

Prior Authorization and Appeals Guide

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



Phone:
844-267-3689



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844-666-1366 or 800-343-9117



Online:
www.cosentyxhcp.com



Portal:
www.covermymeds.health



For questions or support, reach out to your dedicated Access and
Reimbursement Manager (ARM) or contact Novartis Patient Support.

Please see Indications and Important Safety Information on pages 16-18.
Please see full [Prescribing Information](#), including [Medication Guide](#).



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This guide intends to be a resource for you to use if your patient is faced with common insurance restrictions like a prior authorization (PA), step edit, or a plan not having a policy in place for COSENTYX® (secukinumab). Whether using an electronic PA form or submitting requests manually, the tips, checklists, and sample letters included in this guide are designed to help you and your patients gather relevant documentation for complete communications with your patient’s health plan.

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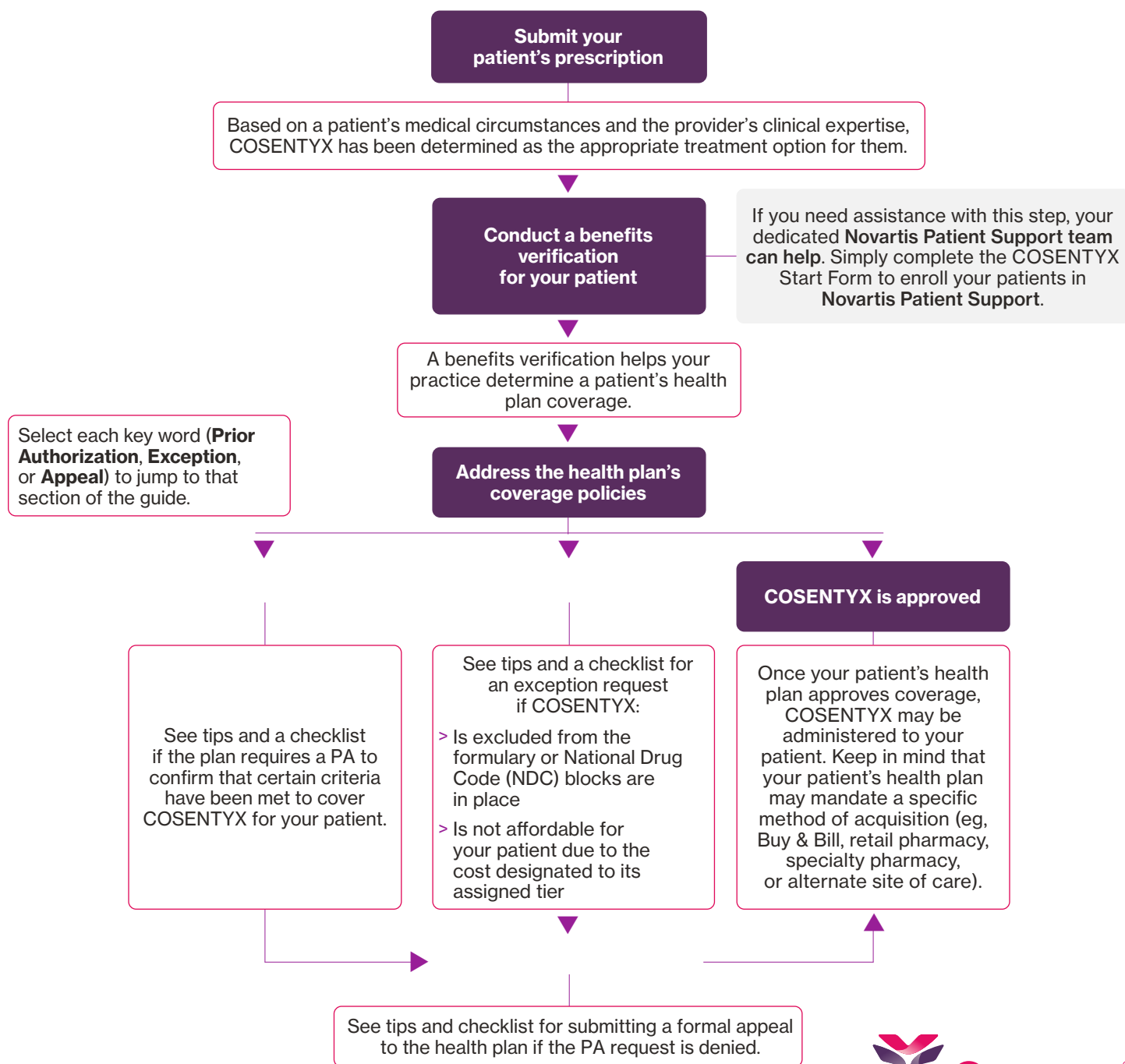
Select a tab on the bottom of each page to go to the section that interests you. Press the home icon button to return to this page. This guide is interactive—keep an eye out for callouts to see where you can click.

