COSENTYX® (secukinumab)

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical 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 BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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COSENTYX (secukinumab) (cont.)

Description:

Cosentyx (secukinumab) is a human interleukin-IL-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis. Secukinumab is an antibody that binds to a protein interleukin-IL-17A which is involved in inflammation. By binding to IL-17A, secukinumab prevents it from binding to its receptor, and inhibits its ability to trigger the inflammatory response that plays a role in the development of plaque psoriasis.

Definitions:

Adult: Age 18 years and older

Preferred Tumor Necrosis Factor (TNF Inhibitor) Medications:
- Enbrel® (etanercept)
- Humira® (adalimumab)
- Remicade® (infliximab)
COSENTYX (secukinumab) (cont.)

Criteria:

See Resources section for FDA-approved dosage, American College of Rheumatology 20 Percent Improvement Criteria (ACR20), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Psoriasis Area and Severity Index (PASI).

- Cosentyx is considered medically necessary for adults with documentation of ALL of the following:
  
  1. **ONE** of the following:
     
     a. Active ankylosing spondylitis in an individual that has failure of or intolerance to 2 or more different non-steroidal anti-inflammatory drugs (NSAIDs) at maximum recommended doses, each used for at least 4 or more weeks
     
     b. Active psoriatic arthritis with documentation of ONE of the following:
        
        a. Individual with axial disease that has failure of or intolerance to 2 or more different NSAIDs at maximum recommended doses, each used for at least 4 or more weeks
        
        b. Individual with non-axial disease that has failure of or intolerance to 2 or more different NSAIDs (at maximum recommended doses) each used for at least 4 or more weeks and conventional disease modifying drug (either methotrexate or leflunomide)
     
     c. Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy with documentation of failure of ANY of the following other treatments to control psoriasis:
        
        a. Photochemotherapy (i.e., psoralen plus ultraviolet A therapy)
        
        b. Phototherapy (i.e., ultraviolet light therapy)
        
        c. Topical agents (e.g., anthralin, calcipotriene, coal tars, corticosteroids, tazarotene)
        
        d. Immunosuppressive treatments (e.g., cyclosporine, methotrexate)
     
  2. Failure of, contraindication to or intolerance to **TWO** of the preferred TNF inhibitor medications Enbrel, Humira, Remicade (refer to, “Small Molecules and Biologics Chart” #AP94 Administrative Procedure Guideline for the preferred medication(s) labeled indications)
  3. No evidence of active serious infections including, clinically important localized infections or sepsis when initiating or continuing therapy
  4. Absence of a severe hypersensitivity reaction to Cosentyx or any of the excipients in Cosentyx
  5. Evidence of testing for latent tuberculosis before Cosentyx use and during therapy and any treatment for latent infection has been initiated prior to Cosentyx therapy
  6. Cosentyx is not being used concurrently with live vaccines
  7. Will not be used with other biologic or targeted medications, including but not limited to: Actemra®, Cimzia®, Enbrel®, Entyvio™, Humira®, Inflectra®, Kinerei®, Ocrevus®, Otezla®, Remicade®, Rituxan®, Simponi®, Stelara®, Taltz®, Xeljanz®, Xeljanz XR®, etc.
COSENTYX (secukinumab) (cont.)

Criteria: (cont.)

- Continuation of Cosentyx for the treatment of adults with ankylosing spondylitis is considered medically necessary with documentation of ALL of the following:

  1. Achieved and maintains at least a 50% improvement (or a 2 unit decrease) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)
  2. Not using other biologic or targeted medications

- Continuation of Cosentyx for the treatment of adults with psoriatic arthritis is considered medically necessary with documentation of ALL of the following:

  1. ONE of the following:
     - Achieved and maintains at least a 20% or more improvement in tender joint count or swollen joint count while on Cosentyx therapy
     - Achieved and maintained ACR20 (American College of Rheumatology) response criteria of 20% or higher while on Cosentyx therapy
  2. Not using other biologic or targeted medications

- Continuation of Cosentyx for the treatment of adults with plaque psoriasis is considered medically necessary with documentation of ALL of the following:

  1. ONE of the following:
     - Achieved and maintains clear or minimal disease while on Cosentyx therapy
     - Achieved and maintains Psoriasis Area and Severity Index (PASI) of at least 50% or more while on Cosentyx therapy
  2. Not using other biologic or targeted medications
Criteria: (cont.)

