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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 12/14/2023

Cosentyx® IV (secukinumab)

HCPCS: C9166

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indications
 - b. FDA approved age
 - c. Diagnosis of psoriatic arthritis (PsA)
 - d. Diagnosis of ankylosing spondylitis (AS)
 - e. Diagnosis of non-radiographic axial spondyloarthritis (NRAS)
 - f. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs)
 - g. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's prior authorization and step therapy documents and/or BCBSM/BCN's utilization management medical drug list

- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing.
 - b. Authorization Period: One year at a time.
 - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Cosentyx IV is an interleukin-17 (IL-17) receptor A antagonist indicated for the following:
 - Active psoriatic arthritis in patients 2 years of age and older

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

- Adults with active ankylosing spondylitis
- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
- Cosentyx is available in a self-administered subcutaneous (SC) formulation and an intravenous (IV) infusion for adults with psoriatic arthritis, active ankylosing spondylitis, and active NRAS. The IV formulation requires a healthcare provider for administration.
- Clinical reasons a patient may be unable to self-administer Cosentyx include:
 - Patient or caregivers are unable to perform subcutaneous injections with proper technique.
 - Member requires monthly medical support from the physician.
- Psoriatic Arthritis
 - PsA is a chronic inflammatory disease often associated with psoriasis. Psoriasis is an autoimmune disease affecting the skin, resulting in scaly red and white patches. These patches, called plaques, may appear anywhere on the body. The inflammation may also develop in the joints, which is classified as PsA. PsA occurs in up to 30% of patients with psoriasis, most commonly appearing between the ages of 30 and 50. PsA causes pain, stiffness, and swelling in and around the joints. If not properly treated, progressive joint damage may occur.
 - Per the 2018 American College of Rheumatology (ACR)/National Psoriasis Foundation (NPF) guideline for the treatment of psoriatic arthritis:
 - All recommendations for treatment-naive patients with active PsA are conditional based on low- to very-low quality evidence.
 - In treatment-naïve patients, oral systemic medications (OSMs), such as methotrexate, sulfasalazine, cyclosporine, and leflunomide, may be used in patients without severe psoriatic arthritis and without severe psoriasis. OSMs have robust longitudinal safety and efficacy data in patients with PsA. Maximal response to OSMs are most commonly achieved within 3 months of therapy.
 - If PsA remains active despite OSM therapy, switching to a tumor necrosis factor inhibitor (TNFi), an IL (interleukin)-17 inhibitor (IL-17i), or an IL-12/23i biologic is recommended over switching to a different OSM; switching to a TNFi biologic over an IL-17i or IL-12/23i biologic is conditionally recommended in this scenario based on moderate quality evidence. Additional treatment options include Orencia® (abatacept) and Xeljanz® (tofacitinib). The detailed recommendations for subsequent therapies can be found in the 2018 ACR/NPF guideline for the treatment of psoriatic arthritis.
- Ankylosing Spondylitis
 - Axial spondyloarthritis, comprising AS and NRAS, is the main form of chronic inflammatory arthritis affecting the axial skeleton. Non-radiographic means that damage to the joints is not visible on X-ray. When changes to the vertebrae (the bones of the spine) or sacroiliac joints don't show any changes on an X-ray, that's known as NRAS. Once the joints are clearly affected on an X-ray, a person can be diagnosed with AS.

- The 2019 American College of Rheumatology recommendations for AS and NRAS are similar. In adult patients who have active disease despite treatment with NSAIDs, treatment with TNFi biologics are recommended. They do not recommend any particular TNFi as the preferred choice for the typical patient. Cosentyx® (secukinumab) or Taltz® (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi, whereas for patients with a secondary nonresponse (i.e. those who relapse after an initial response) it may be beneficial to switch to a different TNFi rather than immediately switch to a different biologic class. In the case of nonresponse (primary or secondary), the guidelines recommend against switching to treatment with a biosimilar since clinical response would not be expected to be different.
- Non-Radiographic Axial Spondyloarthritis
 - Axial spondyloarthritis, comprising AS and NRAS, is the main form of chronic inflammatory arthritis affecting the axial skeleton. Non-radiographic means that damage to the joints is not visible on X-ray. When changes to the vertebrae (the bones of the spine) or sacroiliac joints don't show any changes on an X-ray, that's known as NRAS. Once the joints are clearly affected on an X-ray, a person can be diagnosed with AS.
 - The 2019 ACR recommendations for AS and NRAS are similar. In adult patients who have active disease despite treatment with NSAIDs, treatment with TNFi are recommended. They do not recommend any particular TNFi as the preferred choice for the typical patient. Cosentyx (secukinumab) or Taltz (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi, whereas for patients with a secondary nonresponse (i.e. those who relapse after an initial response) it may be beneficial to switch to a different TNFi rather than immediately switch to a different biologic class. In the case of nonresponse (primary or secondary), the guidelines recommend against switching to treatment with a biosimilar since clinical response would not be expected to be different.

