



# Prior Authorizations, Exceptions & Appeals Kit

Information and sample letters to help you navigate coverage for your patients on COSENTYX®

## INDICATIONS

COSENTYX® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis 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.

## 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 have been reported during treatment with COSENTYX.

The information herein is provided for educational purposes only. Novartis Pharmaceuticals Corporation cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the healthcare provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Please see pages [12](#) and [13](#) for full Important Safety Information.

Please see full [Prescribing Information](#), including [Medication Guide](#).

Click these tabs to switch sections.

## How to use this kit

This kit includes information and suggestions to help you navigate the coverage process for your patients who have been prescribed COSENTYX®. Whether you use an electronic prior authorization (PA) platform or submit requests manually, the tips, checklists, and sample letters throughout this kit are designed to help you and your patients compile relevant documentation for complete communications with health plans.



Click on any section to jump to that page.

This kit is interactive—keep an eye out for callouts to see where you can click.

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**READY  
SET**  
COSENTYX



**Cosentyx**  
(secukinumab)

Visit [ReadySetCosentyx.com](https://www.ReadySetCosentyx.com) to explore additional resources to help you get patients started on COSENTYX.

# Getting your patient started

Various health plans may manage coverage requirements for COSENTYX® (secukinumab) differently. Use this page to review the coverage process and identify which steps apply to your patient.

## 1 SUBMIT YOUR PATIENT'S PRESCRIPTION

COSENTYX can be submitted to any specialty pharmacy you choose, or to a pharmacy mandated by your patient's health plan. For support throughout the coverage process and additional resources for your patient, you can complete the COSENTYX **Start Form** to enroll your patient in the COSENTYX® Connect Personal Support Program.

## 2 CONDUCT A BENEFITS INVESTIGATION FOR YOUR PATIENT

Determine the specific coverage criteria for your patient's health plan. If you need help with this step, reach out to your COSENTYX Access & Reimbursement Manager (ARM).

## 3 ADDRESS THE PLAN'S COVERAGE POLICIES



Click on the step to jump to that section.

### [Prior authorization \(PA\) needed](#) >

See tips and a checklist if the health plan requires a PA to confirm that certain criteria have been met to cover COSENTYX for your patient.

OR

### [Exception appropriate](#) >

See tips and a checklist for an exception request if COSENTYX:

- Is excluded from the formulary or NDC blocks are in place
- Is not affordable for your patient due to the cost designated to its assigned tier

## 4a PA OR EXCEPTION REQUEST APPROVED

## 4b IF DENIED, SUBMIT AN APPEAL

### [Appeals](#) >

See tips and a checklist for submitting a formal appeal to the health plan if the PA or exception request is denied.

## 5 UPON APPROVAL, SCHEDULE DELIVERY

If the patient's health plan approves the PA, exception request, or appeal, the pharmacy will fill and deliver COSENTYX directly to your patient.

NDC, National Drug Code.

Please see pages [12](#) and [13](#) for full Important Safety Information.

Please see full [Prescribing Information](#), including [Medication Guide](#).

## Tips to help you submit a PA request



If a patient's health plan requires a **prior authorization (PA)** for COSENTYX® (secukinumab), review the specific forms and information needed by the health plan to ensure the PA request is as complete as possible.



Click on the **purple** terms to define.

### TIPS

- Conduct a benefits investigation of your patient's health plan to help you determine the specific coverage criteria for COSENTYX. Ensure you understand and satisfy all plan-specific requirements
- Understand if specific forms or submission formats are required for the PA request:
  - The health plan may have a unique PA form—look on their website or contact customer service
  - Some health plans encourage the use of electronic PA submission platforms (eg, CoverMyMeds®)
  - Certain states require a standardized PA form—check if this applies to your state
- Check to see if your patient's health plan requires separate PA submissions for the loading and maintenance doses of COSENTYX. **Click here** to make sure that you have included the appropriate dosing information for your patient
- Consider including a personalized letter with the PA documentation; you may submit a Letter of Medical Necessity to explain your rationale supporting your patient's clinical need for COSENTYX

**Click** the links below to download the appropriate sample letter for your office:

[Letter of Medical Necessity \(Dermatology\)\\* >](#)

[Letter of Medical Necessity \(Rheumatology\)† >](#)



See the following page for a helpful PA submission checklist.

### We are here to help

- Your COSENTYX Access & Reimbursement Manager (ARM) can help you find and understand your patient's health plan coverage criteria
- For support throughout the coverage process and additional resources for your patient, you can submit the **Start Form** to enroll your patient in COSENTYX® Connect

\*Applies to plaque psoriasis in patients 6 years and older.