- Cosentyx for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, but are not limited to:

- Treatment with dosing or frequency outside the FDA-approved dosing and frequency
COSENTYX (secukinumab) (cont.)

Resources:

Literature reviewed 04/09/18. We do not include marketing materials, poster boards and non-published literature in our review.

Cosentyx Package Insert:

- FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque psoriasis</td>
<td>Cosentyx is administered by subcutaneous injection.</td>
</tr>
<tr>
<td></td>
<td>Recommended dose is 300 mg at weeks 0, 1, 2, 3 and 4 followed by 300 mg every 4 weeks. Each 300 mg dose is given as 2 subcutaneous injections of 150 mg.</td>
</tr>
<tr>
<td></td>
<td>For some patients, a dose of 150 mg may be acceptable.</td>
</tr>
<tr>
<td></td>
<td>Safety and effectiveness of Cosentyx in pediatric patients have not been evaluated.</td>
</tr>
<tr>
<td>Psoriatic Arthritis</td>
<td>Cosentyx is administered with or without a loading dose by subcutaneous injection.</td>
</tr>
<tr>
<td></td>
<td>The recommended dosage:</td>
</tr>
<tr>
<td></td>
<td>• With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter</td>
</tr>
<tr>
<td></td>
<td>• Without a loading dosage is 150 mg every 4 weeks</td>
</tr>
<tr>
<td></td>
<td>• If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg</td>
</tr>
<tr>
<td></td>
<td>Cosentyx may be administered with or without methotrexate.</td>
</tr>
<tr>
<td></td>
<td>For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosage and administration recommendations for plaque psoriasis.</td>
</tr>
<tr>
<td></td>
<td>Safety and effectiveness of Cosentyx in pediatric patients have not been evaluated.</td>
</tr>
</tbody>
</table>

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COSENTYX (secukinumab) (cont.)

Resources: (cont.)

Cosentyx Package Insert: (cont.)

- FDA-approved indication and dosage: (cont.)

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ankylosing Spondylitis</td>
<td>Cosentyx is administered with or without a loading dosage by subcutaneous injection.</td>
</tr>
<tr>
<td></td>
<td>The recommended dosage:</td>
</tr>
<tr>
<td></td>
<td>▪ With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter</td>
</tr>
<tr>
<td></td>
<td>▪ Without a loading dosage is 150 mg every 4 weeks</td>
</tr>
<tr>
<td></td>
<td>Safety and effectiveness of Cosentyx in pediatric patients have not been evaluated.</td>
</tr>
</tbody>
</table>

Initial Approval Duration:
6 months

Renewal Approval Duration:
12 months

American College of Rheumatology 20 Percent Improvement Criteria (ACR20):

At least 20 percent improvement in the following:

1. Swollen joint count
2. Tender joint count

And three of the following five variables:
3. Patient-assessed global disease activity (e.g., by VAS)
4. Evaluator-assessed global disease activity (e.g., by VAS)
5. Patient pain assessment (e.g., by VAS)
6. Functional disability (e.g., by HAQ)
7. Acute phase response (ESR or CRP)

A 50 and 70 percent ACR response (ACR50 and ACR70, respectively) represents respective improvement of at least 50 or 70 percent.¹

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COSENITYX (secukinumab) (cont.)

Resources: (cont.)

**Bath Ankylosing Spondylitis Disease Activity Index (BASDAI):**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Score Options</th>
<th>None</th>
<th>0 1 2 3 4 5 6 7 8 9 10</th>
<th>Very Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>How would you describe the overall level of fatigue/tiredness you have experienced?</td>
<td>None</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td>Very Severe</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>How would you describe the overall level of ankylosing spondylitis neck, back or hip pain you have had?</td>
<td>None</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td>Very Severe</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>How would you describe the overall level of pain/swelling you have had in joints other than neck, back and hips?</td>
<td>None</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td>Very Severe</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>How would you describe the level of discomfort you have had from an area tender to touch or pressure?</td>
<td>None</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td>Very Severe</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>How would you describe the level of morning stiffness you have had from the time you wake up?</td>
<td>None</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td>Very Severe</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>How long does your morning stiffness last from the time you wake up?</td>
<td>0 hours</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td>2 or more hours</td>
<td></td>
</tr>
</tbody>
</table>

**Calculation of BASDAI:**
Compute the mean of questions 5 and 6
Calculate the sum of the values of question 1-4 and add the result to the mean of questions 5 and 6

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COSENTYX (secukinumab) (cont.)

