Cosentyx®
(secukinumab)

The **FIRST and ONLY IL-17A antagonist** available in IV form
for adult patients with active PsA, AS, or nr-axSpA[1-6]

Getting patients started with the **IV formulation of COSENTYX®**

A comprehensive guide to dosing, administering, and billing for the IV formulation of COSENTYX

AS, ankylosing spondylitis; IL, interleukin; IV, intravenous; nr-axSpA, non-radiographic axial spondyloarthritis; PsA, psoriatic arthritis.

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.

Please see pages 10 and 11 for full Important Safety Information.

Please see full Prescribing Information, including Medication Guide.

How to use this guide

This guide conveniently includes the information, tools, and resources you need to help your patients start and stay on the IV formulation of COSENTYX®.

The following sections provide guidance at each step of the onboarding process:

Visit **Cosentyx-DosingCalculator.com** or scan the QR code for additional information and resources to help you get patients started on the IV formulation.

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IV dosing information[1]

Recommended IV dosing regimen of COSENTYX® for adults with PsA, AS, or nr-axSpA:

Individualized weight-based dosing

6 mg/kg
given at Week 0
as a loading dose

1.75 mg/kg
every 4 weeks
thereafter

COSENTYX IV formulation can also be administered without a loading dose at 1.75 mg/kg every 4 weeks.

COSENTYX solution in vials requires dilution prior to administration. Total doses exceeding 300 mg per infusion are not recommended for the 1.75-mg/kg maintenance dose in patients with PsA, AS, or nr-axSpA.

No premeds required

No reconstitution required

30-minute infusion Q4W

Q4W, every 4 weeks.

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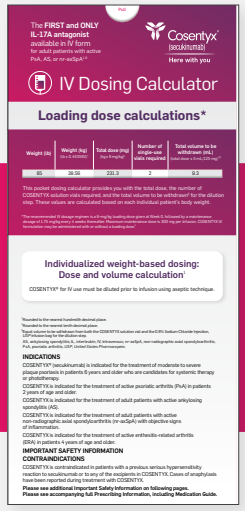
Preparation and administration of COSENTYX® for IV use[1]

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 as follows:
  - Loading dose (6 mg/kg) is 0.24 mL/kg
  - Maintenance dose (1.75 mg/kg) is 0.07 mL/kg
- Use the number of vials based on total volume needed (1 vial contains 5 mL of COSENTYX solution)



For help with loading and maintenance dose calculations, visit **Cosentyx-DosingCalculator.com**, scan the QR code, or ask your COSENTYX representative about the IV Pocket Dosing Calculator for your office.*

*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.

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Preparation and administration of COSENTYX® for IV use[1] (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
- Follow the table below for recommended infusion-bag size based on patient's body weight

Recommended infusion bags for dilution and preparation of COSENTYX for IV use based on body weight and dose

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	100 mL	100 mL
≤52 kg	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 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 diluted 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

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USP, United States Pharmacopeia.

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Preparation and administration of COSENTYX® for IV use[1] (cont)

Step 3: Administration

- Use only an infusion set with an in-line, sterile, nonpyrogenic, low-protein-binding filter (pore size 0.2 micrometer)
- Administer the infusion at a flow rate of about 3.3 mL/minute for a 100-mL bag or 1.7 mL/minute 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 diluted COSENTYX solution for infusion in the line has been administered
- Do not infuse COSENTYX concomitantly in the same IV line with other drugs. No physical or biochemical compatibility studies have been conducted to evaluate the IV coadministration of COSENTYX with other drugs

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How the IV formulation of COSENTYX® is supplied and stored

How supplied[1]	Packaging[1]	10-digit NDC[1]	11-digit NDC
125-mg/5-mL solution in a single-dose vial	Individually packaged in a carton	0078-1168-61	00078-1168-61

Product description: COSENTYX for intravenous use is a sterile, preservative free, clear to opalescent, colorless to slightly yellowish solution in a single-dose vial for dilution prior to intravenous infusion (for healthcare professional use only).[1]

Storage: Refrigerate COSENTYX for intravenous use at 2-8 °C (36-46 °F). Keep the product in its 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. If not administered immediately, store the diluted solution either[1]:

- At room temperature 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

If your office is acquiring COSENTYX in IV form via Buy and Bill, see a list of **authorized distributors** from which you can order.* Keep in mind that your patient's health plan may require a certain method of acquisition.