†Applies to PsA in patients 2 years of age and older, adult patients with AS, adult patients with nr-axSpA, and ERA in patients 4 years of age and older.

AS, ankylosing spondylitis; ERA, enthesitis-related arthritis; nr-axSpA, non-radiographic axial spondyloarthritis; PsA, psoriatic arthritis.

**Please see pages 12 and 13 for full Important Safety Information.**

**Please see full Prescribing Information, including Medication Guide.**

# Preparing a PA submission

## PA SUBMISSION CHECKLIST

Check that you have completed the following when submitting a PA for your patient:

**Fill out the plan- and/or state-specific PA form**

- Remember to conduct a benefits investigation to ensure that you satisfy all of the health plan's requirements for COSENTYX® (secukinumab)

**Attach relevant clinical documentation supporting treatment with COSENTYX, such as:**

- Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
- Appropriate clinical information from the [Prescribing Information](#) for COSENTYX
- Relevant medical records and clinical notes that support treatment with COSENTYX. Ensure that you include any disease-specific criteria required by the health plan. Below are examples of information you may want to include:

### Dermatology\*

- Diagnosis and the date of diagnosis
- Tuberculosis test results
- BSA and/or PASI score
- Indication of persistent troublesome areas of the body to treat (if any)
- List of previous therapies used, duration of therapy, and reason for discontinuation
- If appropriate, description of any examples in the rheumatology column that apply to your patient

### Rheumatology†

- Diagnosis and the date of diagnosis
- Tuberculosis test results
- Lab results (eg, hsCRP, ESR, or HLA-B27)
- If appropriate, PASI score
- If appropriate, number of active joints, enthesitis, and/or dactylitis
- Assessment of disease severity
- List of previous therapies used, duration of therapy, and reason for discontinuation

- [Click here](#) for a list of *ICD-10* codes

\*Applies to plaque psoriasis in patients 6 years and older.

†Applies to PsA in patients 2 years of age and older, adult patients with AS, adult patients with nr-axSpA, and ERA in patients 4 years of age and older.

BSA, body surface area; ESR, erythrocyte sedimentation rate; HLA, human leukocyte antigen; hsCRP, high-sensitivity C-reactive protein; *ICD-10*, *International Classification of Diseases, Tenth Revision*; PASI, Psoriasis Area and Severity Index.

Please see pages [12](#) and [13](#) for full Important Safety Information.

Please see full [Prescribing Information](#), including [Medication Guide](#).

## Tips to help you submit exception requests



If the patient's health plan has placed certain restrictions on COSENTYX® (secukinumab), such as [formulary](#) exclusion or [tier](#) assignment, you will need to submit an exception request.



Click on the [purple](#) terms to define.

### Tiering exception request

Use this type of exception request to support patients seeking approval for COSENTYX as a [preferred drug](#) that has a lower [co-payment](#) than its assigned tier.

### Formulary exception request

Use this type of exception request to support patients seeking approval for COSENTYX or to remove any applicable [National Drug Code \(NDC\)](#) blocks if COSENTYX is excluded from the formulary of your patient's health plan.

### TIPS

- Conduct a benefits investigation of your patient's health plan to help you determine the specific coverage criteria for COSENTYX. Ensure you understand and satisfy all plan-specific requirements
- Check to see if the patient's health plan has its own exception request form—it can be located on their website or by contacting their customer service
- You may also submit a tiering exception request or formulary exception request if your patient's health plan previously approved COSENTYX but has since changed their formulary to exclude or move COSENTYX to a higher tier without grandfathering in current patients
- Consider asking your patient or their legal guardian to write their own exception request letter that is signed by the physician. [Click here](#) to download a checklist with helpful tips for your patient when writing to their health plan



See the following page for a helpful exception request checklist.

### We are here to help

- Your COSENTYX Access & Reimbursement Manager (ARM) can help you find and understand your patient's health plan coverage criteria
- For support throughout the coverage process and additional resources for your patient, you can submit the [Start Form](#) to enroll your patient in COSENTYX® Connect

Please see pages [12](#) and [13](#) for full Important Safety Information.

Please see full [Prescribing Information](#), including [Medication Guide](#).

