October 7, 2023

FDA-approved IV formulation

Effective July 1, 2024

Permanent J-code: J3247

IV Formulation of COSENTYX® Hospital Formulary Review Guide

For adult patients with PsA, AS, or nr-axSpA

INDICATIONS

COSENTYX® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy.

COSENTYX is indicated for the treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older.

COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis (AS).

COSENTYX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

COSENTYX is indicated for the treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older.

COSENTYX is indicated for the treatment of adult patients with moderate to severe hidradenitis suppurativa (HS).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients in COSENTYX. Cases of anaphylaxis and angioedema have been reported during treatment with COSENTYX.

Cosentyx® (secukinumab)

AS, ankylosing spondylitis; FDA, US Food and Drug Administration; IV, intravenous; nr-axSpA, non-radiographic axial spondyloarthritis; PsA, psoriatic arthritis.

Please see pages 9 and 10 for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Overview of IV formulation

The FIRST and ONLY IL-17A antagonist available in IV form

for adult patients with PsA, AS, or nr-axSpA[1-6]

The intravenous formulation of COSENTYX® was approved by the FDA on October 7, 2023.

The effectiveness and safety of COSENTYX you're familiar with, in an IV formulation[1]*

- **Individualized** weight-based dosing[1]
- **No premeds** required[1]
- **No reconstitution** required[1†]
- **30-minute** infusion Q4W (infliximab infusion time ≥2 hours)[1,2‡]

‡This is not intended to compare the relative safety or efficacy of these treatments for PsA and AS. Please refer to the full Prescribing Information of each agent for dosage and administration.

J3247: Permanent J-code effective July 1, 2024, for the IV formulation of COSENTYX[7§]

Permanent J-code[7]	J3247
Package strength[1]	125-mg/5-mL (25-mg/mL) solution in a single-dose vial for dilution prior to intravenous infusion
Description[7]	Injection, secukinumab, intravenous, 1 mg
Billing unit	1 unit per 1 mg
NDC[1]	10 digit: 0078-1168-61 11 digit: 00078-1168-61

*The effectiveness and safety of COSENTYX IV formulation are based on the pharmacokinetic exposure and extrapolation of the established effectiveness and safety of SC COSENTYX in adult patients with active PsA, AS, or nr-axSpA.[1]

†COSENTYX for IV use requires dilution prior to administration.[1]

§If COSENTYX is administered on or after July 1, 2024, the permanent J-code replaces the miscellaneous J-code, J3590.

IL, interleukin; NDC, National Drug Code; Q4W, every 4 weeks SC, subcutaneous.

References: 1. Cosentyx. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Remicade. Prescribing information. Janssen Biotech, Inc. **3.** Simponi Aria. Prescribing information. Janssen Biotech, Inc. **4.** Orencia. Prescribing information. Bristol-Myers Squibb Co. **5.** Taltz. Prescribing information. Eli Lilly & Co. **6.** Siliq. Prescribing information. Bausch Health US LLC. **7.** Centers for Medicare & Medicaid Services. *Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations. First Quarter, 2024 HCPCS Coding Cycle.* US Dept of Health and Human Services; 2024. Accessed April 11, 2024. https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-1-2024-drugs-and-biologicals-posted-04/02/2024.pdf

Please see pages 9 and 10 for Important Safety Information.
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Cosentyx® (secukinumab)

Clinical overview

Mechanism of action[1]

COSENTYX® is a human IgG1 monoclonal antibody that selectively binds to the 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
- COSENTYX inhibits the release of proinflammatory cytokines and chemokines

The IV formulation of COSENTYX was developed in response to the need for additional options for patients who[1,2]:

- May not be comfortable with SC self-injections
- Prefer in-office administration by their healthcare provider
- Might be interested in a new MOA for an IV formulation

Dosing was based on pharmacokinetic modeling predictions[1]

The IV formulation of COSENTYX was developed based on PK modeling, targeting an IV dose that was within the steady-state concentration parameters of the 150-mg and 300-mg doses given Q4W.

