Reference number
6360-A

STANDARD MEDICARE PART B MANAGEMENT

COSENTYX IV (secukinumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, the member has no exclusions to the prescribed therapy, and the drug or biological is usually not self-administered. The criteria outlined in this policy is only applicable to drugs not usually self-administered and are furnished incident to a physician's service. Requests for drugs on a region's self-administered drug list are not covered. Members enrolled in Medicare Part D may seek coverage under their Medicare Part D plan.

A. FDA-Approved Indications
1. Adults with active psoriatic arthritis (PsA)
2. Adults with active ankylosing spondylitis (AS)
3. Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

The following indications are FDA-approved but the drug approved to treat the indication is usually self-administered and thus not covered by this policy.
1. Moderate to severe plaque psoriasis (PsO) in patients 6 years of age and older who are candidates for systemic therapy or phototherapy
2. Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
3. Adults with moderate to severe hidradenitis suppurativa (HS)
4. Active psoriatic arthritis in pediatric patients 2 years of age and older

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
For continuation requests: Chart notes or medical record documentation supporting benefit of therapy.

III. CRITERIA FOR INITIAL APPROVAL

A. Psoriatic arthritis (PsA)
Authorization of 12 months may be granted for treatment of active psoriatic arthritis.

B. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)
Authorization of 12 months may be granted for treatment of active ankylosing spondylitis and active non-radiographic axial spondyloarthritis.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

All indications
Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Cosentyx.
B. Cosentyx is being used to treat an indication enumerated in Section III.
C. The member is receiving benefit from therapy.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Cosentyx.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. 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.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Cosentyx are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCE

1. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2023.