# Preparing an exception request

## EXCEPTION REQUEST CHECKLIST

Check that you have completed the following when requesting an exception for your patient:

**Fill out the health plan's exception request form, if required**

- Remember to conduct a benefits investigation to ensure that you satisfy all of the health plan's requirements

**Complete a Letter of Medical Necessity with relevant information, including:**

- Patient's name, date of birth, and insurance information
- A statement of the exception you are requesting for the patient and the reason for the request
- Patient's diagnosis ([Click here for ICD-10 codes](#))
- Summary of the patient's current condition and relevant treatment history
- Rationale for choosing COSENTYX® (secukinumab)
- If appropriate, a statement of the patient's financial hardship

**Click** the links below to download the appropriate sample letter for your office:

[Letter of Medical Necessity \(Dermatology\)\\*](#) >

[Letter of Medical Necessity \(Rheumatology\)†](#) >

**Attach relevant clinical documentation supporting treatment with COSENTYX, such as:**

- Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
- Appropriate clinical information from the [Prescribing Information](#) for COSENTYX
- Relevant medical records and clinical notes that support treatment with COSENTYX. Ensure that you include any disease-specific criteria needed by the health plan. Below are examples of information you may want to include:

### Dermatology\*

- Diagnosis and the date of diagnosis
- Tuberculosis test results
- BSA and/or PASI score
- Indication of persistent troublesome areas of the body to treat (if any)
- List of previous therapies used, duration of therapy, and reason for discontinuation
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Please see full [Prescribing Information](#), including [Medication Guide](#).

## Tips to help you submit an appeal



If the patient's [PA](#) or [exception](#) request has been denied, their health plan will provide a written explanation and include information about how to request an [appeal](#).


Review the insurer's guidelines about the appeal process to ensure the appeal is as complete as possible.



Click on the [purple](#) terms to define.

### TIPS

- Conduct a benefits investigation of your patient's health plan to help you determine the specific coverage criteria for COSENTYX® (secukinumab)
- Promptly submit the appeal upon receipt of the denial to help avoid delays
- Clearly respond to the health plan's specific reason(s) for denial within your appeal letter
- Review the appeals process for your patient's health plan:
  - Many health plans will allow up to 3 levels of appeals—the third level of appeal may include review by an independent external review board or hearing
  - Your patient's appeals rights and the appeals process are covered in health plan documents and on each [Explanation of Benefits \(EOB\)](#) form
- If your office uses an electronic PA submission site, check to see if you can submit an appeal via the platform

 See the following page for a helpful appeal submission checklist.

### We are here to help

- Up to 2 years of free COSENTYX is available with Covered Until You're Covered for qualified\*† commercially insured patients if a PA is denied while coverage is pursued
- Your COSENTYX Access & Reimbursement Manager (ARM) can help you find and understand your patient's health plan coverage criteria
- For support throughout the coverage process and additional resources for your patient, you can submit the [Start Form](#) to enroll your patient in COSENTYX® Connect

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

†For terms, conditions, and limitations related to Covered Until You're Covered, please see the [last page](#) of this kit.

Please see pages [12](#) and [13](#) for full Important Safety Information.

Please see full [Prescribing Information](#), including [Medication Guide](#).



# Preparing an appeal

## APPEAL SUBMISSION CHECKLIST

Check that you have completed the following when submitting an appeal for your patient:

- Fill out an appeal form in response to the denial, if required by the health plan**
  - Remember to conduct a benefits investigation to ensure that you satisfy all of the health plan's requirements
  - Make sure that you review and attach the denial letter
- Complete an appeal letter with relevant patient information and clinical support, including:**
  - Patient's name, date of birth, and insurance information
  - Denial date and denial reference number
  - A statement clearly addressing the plan's specific reason(s) for denial
  - Summary of patient's diagnosis and current condition ([Click here for ICD-10 codes](#))
  - Summary of patient's treatment history
  - Explanation detailing why each of the health plan's suggested alternative therapies are not appropriate for your patient
  - Rationale for choosing COSENTYX® (secukinumab)

**Click the links below to download the appropriate sample letter for your office:**

[Appeal letter \(Dermatology\)\\* >](#)    [Appeal letter \(Rheumatology\)† >](#)

- Attach relevant clinical documentation supporting treatment with COSENTYX, such as:**
  - Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
  - Appropriate clinical information from the [Prescribing Information](#) for COSENTYX
  - Relevant medical records and clinical notes that support treatment with COSENTYX. Ensure that you include any disease-specific criteria needed by the health plan. Below are examples of information you may want to include:

### Dermatology\*

- Diagnosis and the date of diagnosis
- Tuberculosis test results
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# Sample letters