- It is a 1.75-mg/kg maintenance dose Q4W following a 6-mg/kg loading dose with an overall exposure within the range of the SC doses, to extrapolate to the established effectiveness and safety profile of the 150-mg and 300-mg SC doses. Maximum maintenance dose is 300 mg per infusion. COSENTYX IV formulation may be administered with or without a loading dose

For SC clinical trial results in adult patients with PsA, AS, or nr-axSpA, please see the COSENTYX full Prescribing Information.

IgG1, immunoglobulin G1; MOA, mechanism of action; PK, pharmacokinetic.

References: 1. Cosentyx. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Bolge SC, Eldridge HM, Lofland JH, Ravin C, Hart PJ, Ingham MP. Patient experience with intravenous biologic therapies for ankylosing spondylitis, Crohn's disease, psoriatic arthritis, psoriasis, rheumatoid arthritis, and ulcerative colitis. *Patient Prefer Adherence*. 2017;11:661-669.

Please see pages 9 and 10 for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

FDA approval letter

U.S. FOOD & DRUG ADMINISTRATION

BLA 761349

BLA APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Jake Myhill, PharmD, MBA
Senior Global Program Regulatory Manager
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Myhill:

Please refer to your biologics license application (BLA) dated and received December 7, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Cosentyx (secukinumab) injection, for intravenous (IV) use.

LICENSING

We have approved your BLA for Cosentyx (secukinumab) for IV use effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Cosentyx under your existing Department of Health and Human Services U.S. License No. 1244.

Cosentyx for IV use is indicated for adults with:

- Active psoriatic arthritis (PsA),
- Active ankylosing spondylitis (AS),
- Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture secukinumab drug substance at Novartis Pharma S.A.S. Centre de Biotechnologie in Huningue, France, and Sandoz GmbH Business Unit Biopharmaceuticals in Langkampfen, Austria. The final formulated drug product will be manufactured, filled, labeled, and packaged at Novartis Pharma Stein AG, Stein, Switzerland. You may label your product with the proprietary name, Cosentyx, and market it in 125 mg/5 mL single-dose vial.

DATING PERIOD

The dating period for Cosentyx shall be 24 months from the date of manufacture when stored at 2˚C to 8°C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be 60 months from the date of manufacture when stored at ≤ -60°C.

Please see pages 9 and 10 for Important Safety Information.
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Cosentyx® (secukinumab)

FDA approval letter (cont)

We have approved the stability protocol(s) in your license application for the purpose of extending the expiration dating period of your drug product under 21 CFR 601.12.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Cosentyx to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of Cosentyx, or in the manufacturing facilities, will require the submission of information to your BLA for our review and written approval, consistent with 21 CFR 601.12.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Medication Guide, and Instructions for Use). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As (October 2009)*.[2]

The SPL will be accessible via publicly available labeling repositories.

[1] See http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

Reference ID: 5257107

FDA approval letter (cont)

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 761349**." Approval of this submission by FDA is not required before the labeling is used.

ADVISORY COMMITTEE

Your application for secukinumab was not referred to an FDA advisory committee because outside expertise was not necessary; there were no controversial issues that would benefit from advisory committee discussion.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric studies requirements for patients with AS and nr-axSpA ages 0 to <18 years and for patients with PsA ages 0 to <2 years because these conditions are extremely rare in these age groups and the necessary studies are impossible or highly impracticable.

We are deferring submission of your pediatric study for patients with PsA ages 2 to <18 years for this application because this product is ready for approval for use in adults and the pediatric study have not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 601.28 and section 505B(a)(4)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

U.S. Food and Drug Administration
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Reference ID: 5257107

FDA approval letter (cont)

4523-1 Conduct an open-label study to evaluate the pharmacokinetics and safety of IV secukinumab plus background standard therapy in pediatric subjects ages 2 years to 17 years of age with psoriatic arthritis.

