

Medical Policy:

Cosentyx (secukinumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.407	March 15, 2024	March 28, 2024

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Length of Authorization

Coverage will be provided for one loading dose.

Dosing Limits [Medical Benefit]

The recommended IV dose of Cosentyx with a loading dose is 6 mg/kg at Week 0, followed by 1.75 mg/kg once every 4 weeks thereafter. The recommended IV dose without a loading dose is 1.75 mg/kg once every 4 weeks. In either regimen, the maximum recommended maintenance dose is 300 mg.

Max Units (per dose and over time) [HCPCS Unit]

Indication	Max Units
Psoriatic Arthritis and Ankylosing Spondylitis	Intravenous Administration • Loading: 750 billable units at week 0
Non-Radiographic Axial Spondyloarthritis	Intravenous Administration • Loading: 750 billable units at week 0

Guideline

I. INITIAL CRITERIA

Coverage is provided in the following conditions:

1. Patient is at least 18 years of age (unless otherwise specified); **AND**
2. Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
3. Patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
4. Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
5. Will not be administered concurrently with live vaccines; **AND**
6. Patient does not have an active infection, including clinically important localized infections; **AND**
7. Patient is not on concurrent treatment with another IL-inhibitor, TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent (e.g., apremilast, abrocitinib, tofacitinib, baricitinib, upadacitinib, deucravacitinib, etc.); **AND**

1. Adult Psoriatic Arthritis (PsA) †

- A. Documented moderate to severe active disease; **AND**
 - i. For patients with predominantly axial disease, a trial and failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; **OR**
 - ii. For patients with peripheral arthritis, dactylitis **OR** active enthesitis, a trial and failure of at least a 3-month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, etc.; **AND**
- B. May be used as a single agent or in combination with an oral non-biologic DMARD (e.g., methotrexate, etc.)

Note: Patients new to therapy must initiate treatment at the lower dosing regimen of the 150 mg dose before increasing to the 300 mg dose (unless they have co-existent plaque psoriasis)

2. Ankylosing Spondylitis (AS) †

- A. Documented active disease; **AND**
- B. Patient had an adequate trial and failure of at least TWO (2) non-steroidal antiinflammatory agents (NSAIDs) over 4 weeks (in total), unless use is contraindicated

Note: Patients new to therapy must initiate treatment at the lower dosing regimen of the 150 mg dose before increasing to the 300 mg dose

3. Non-Radiographic Axial Spondyloarthritis (nr-axSpA) †

- A. Patient has objective signs of inflammation noted by an elevation of C-reactive protein (CRP) above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI); **AND**
- B. Patient is without definitive radiographic evidence of structural damage on sacroiliac joints; **AND**
- C. Documented active disease; **AND**
- D. Patient had an adequate trial and failure of at least TWO (2) non-steroidal antiinflammatory agents (NSAIDs) unless use is contraindicated

† FDA Approved Indication(s); ‡ Compendia Recommended Indication

Applicable Procedure Codes

Code	Description
J3247	Injection, secukinumab, intravenous, 1 mg

Applicable NDCs

Code	Description
00078-1168-61	Cosentyx 25mg/1mL, 5 mL vial

ICD-10 Diagnoses

Code	Description
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
M45.2	Ankylosing spondylitis of cervical region
M45.3	Ankylosing spondylitis of cervicothoracic region
M45.4	Ankylosing spondylitis of thoracic region
M45.5	Ankylosing spondylitis of thoracolumbar region
M45.6	Ankylosing spondylitis lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region
M45.9	Ankylosing spondylitis of unspecified sites in spine
M45.A0	Non-radiographic axial spondyloarthritis of unspecified sites in spine
M45.A1	Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region
M45.A2	Non-radiographic axial spondyloarthritis of cervical region
M45.A3	Non-radiographic axial spondyloarthritis of cervicothoracic region
M45.A4	Non-radiographic axial spondyloarthritis of thoracic region
M45.A5	Non-radiographic axial spondyloarthritis of thoracolumbar region
M45.A6	Non-radiographic axial spondyloarthritis of lumbar region
M45.A7	Non-radiographic axial spondyloarthritis of lumbosacral region
M45.A8	Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region
M45.AB	Non-radiographic axial spondyloarthritis of multiple sites in spine

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/28/2024	New Policy

References

1. Product Information: COSENTYX® subcutaneous, intravenous injection, secukinumab subcutaneous, intravenous injection. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2023.