formation[g] in the hand or foot

[a] Specificity of 99% and sensitivity of 91%. [b] Current psoriasis is assigned 2 points; all other features are assigned 1 point. [c] Psoriatic skin or scalp disease present at the time of examination, as judged by a rheumatologist or dermatologist. [d] H
hyperkeratosis. [e] Swelling of an entire digit. [g] Ill-defined ossification near joint margins, excluding osteophyte formation.

Source: From W Taylor et al: Arthritis Rheum, 54:2665, 2006.

Psoriatic Arthritis

An estimated 1% of the U.S. adult population harbors cutaneous evidence of psoriasis, characterized by well-demarcated erythematous scaly plaques, some of whom develop a related arthritis. In fact, there are several distinct subsets of psoriatic arthritis, including (a) an asymmetric oligoarthritis affecting lower extremity joints; (b) a symmetric polyarthritis affecting upper and lower extremity joints; (c) monoarticular involvement of a distal interphalangeal joint alone; (d) a destructive finger joint arthritis that produces "telescoping," a shortening of the digit as a consequence of aggressive bone destruction and resorption (arthritis mutilans); and (e) axial skeleton involvement (spondylitis, sacroiliitis).

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Cosentyx, a human interleukin (IL)-17A antagonist, is indicated for moderate to severe plaque psoriasis, active psoriatic arthritis (PsA), and ankylosing spondylitis (AS) in adults. It is a recombinant human monoclonal Immunoglobulin G (IgG)1/κ antibody binds specifically to the IL-17A cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine involved in normal inflammatory and immune responses; therefore, Cosentyx inhibits the release of proinflammatory cytokines and chemokines. The recommended dose for plaque psoriasis is 300 mg by subcutaneous (SC) injection at every week for five doses followed by 300 mg every 4 weeks thereafter. For some patients, a dose of 150 mg may be acceptable. Recommended dosing for active psoriatic arthritis (PsA) and ankylosing spondylitis (AS) is either: a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4 and 150 mg every four weeks thereafter or 150 mg every four weeks without a loading dose. For PsA the dose can be increased to 300 mg. Cosentyx is intended for use under the guidance and supervision of a physician. Those trained in SC injection technique using the pen or prefilled syringe may self-inject when deemed appropriate. Cosentyx is indicated for moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Guidelines developed by the National Psoriasis Foundation Medical Board (2012), prior to the availability of Cosentyx, note that Stelara, Humira, and Enbrel are appropriate first-line biologics for treatment of psoriasis. It is also stated that oral agents for psoriasis (i.e., acitretin, cyclosporine, and MTX) may be used first line in various clinical situations. For example, Acitretin is a first-line systemic drug for palmoplantar or pustular psoriasis and is especially useful in those with severely sun damaged skin, in which it may suppress actinic 2andomize and even invasive malignant neoplasms. Cyclosporine may be effective long-term but is normally reserved for intermittent use (up to 12weeks) to control a flare so the member can transition to another drug for long-term maintenance. When used intermittently, a course of cyclosporine can induce an average decrease of > 75% in psoriasis severity. MTX is considered a first-line systemic agent for plaque psoriasis that may be used continuously for many years or decades with durable benefits. Cosentyx is also indicated for active psoriatic arthritis (PsA) and ankylosing spondylitis (AS).. Initial therapy for moderate or severe active PsA currently recommends methotrexate and/or TNF blockade. TNFi are conditionally recommended over treatment with interleukin based therapy. For ankylosing spondylitis, guidelines strongly recommend use of nonsteroidal anti- inflammatory drugs (NSAIDs) and use of tumor necrosis factor inhibitors (TNFi) if activity persists despite NSAID treatment. For patients with ankylosing spondylitis despite treatment with NSAIDs, guidelines conditionally recommend treatment with TNFi over treatment with secukinumab. For patients with active nonradiographic axial SpA despite treatment with NSAIDs, guidelines conditionally recommend treatment with TNFi.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cosentyx (secukinumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Cosentyx (secukinumab) include: Serious hypersensitivity to secukinumab or any excipients in COSENTYX, use of live vaccines

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J3590	Unclassified biologic (Cosentyx IV)

AVAILABLE DOSAGE FORMS:
Cosentyx Sensoready Pen SOAJ 150MG/ML
Cosentyx Sensoready 300MG Dose SOAJ 150MG/ML
Cosentyx UnoReady SOAJ 300MG/2ML
Cosentyx SOSY 150MG/ML
Cosentyx 300 MG Dose SOSY 150MG/ML
Cosentyx SOSY 75MG/0.5 ML
Cosentyx INJ 125/5ML

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Prescriber Requirements Age Restrictions Quantity FDA-Approved Uses References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Required Medical Information FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file