Final Protocol Submission: 10/2024
Study Completion: 10/2029
Final Report Submission: 04/2030

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit the protocol to your IND 012678, with a cross-reference letter to this BLA. Reports of this required pediatric postmarketing study must be submitted as a BLA or as a supplement to your approved BLA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.[4]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements at 21 CFR 600.80.

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[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

U.S. Food and Drug Administration
Silver Spring, MD 20993
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FDA approval letter (cont)

Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements at 21 CFR 600.81.

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

If you have any questions, call Saharat Patanavanich, Regulatory Project Manager, at (240) 402-0139.

Sincerely,

{See appended electronic signature page}

Nikolay P. Nikolov, MD
Director (Acting)
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use
- Carton and Container Labeling

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

Reference ID: 5257107

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COSENTYX® is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients in COSENTYX. Cases of anaphylaxis and angioedema have been reported during treatment with COSENTYX.

WARNINGS AND PRECAUTIONS

Infections

COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in COSENTYX treated subjects compared to placebo-treated subjects. In placebo-controlled clinical trials in subjects with moderate to severe PsO, higher rates of common infections, such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%) and mucocutaneous infections with candida (1.2% versus 0.3%) were observed in subjects treated with COSENTYX compared to placebo-treated subjects. A similar increase in risk of infection in subjects treated with COSENTYX was seen in placebo-controlled trials in subjects with PsA, AS and nr-axSpA. The incidence of some types of infections, including fungal infections, appeared to be dose-dependent in clinical trials.

In the postmarketing setting, serious bacterial, viral, and fungal opportunistic infections, and some fatal infections have been reported in patients receiving IL-17 inhibitors including COSENTYX. Cases of Hepatitis B virus reactivation have been reported.

Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, monitor the patient closely and discontinue COSENTYX until the infection resolves.

If signs of Hepatitis B virus reactivation occur, consult a hepatitis specialist. COSENTYX is not recommended for use in patients with active viral hepatitis.

Pre-treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX. Avoid administration of COSENTYX to patients with active TB infection. Initiate treatment of latent TB prior to administering COSENTYX. Consider anti-TB therapy prior to initiation of COSENTYX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients closely for signs and symptoms of active TB during and after treatment.

Please see page 10 for additional Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

Inflammatory Bowel Disease

Inflammatory Bowel Disease (IBD) exacerbations, in some cases serious and/or leading to discontinuation of COSENTYX®, occurred in COSENTYX treated subjects during clinical trials in PsO, PsA, AS, nr-axSpA, and HS. In adult subjects with HS, the incidence of IBD was higher in subjects who received COSENTYX 300 mg every 2 weeks (Ulcerative Colitis [UC] 1 case, EAIR 0.2/100 subject-years; Crohn's Disease [CD] 1 case, EAIR 0.2/100 subject-years) compared to subjects who received COSENTYX 300 mg every 4 weeks (IBD 1 case, EAIR 0.2/100 subject-years). In addition, new onset IBD cases occurred in subjects treated with COSENTYX in clinical trials. In an exploratory trial in 59 subjects with active Crohn's disease [COSENTYX is not approved for the treatment of Crohn's disease], there were trends toward greater disease activity and increased adverse reactions in subjects treated with COSENTYX as compared to placebo-treated subjects.

Exercise caution when prescribing COSENTYX to patients with IBD. Patients treated with COSENTYX should be monitored for signs and symptoms of IBD.

Eczematous Eruptions

In postmarketing reports, cases of severe eczematous eruptions, including atopic dermatitis-like eruptions, dyshidrotic eczema, and erythroderma, were reported in patients receiving COSENTYX; some cases resulted in hospitalization. The onset of eczematous eruptions was variable, ranging from days to months after the first dose of COSENTYX.

Treatment may need to be discontinued to resolve the eczematous eruption. Some patients were successfully treated for eczematous eruptions while continuing COSENTYX.

Hypersensitivity Reactions

Serious hypersensitivity reactions including anaphylaxis, angioedema, and urticaria have been reported in COSENTYX treated subjects in clinical trials and in the post-marketing setting. If an anaphylactic or other serious allergic reaction occurs, immediately discontinue administration of COSENTYX and initiate appropriate therapy.