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Overview of the Reimbursement Process for the Subcutaneous (SC) Formulation

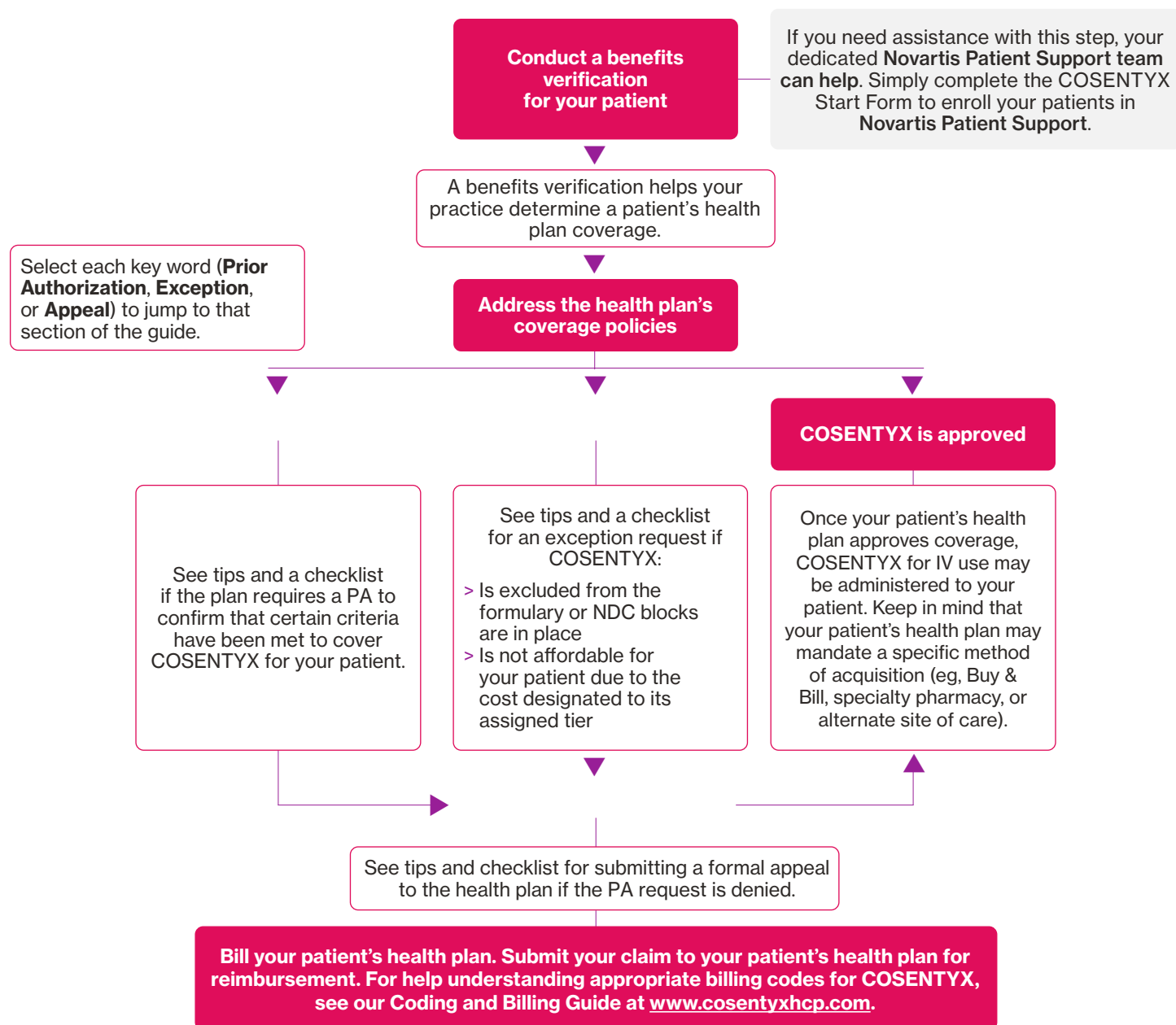
Various health insurance providers may manage access to COSENTYX® (secukinumab) differently. Use this page to review the coverage process and identify which steps apply to your patient.