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

NDC, National Drug Code.

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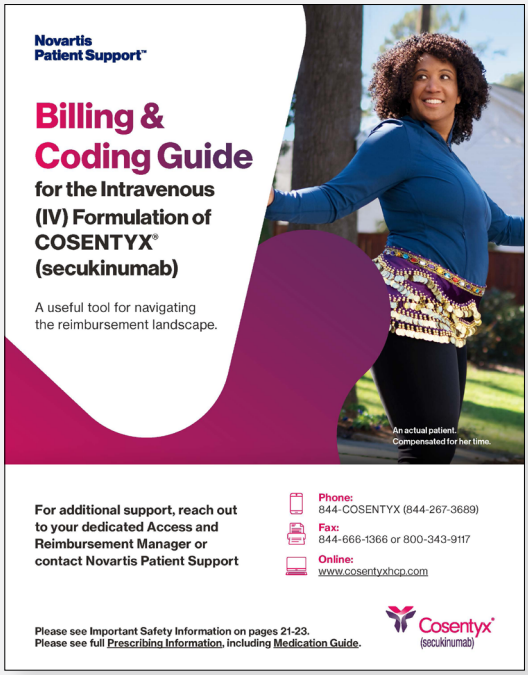
Coding and billing for the IV formulation

We want to make sure you have all the information you need when navigating insurance and reimbursement for the IV formulation of COSENTYX®. Use the resource below to help you determine the required claim form information and compile relevant documentation for complete communications with health plans.



Coding & Billing Guide* >

Provides an overview of coding and coverage information related to the IV formulation of COSENTYX, including:

- Drug codes
- CPT codes
- *ICD-10* codes
- Setting-of-care codes
- Claims submission checklists with sample forms

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We are here to help you help your patients.

For additional support and resources, visit **cosentyx-hcpiv.com**.

*Novartis does not guarantee payment or coverage for any product or service. Information specific to coding and billing is subject to change without notice and should be verified by the provider for each patient prior to treatment. It is always the provider's responsibility to determine the appropriate healthcare setting, and to submit true and correct claims for the products and services rendered. Providers should contact third-party health plans for specific information on their coding, coverage and payment policies, and fee schedules.

CPT, Current Procedural Terminology; *ICD-10*, *International Classification of Diseases, Tenth Revision*.

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Comprehensive support with Novartis Patient Support™

Designed to make onboarding seamless and efficient for patients and HCPs

Benefits verification

Investigate coverage obstacles and take action

- Obstacles may include lack of coverage, prior authorization (PA) denial, or step therapy

Facilitate PA process

- Our team can help initiate PA requests or letters of appeal directly with your office and/or have your office follow up with your patient's health plan regarding PA status
- Many health plans will allow up to 3 levels of appeal of PA denials

Savings options

$0 Co-Pay Plus offer*

Co-pay* Plus offer†

- Helps patients save on their out-of-pocket costs for BOTH COSENTYX® and administration
- Get patients started using the COSENTYX Start Form or by enrolling them in the Co-pay Plus Portal
- Once the Explanation of Benefits has been received, you can submit a co-pay claim electronically or by fax

Acquisition support

Guidance on appropriate distributors and specialty pharmacies

- Our team can help your office understand the authorized distributors available to order the IV formulation of COSENTYX
- Novartis Patient Support can also determine if there are any specialty pharmacy requirements

Coding & billing

Support with understanding relevant reimbursement codes

- Our team is here to help your office understand the appropriate codes
- Our Coding & Billing Guide also provides a comprehensive overview of the available codes
- Offices should contact third-party health plans for specific information regarding their coding, coverage, and payment policies

To learn more, visit **cosentyx-hcpiv.com** or call Novartis Patient Support at 844-COSENTYX (844-267-3689).

*__Limitations apply.__ Subject to annual co-pay benefit limit. Offer not valid under Medicare, Medicaid, or any other federal or state programs. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply. See complete Terms & Conditions at cosentyxhcp.com/rheumatology/novartis-patient-support details.

†Certain payers have carve-outs that restrict utilization of manufacturer support programs.

HCP, healthcare professional.

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Indications and Important Safety Information

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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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.

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See page 11 for additional Important Safety Information.
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Indications and Important Safety Information (cont)

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.

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.

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NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080