The removable caps of the COSENTYX Sensoready® pen and the COSENTYX 1 mL and 0.5 mL prefilled syringes contain natural rubber latex, which may cause an allergic reaction in latex-sensitive individuals. The safe use of the COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.

Immunizations

Prior to initiating therapy with COSENTYX, consider completion of all age-appropriate immunizations according to current immunization guidelines. COSENTYX may alter a patient's immune response to live vaccines. Avoid use of live vaccines in patients treated with COSENTYX.

MOST COMMON ADVERSE REACTIONS

Most common adverse reactions (>1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection.

Please see page 9 for additional Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

Dosing and administration[1]

COSENTYX® for IV use must be diluted prior to infusion. Using aseptic technique, prepare COSENTYX for IV use as follows:

Step 1: Volume calculation

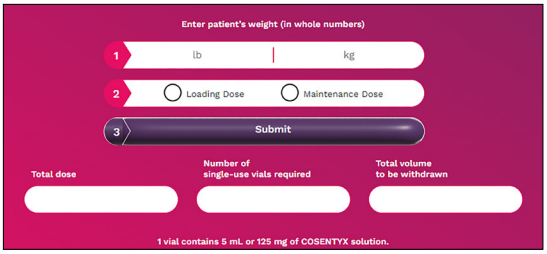
Calculate the total volume of COSENTYX for IV use solution (in mL) required based on the patient's actual body weight, using the table below.

Dosage		Volume of COSENTYX solution per kg of body weight
Loading dose	6 mg/kg	0.24 mL/kg
Maintenance dose	1.75 mg/kg	0.07 mL/kg

The intravenous formulation of COSENTYX may be dosed with or without a loading dose.

Use the number of vials based on total volume needed (1 vial contains 5 mL of COSENTYX solution).

For more information on dosing for the IV formulation of COSENTYX, visit Cosentyx-DosingCalculator.com.*



*In using this guide, you are agreeing to the following: This guide is intended for use by qualified healthcare providers only and is not a substitute for clinical judgment. Novartis Pharmaceuticals Corporation makes no claims pertaining to the accuracy of the information contained within the guide. All calculations should be confirmed prior to administration of COSENTYX for IV use. Neither Novartis Pharmaceuticals Corporation nor any party involved in the creation of this website is liable to you or others for any actions taken or decisions made in reliance on this guide.

Please see pages 9 and 10 for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

Dosing and administration (cont)

Step 2: Dilution

- Allow the diluted COSENTYX® solution for infusion to warm to room temperature prior to the start of the intravenous infusion
- Parenteral drug product should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if particulates or discolorations are noted
- Refer to the table below for recommended infusion bag size based on patient's body weight

Body weight at time of dosing	For loading dose (6 mg/kg) recommended infusion bag	For maintenance dose (1.75 mg/kg) recommended infusion bag
>52 kg (>115 lb)	100 mL	100 mL
≤52 kg (≤115 lb)	100 mL	50 mL*

*If a 50-mL infusion bag is unavailable, then use a 100-mL infusion bag and withdraw and discard 50 mL of saline, using aseptic technique and continue to follow the preparation and administration steps.

- From the infusion bag, withdraw and discard a volume of 0.9% Sodium Chloride Injection, *USP* equal to the calculated volume of the COSENTYX solution required for the patient's dose
- From the vial(s), withdraw the calculated volume (mL) of COSENTYX solution (as per the table in Step 1) and add slowly into the 0.9% Sodium Chloride Injection, *USP* infusion bag. To mix the solution, gently invert the bag to avoid foaming. Do not shake
- Discard unused COSENTYX product in vials because it does not contain preservatives

Administer the diluted COSENTYX solution for infusion as soon as possible. If not administered immediately, store the prepared solution either:

- At room temperature up to 20-25 °C (68-77 °F) for no more than 4.5 hours from the start of the preparation (piercing the first vial) to the completion of infusion
- Under refrigeration at 2-8 °C (36-46 °F) for no more than 24 hours, from the start of the time of the preparation (piercing the first vial) to the completion of infusion. This time includes the refrigeration of the diluted solution and the time to allow the diluted solution to warm to room temperature. Protect the diluted solution from light during storage under refrigeration

USP, United States Pharmacopeia.