References:

1. Cosentyx [prescribing information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; October 2023.
2. Ward, MM, Deodhar, A, Akl, EA, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol.* 2019 Oct;71(10):1599-1613.
3. Ringold S, Angeles-Han ST, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Entesitis. *Arthritis Rheumatol.* 2019 June ; 71(6): 846–863. doi:10.1002/art.40884.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis & Rheumatology.* 2018; 0(0): 1-28. <https://www.rheumatology.org/Portals/0/Files/PsA-Guideline-Early-View-Version.pdf>.
5. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in *J Am Acad Dermatol.* 2020 Mar;82(3):780]. *J Am Acad Dermatol.* 2019;81(3):775-804. doi:10.1016/j.jaad.2019.04.042
6. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures [published online ahead of print, 2020 Jul 30]. *J Am Acad Dermatol.* 2020;S0190-9622(20)32288-X. doi:10.1016/j.jaad.2020.07.087
7. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044
8. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057

9. Ward, MM, Deodhar, A, Akl, EA, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613.
10. Klein-Gitelman, Marisa. Spondyloarthritis in children. In: UpToDate, Post TW (Ed), UpToDate, Waltham, Ma. (Accessed on January 12, 2022).
11. Ruperto N, Foeldvari I, Alexeeva E on behalf of PRCSSG and PRINTO investigative sites, et al. LB0004 EFFICACY AND SAFETY OF SECUKINUMAB IN ENTHESITIS-RELATED ARTHRITIS AND JUVENILE PSORIATIC ARTHRITIS: PRIMARY RESULTS FROM A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, TREATMENT WITHDRAWAL, PHASE 3 STUDY (JUNIPERA). Annals of the Rheumatic Diseases 2021;80:201-202.
12. Alikhan A, Sayed C, Alavi, A et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part II: Topical, intralesional, and systemic medical management. Journal of the American Academy of Dermatology, Volume 81, Issue 1, 91 - 101.

Policy History												
#	Date	Change Description										
1.2	Effective Date: 02/12/2024	UM medical management system update for MAPPO and BCNA <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>Yes</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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BCBS	Yes											
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1.1	Effective Date: 12/14/2023	New policy										
1.0	Effective Date: 11/09/2023	UM medical management system update for BCBS and BCN <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>Yes</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>No</td> </tr> <tr> <td>BCNA</td> <td>No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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BCBS	Yes											
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

Blue Cross Blue Shield/Blue Care Network of Michigan Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. <input type="checkbox"/> Male <input type="checkbox"/> Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: Initiation Continuation *Date patient started therapy:* _____
2. Administered by patient or a medical professional? patient (self) health care professional (physician, nurse, etc.)
3. Site of administration? Provider office/Home infusion Other: _____
 Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
 Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
4. Please specify location of administration if hospital outpatient infusion: _____
5. Please specify location of administration if hospital inpatient infusion: _____
6. Please provide the NPI number for the place of administration: _____
7. **Initiation AND Continuation of therapy:**
 - a. What is the patient's diagnosis? _____
 - b. What other medication has the patient received for their condition? Please list _____
 - i. Please describe the response to previous therapies:

 - c. Will the patient be receiving any other treatment for the listed condition while on this medication? Please list:

 - d. Please list any labs values important for diagnosing or monitoring this patient's condition:

8. **Continuation of therapy:**
 - a. Has the patient progressed while on this medication? yes no
 - b. How has the patient's condition changed while on this medication?
 Improved; Please describe: _____
 Stable; please describe: _____
 Worsened; Please describe: _____
 Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	<input type="checkbox"/> Form Completely Filled Out <input type="checkbox"/> Provide chart notes	<input type="checkbox"/> Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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