Resources: (cont.)

Psoriasis Area and Severity Index (PASI):

<table>
<thead>
<tr>
<th></th>
<th>Head</th>
<th>Upper Extremities</th>
<th>Trunk</th>
<th>Lower extremities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Redness&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Thickness&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Scale&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Sum of rows 1, 2 and 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Area score&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Score of row 4 x row 5 x the area multiplier</td>
<td>row 4 x row 5 x 0.1</td>
<td>row 4 x row 5 x 0.2</td>
<td>Row 4 x row 5 x 0.3</td>
<td>Row 4 x row 5 x 0.4</td>
</tr>
<tr>
<td>7. Sum row 6 for each column for PASI score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Steps in generating PASI score

(a) Divide body into four areas: head, arms, trunk to groin, and legs to top of buttocks.
(b) Generate an average score for the erythema, thickness, and scale for each of the 4 areas (0 = clear; 1–4 = increasing severity)<sup>1</sup>.
(c) Sum scores of erythema, thickness, and scale for each area.
(d) Generate a percentage for skin covered with psoriasis for each area and convert that to a 0–6 scale (0 = 0%; 1 = <10%; 2 = 10–<30%; 3 = 30–<50%; 4 = 50–<70%; 5 = 70–<90%; 6 = 90–100%).
(e) Multiply score of item (c) above times item (d) above for each area and multiply that by 0.1, 0.2, 0.3, and 0.4 for head, arms, trunk, and legs, respectively.
(f) Add these scores to get the PASI score.

<sup>1</sup> Erythema, induration and scale are measured on a 0–4 scale (none, slight, mild, moderate, severe)
<sup>2</sup> Area scoring criteria (score: % involvement)

0: 0 (clear)
1: <10%
2: 10–<30%
3: 30–<50%
4: 50–<70%
5: 70–<90%
6: 90–<100%

COSENTYX (secukinumab) (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’ é atah nilíñígíí Blue Cross Blue Shield of Arizona haadá yít’éego bina’íidídidx éí doodago Háida bítì aniýéeédídií t’áadóo le’e yínàíidídx beeáz’áanii hóóló díí t’áá hazaadke’ehíí háká a’dowolgo bee haz’a doo báqäh ilínígóó. Atá’ halne’i’ígíí kójí bich’íí hodíílnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插件項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو أدى شخص تسعة أسلطة بخصوص Blue Cross Blue Shield of Arizona، فنحن نحن نقدم لك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أي تكلفة، للتحدث مع مترجم للحصول على المساعدة والمعلومات. 877-475-4799.
COSENTYX (secukinumab) (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ipapakita o unang lingkod ng mga tao sa Blue Cross Blue Shield of Arizona, may kakayahang makapagbayad ang mga kaaralan. Sa ilang mga tao, sana'y makapag-unahang unang lingkod ng mga tao sa Blue Cross Blue Shield of Arizona.

Korean: 만약 휴가 또는 코로나가 되고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 휴가 또는 코로나가 되고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면, 그에 따라, 휴가 또는 코로나가 되고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면, 그에 따라, 877-475-4799 로 전화해주시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue sans aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dementscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если вы или лицо, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы можете запросить бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

Farsi: اگر شما یا کسی که شما به آن کمک می‌کنید، سوالاتی دارد در مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian:

Assyrian: یا کسی که شما به آن کمک می‌کنید، سوالاتی دارد در مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobitete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือผู้ที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้รับบริการฟรีและข้อมูลภาษา ของคนในไทยโดยไม่เสียค่าใช้จ่าย พูดคุยกับ โทร 877-475-4799.