Please see pages 9 and 10 for Important Safety Information.
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Cosentyx® (secukinumab)

Dosing and administration (cont)

Preinfusion checklist

- [ ] Assess patient's weight

Verify if the patient:

- [ ] Is being treated for an infection
- [ ] Has a chronic or reoccurring infection
- [ ] Has tuberculosis (TB) or has been in close contact with someone with TB
- [ ] Has recently received or is scheduled to receive an immunization
- [ ] Is pregnant or plans to become pregnant
- [ ] Is breastfeeding or plans to breastfeed

Step 3: Administration

- Use only an infusion set with an in-line, sterile, nonpyrogenic, low-protein-binding filter (pore size 0.2 micrometers)
- The infusion should be administered at a flow rate of about 3.3 mL/min for a 100-mL bag or 1.7 mL/min for a 50-mL bag (total administration time: 30 minutes)
- When administration is complete, flush the line with 0.9% Sodium Chloride Injection, *USP* to guarantee that all the COSENTYX® solution for infusion in the line has been administered
- COSENTYX should not be infused concomitantly in the same intravenous line with other drugs. No physical or biochemical compatibility studies have been conducted to evaluate the intravenous coadministration of COSENTYX with other drugs

Infusion protocols are at the discretion of the clinician and site of care.

Reference: 1. Cosentyx. Prescribing information. Novartis Pharmaceuticals Corp.

Please see pages 9 and 10 for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

Distribution and acquisition

Supplied and marketed by	Novartis Pharmaceuticals Corporation www.novartis.com www.COSENTYXhcp.com		
Product name	COSENTYX®		
Established name	secukinumab		
Product information[1]	The intravenous formulation of COSENTYX is provided as a 125-mg/5-mL solution in a single-dose vial that should be further diluted and prepared using aseptic technique and administered by a healthcare professional.		
	NDC: 10-digit NDC: 0078-1168-61 11-digit NDC: 00078-1168-61	**Description:** 125-mg/5-mL (25-mg/mL) single-dose vial for dilution	**Sale pack quantity:** Carton of 1 single-dose vial
Wholesale price	$2136.15, as of July 3, 2024		
Average sales price (ASP)[2]	ASP July 2024: $2071.23		
Product availability	The intravenous formulation of COSENTYX is available to ship. If your office is acquiring COSENTYX via Buy & Bill, the table on the following page provides an overview of the authorized distributors through which you can order.		

Please see pages 9 and 10 for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

Distribution and acquisition (cont)

Carton dimensions	3.82" x 2.85" x 1.32"
Storage and handling[1]	• Refrigerate vials of COSENTYX® at 2-8 °C (36-46 °F). Keep the product in the original carton to protect from light until the time of use. Do not freeze. To avoid foaming, do not shake. COSENTYX does not contain a preservative; discard any unused portion
Product returns	• If you have questions about COSENTYX returns, please contact Novartis Pharmaceuticals Corporation by phone at 1-800-526-0175, or email tradeoperations.phuseh@novartis.com • For returns of COSENTYX damaged in shipment, please contact your distributor
Patient support program	• Novartis Patient Support™ is a comprehensive program designed to help your patients start, stay, and save on COSENTYX. • Your practice and patients will have access to a Novartis Patient Support team committed to providing the support your patients need when they need it, including: -Dedicated assistance with insurance and reimbursement -Personalized support for your patients on therapy -Single point of contact for you and your patients • For tools and downloadable resources, visit CosentyxHCP.com
Additional information	Novartis Medical Information https://medinfo.novartispharmaceuticals.com/