Click the links below to download customizable letters for your office in Word Doc format:

## Physician letters

[Appeal letter \(Dermatology\)\\*](#)



[Appeal letter \(Rheumatology\)†](#)



[Letter of Medical Necessity \(Dermatology\)\\*](#)



[Letter of Medical Necessity \(Rheumatology\)†](#)



## Patient letters

[Patient letter checklist](#)



**READY  
SET**  
COSENTYX



**Cosentyx**<sup>®</sup>  
(secukinumab)

## We are here to help you and your patients.

For additional support and resources, reach out to your Access & Reimbursement Manager (ARM) or visit [ReadySetCosentyx.com](https://www.ReadySetCosentyx.com).

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# Glossary

**Appeal:** A request to a patient's health plan to reconsider their decision to deny coverage.

**Co-payment:** A cost-sharing arrangement in which a covered person pays a specified charge when they receive a covered service—like doctor visits, prescription medications, and other healthcare services.

**Exception:** A coverage request made to a patient's health plan to remove a plan restriction placed on a treatment.

**Explanation of benefits (EOB):** A statement from the health plan sent to members to track the use of medications and/or healthcare services and the associated costs and payments.

**Formulary:** A list of prescription medications covered by a health plan.

**Health plan:** An organization that provides financial coverage for healthcare services or medications.

**National Drug Code (NDC):** Universal product identifier with a unique set of numbers used for human drugs in the United States.

**Pharmacy Benefit Manager (PBM):** A third-party organization hired to manage pharmacy benefits.

**Preferred drug:** A medication designated as a valuable, cost-effective treatment option. In a multiple-tiered plan, preferred drugs are assigned to a lower tier than nonpreferred drugs.

**Prior authorization (PA):** Also called preauthorization, an administrative tool used by health plans to determine if they will cover a prescribed procedure, service, or medication based on the patient's medical necessity.

**Step therapy:** A health plan policy that requires a patient to try and fail treatment with 1 or more plan-preferred drugs before the plan will cover a different drug for their health condition.

**Tiers:** Most health plans' formularies are divided into different categories, called tiers, with scaled co-payments. Tiers are commonly based on brand or generic medications, preferred or nonpreferred medications, and traditional or specialty medications.

## INDICATIONS AND IMPORTANT SAFETY INFORMATION

### INDICATIONS

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

### 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 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 plaque psoriasis, 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 with COSENTYX compared with placebo. A similar increase in risk of infection was seen in placebo-controlled trials in subjects with psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis. The incidence of some types of infections appeared to be dose-dependent in clinical studies. In the postmarketing setting, serious and some fatal infections have been reported in patients receiving COSENTYX.

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.

##### 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 additional Important Safety Information on the following page.  
Please see full [Prescribing Information](#), including [Medication Guide](#).**

## IMPORTANT SAFETY INFORMATION (cont)

### Inflammatory Bowel Disease

Caution should be used when prescribing COSENTYX® to patients with inflammatory bowel disease. Exacerbations, in some cases serious, occurred in COSENTYX treated subjects during clinical trials in plaque psoriasis, psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis. In addition, new onset inflammatory bowel disease cases occurred in clinical trials with COSENTYX. In an exploratory trial in 59 subjects with active Crohn's disease, there were trends toward greater disease activity and increased adverse events in the secukinumab group as compared to the placebo group. Patients who are treated with COSENTYX should be monitored for signs and symptoms of inflammatory bowel disease.

### 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

Anaphylaxis and cases of urticaria occurred in COSENTYX treated subjects in clinical trials. If an anaphylactic or other serious allergic reaction occurs, administration of COSENTYX should be discontinued immediately and appropriate therapy initiated.

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.

The Covered Until You're Covered Program is available for COSENTYX subcutaneous injection only. Eligible patients must have commercial insurance, a valid prescription for COSENTYX, and a denial of insurance coverage based on a prior authorization request. Program requires the submission of an appeal of the coverage denial within the first 90 days of enrollment in order to remain eligible. Program provides COSENTYX for free to eligible patients for up to 2 years, or until they receive insurance coverage approval, whichever occurs earlier. A valid prescription consistent with FDA-approved labeling is required. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Patients may be asked to reverify insurance coverage status during the course of the program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Limitations may apply. Enrolled patients awaiting coverage for COSENTYX after 2 years may be eligible for a limited Program extension. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this Program without notice.

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**Please see additional Important Safety Information on the previous page.**

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