ALASKA MEDICAID
Prior Authorization Criteria

Cosentyx®(secukinumab)

150mg/mL Sensoready pen, prefilled syringe, and lyophilized powder in vial for reconstitution
For subcutaneous administration

Indication:

"COSENTYX is a human interleukin-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis in adult patients who are candidates for systemic therapy or phototherapy, adults with active psoriatic arthritis (PsA) , and adults with active ankylosing spondylitis (AS)."[1]

Dosage Form/Strength:

- Injection: 150 mg/mL solution in a single-use Sensoready® pen.
- Injection: 150 mg/mL solution in a single-use prefilled syringe.
- For Injection: 150 mg, lyophilized powder in a single-use vial for reconstitution for healthcare professional use only.

Criteria for Approval:

1. Initial Authorization Request must include:
   * Monitoring plan
   * Previous therapies trialed and the nature of the failure
   * Complete medication regimen
2. The patient has had a negative tuberculosis test; **AND,**
3. The patient is greater than or equal to 18 years old; **AND,**
4. The patient has a diagnosis of moderate to severe plaque psoriasis, psoriatic arthritis, or ankylosing spondylitis; **AND,**
5. Has one of the following scores [2, 3, 4]
   - Plaque Psoriasis: Psoriasis Area and Severity Index (PASI) score of greater than or equal to 12 (or equivalent); or
   - Psoriatic Arthritis: Health Assessment Questionnaire-Disability Index (HAQ-DI) score ≥ 2 (or equivalent); or
   - Ankylosing Spondylitis: Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4 and Bath Ankylosing Spondylitis Functional Index (BASFI) ≥ 4 (or equivalent); **AND,**
6. The patient has previously tried and failed, or has a contraindication to, a TNF blocker (i.e. Humira or Enbrel), and at least one other therapy.

Criteria for Reauthorization Approval:

1. A letter of medical necessity is submitted with chart notes demonstrating therapeutic benefit.

2. Baseline and current PASI score (for plaque psoriasis), HAQ-DI (for psoriatic arthritis), or BASDAI/BASFI (for ankylosing spondylitis) or equivalents are submitted.
3. Documentation of tolerance and absence of adverse events are submitted.

Criteria for Denial:

1. Known hypersensitivity to Cosentyx or any of its excipients; **OR**,
2. Patient is less than 18 years old; **OR**,
3. Has active tuberculosis or a positive tuberculosis test; **OR**,
4. The patient has a current active severe infection, has chronic or recurrent infections; **OR**,
5. The patient will be using concurrent therapy with a TNF blocker; **OR**,
6. One of the following for patients initiating therapy (depending on applicable diagnosis):
   - PASI score of less than 12 (or equivalent); or
   - Health Assessment Questionnaire-Disability Index (HAQ-DI) score < 2 (or equivalent); or
   - Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) < 4 and Bath Ankylosing Spondylitis Functional Index (BASFI) < 4;
7. If the Sensoready pen is being requested, the patient has a latex allergy

Length of Authorization:

1. Initial coverage may be approved for up to 3 months (7 doses total - Injections at Weeks 0, 1, 2, 3, 4, 8, and 12).
2. Subsequent re-authorizations may be approved for 12 months (Injections at Weeks 16 and thereafter at 4 week intervals).

Quantity Limit:

1. The dispensing limit is two vials, syringes, or pens per 30 days.
2. Quantity limit overrides are approvable for up to 5 doses (10 vials, syringes, or pens) per 28 days for a patient who is beginning therapy and has not reached the monthly maintenance dose.

CAUTIONS:

- While approved for subcutaneous administration, initial Cosentyx doses should only be administered under the supervision of a physician. Cosentyx is intended for use under the guidance and supervision of a physician. Patients may self-inject after proper training in subcutaneous injection technique using the Sensoready pen or prefilled syringe and when deemed appropriate. The lyophilized powder for reconstitution is for healthcare provider use only. Administration of Cosentyx in the upper, outer arm may be performed by a caregiver or healthcare provider. Close monitoring and adequate follow-up is required in both circumstances for the safety of the patient.

- Live vaccines should not be administered while patients are receiving Cosentyx unless determined that the benefit outweighs the risk.
- The removable cap of the Sensoready pen and the prefilled syringe contains natural rubber latex.

Mechanism of Action:
"Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Secukinumab inhibits the release of proinflammatory cytokines and chemokines." [1]

References / Footnotes:

[1] Cosentyx™ Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2016.

[2] Calin A, Garrett S, Whitelock H, Kennedy LG, O'Hea J, Mallorie P, Jenkinson T. "A new approach to defining functional ability in ankylosing spondylitis: the development of the Bath Ankylosing Spondylitis Functional Index." *J. Rheumatol*. 1994 Dec;21(12):2281-5.

[3] Garrett S, Jenkinson T, Kennedy LG, Whitelock H, Gaisford P, Calin A. "A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Soondylitis Disease Activity Index." J Rheumatol. 1994 Dec;21(12):2286-91.

[4] BASFAI, Bath ankylosing spondylitis functional index. http://basdai.com/BASFI.php. 2005. Accessed 01/15/2016.