References: 1. Cosentyx. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Centers for Medicare & Medicaid Services. ASP Pricing Files 2024. Accessed May 22, 2024. https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files

Please see pages 9 and 10 for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

Distribution and acquisition (cont)

If your office is acquiring COSENTYX® via **Buy & Bill**, the list below provides an overview of the authorized distributors through which you can order:

Distributor*	Contact Information	Website
AmerisourceBergen (Cencora) Besse Medical (practice distribution)	Phone: 1-800-543-2111 Fax: 1-800-543-8695	https://besse.com
AmerisourceBergen (Cencora) Oncology Supply (practice distribution)	Phone: 1-800-633-7555 Fax: 1-800-248-8205	https://oncologysupply.com
AmerisourceBergen (Cencora) Specialty Distribution (health systems and specialty pharmacy)	Phone: 1-800-746-6273 Fax: 1-800-547-9413	https://asdhealthcare.com
Anda	Phone: 1-855-772-2879 Fax: 1-800-989-0700	https://andameds.com
Cardinal Health Specialty Pharmaceuticals	Phone: 1-866-677-4844	https://specialtyonline.cardinalhealth.com
CuraScript SD	Phone: 1-877-599-7748	https://curascriptsd.com
Henry Schein	Phone: 1-800-772-4346 Fax: 1-800-329-9109	https://henryschein.com
McKesson Medical-Surgical (practice distribution)	Phone: 1-866-625-2679	https://mms.mckesson.com
McKesson MPB (health systems distribution)	Phone: 1-877-625-2566	https://connect.mckesson.com
McKesson Specialty Care Distribution (practice distribution)	Phone: 1-855-477-9800	https://mscs.mckesson.com
Metro Medical (A Cardinal Health Company)	Phone: 1-800-768-2002 Fax: 1-615-256-4194	https://metromedicalorder.com

*Novartis does not recommend the use of any particular distributor.

Specialty Pharmacies (SPs)†

COSENTYX for IV use is available through SPs, including IDN/system-owned SPs and many national SPs. Payers may dictate a specific specialty pharmacy. Be sure to confirm SP eligibility with the insurance provider. Novartis Patient Support can conduct a benefits verification to determine the specialty pharmacies available for your patient(s).

†Novartis does not recommend the use of any particular SP.

IDN, integrated delivery network.

Please see pages 9 and 10 for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

Distribution and acquisition (cont)

Group Purchasing Organizations (GPOs)
If you intend to work with a GPO, you can order through the following companies:

GPO*	Phone number	Website/Email	Notes
Cornerstone Rheumatology GPO	1-800-768-2002	https://cardinalhealth.com/cornerstonerheumatology	For Cardinal Health SD/ Metro Medical customers
MosaicGPO™ Solutions	1-800-768-2002	https://cardinalhealth.com/mosaicgpo	
VitalSource GPO	1-877-453-3972	https://cardinalhealth.com/vitalsourcegpo	
Specialty Networks	N/A	https://specialtynetworks.com membership@specialtynetworks.com	For Cardinal Health SD and Besse Medical customers
Matrix GPO	1-888-263-9982	https://matrixgpo.com	For CuraScript SD customers
Onmark GPO	1-855-477-9800	https://mckesson.com/Specialty/Group-Purchasing	For McKesson Specialty Care and Plasma and Biologics customers
Unity Oncology	1-855-477-9800	https://mckesson.com	
IPN Solutions	1-610-727-7000	https://specialtypracticenetwork.com	For ASD Healthcare (Amerisource Bergen/Cencora) and Besse Medical customers
ION Solutions	1-800-543-2111	https://iononline.com	
Vizient	1-800-842-5146	vizientsupport@vizientinc.com	For acute care customers
Cardinal Health	1-800-926-3161	https://cardinalhealth.com	
Remedy GPO	1-832-303-0612	https://remedygpo.com	

*Novartis does not recommend the use of any particular GPO.

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Cosentyx® (secukinumab)

Frequently asked questions

Q. How were the loading IV dose of 6 mg/kg and maintenance IV dose of 1.75 mg/kg chosen?

The modeling for the IV dose was designed to provide levels of drug in the blood within the range of COSENTYX® adult 150-mg to 300-mg SC dosages.[1]

Q. Why was PK modeling used in the FDA submission for the IV formulation of COSENTYX?

- PK modeling is an accepted and recognized approach by the FDA that uses a variety of quantitative methods to help balance the risks and benefits of drug products in development[2]
- When successfully applied, the FDA believes that PK modeling can improve clinical trial efficiency, increase the probability of regulatory success, and optimize drug dosing/therapeutic individualization in the absence of dedicated trials[2]
- The IV formulation of COSENTYX was developed based on PK modeling. FDA approval of IV was based on pharmacokinetic exposure analysis where the dose is modeled to be within the range of the blood levels achieved with the SC formulation of COSENTYX[1]

Q. How do I switch my patients from subcutaneous (SC) to IV dosing? Is there any guidance available?

No clinical trials have been performed to evaluate patients who switched from the SC to the IV formulation of COSENTYX.

Q. What are the most commonly seen side effects of COSENTYX?

Based on the SC clinical trial information, the most common adverse reactions (>1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection.[1]

Q. How is the IV formulation of COSENTYX administered?

The IV formulation of COSENTYX is administered as an IV infusion over 30 minutes[1]

- No premedication required
- No routine lab monitoring required
- No reconstitution required*

*COSENTYX solution in vials requires dilution prior to administration.[1]

Please see pages 9 and 10 for Important Safety Information.
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Cosentyx® (secukinumab)

Frequently asked questions (cont)

Q. What are the most common infusion reactions? Is there any guidance on protocols if there is a reaction?

- The safety and efficacy of IV formulation of COSENTYX® is based on the pharmacokinetic exposure and extrapolation of the established safety and efficacy of subcutaneous COSENTYX in PsA, AS, and nr-axSpA patients[1]
- No specific guidance can be provided. This is up to the discretion of the clinician and institution protocols

Q. What is the recommended monitoring time following the IV infusion?

No specific guidance can be provided. Monitoring protocols are at the discretion of the clinician and site of care.

Q. What is the cost per patient?

The WAC of the IV formulation of COSENTYX is **$2136.15** per vial as of July 3, 2024. Check with your preferred distributor or GPO for details on pricing. The total number of vials needed is dependent on patient body weight for loading vs maintenance dosing.[1]

Q. What is the permanent J-code? How do I bill claims following the administration of IV formulation of COSENTYX?

- The permanent J-code (J3247) for the IV formulation of COSENTYX is effective for infusion dates of service on or after July 1, 2024[3]
- Due to the weight-based dosing for the IV formulation of COSENTYX, customers should be sure to bill according to the amount of COSENTYX administered or wasted (1 unit per 1 mg). Keep in mind that CMS does not use fractional billing units. Units should be rounded up to the nearest whole number
- For more information, please refer to the IV Billing & Coding Guide on cosentyxhcpiv.com

Q. Where can I find more information about coding and billing?

For more information, visit cosentyxhcpiv.com to access the IV Billing & Coding Guide. This guide provides an overview of coding and coverage information related to the IV formulation of COSENTYX.

CMS, Centers for Medicare and Medicaid Services; WAC, wholesale acquisition cost.

References: 1. Cosentyx. Prescribing information. Novartis Pharmaceuticals Corp. **2.** US Food and Drug Administration. Model-informed drug development paired meeting program. Accessed September 29, 2023. https://www.fda.gov/drugs/development-resources/model-informed-drug-development-paired-meeting-program **3.** Centers for Medicare & Medicaid Services. *Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations. First Quarter, 2024 HCPCS Coding Cycle.* US Dept of Health and Human Services; 2024. Accessed April 11, 2024. https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-1-2024-drugs-and-biologicals-posted-04/02/2024.pdf

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Cosentyx® (secukinumab)

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