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Overview of the Reimbursement Process for the Intravenous (IV) Formulation

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



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Tips for Completing a PA Request

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

Tips



- **Conduct** a benefits verification of your patient's health plan to help determine the specific coverage criteria for COSENTYX
- For IV formulation,* PA is not required if during benefits verification a predetermination documentation can be obtained



- **Ensure** that you understand and satisfy all plan-specific requirements
 - The patient's health plan may have a unique PA form that can be located on their website or by contacting their customer service
 - In certain states, a standardized PA form may be required for submission to a health plan along with clinical documentation
 - Some health plans encourage the use of electronic PA submission platforms (eg, CoverMyMeds®)
 - Quickly enroll patients and track their progress

- **Check** to see if your patient's health plan requires separate PA submissions for the loading and maintenance doses of COSENTYX. Make sure that you have included the appropriate dosing information for your patient. Visit www.cosentyxhcp.com for SC and IV dosing resources

Start a request

Visit www.covermymeds.health

Log in to your account

Select "New Request" for HCP-initiated requests or "Enter Key" for pharmacy-initiated requests

covermymeds®

- Complete PA requests in minutes and get a response as quickly as a few hours
- No paper, no fax, no duplicate services
- Electronic paper signatures



- **Consider** including a personalized letter with PA documentation; you may prefer to submit a Letter of Medical Necessity to explain your rationale supporting your patient's clinical need for COSENTYX. For adult patients with PsA, AS, or nr-axSpA prescribed COSENTYX for IV use, be sure to include documentation of medical necessity for IV administration

↓ [Click here](#) to view sample **Letter(s) of Medical Necessity (Dermatology)** for your office.

↓ [Click here](#) to view sample **Letter(s) of Medical Necessity (Rheumatology)** for your office.

A PA may be denied for COSENTYX based on various reasons. Common causes of a PA denial are shown below.

Medical Necessity

Health plans may deny access if the proposed treatment does not meet the threshold for being medically necessary or clinically appropriate.

Administrative Errors

An incorrect billing code, spelling errors, insufficient information, or other administrative inaccuracies can result in a denied PA request.

Step Therapy

Depending on a health plan's formulary, patients are often required to receive a less expensive drug before a more expensive treatment can be prescribed.

If a drug is not listed on formulary or is NDC blocked, you may be able to submit an exception for these scenarios.

See the following pages for helpful PA request checklists.

*Indicated for adults with active PsA, active nr-axSpA, and AS.

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

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 **Cosentyx®**
(secukinumab)

Preparing a PA Submission

Submission checklist for dermatology*

Consider the following points when preparing to submit a PA for your patient. The checklist below is provided to help ensure your PA Request Letter is as complete as possible when communicating with health plans. The following page contains a sample letter that you may reference when crafting your own letter to the patient's health plan. The list below is intended to provide examples of what information is usually required.

- ▶ **Fill out the plan- and/or state-specific PA form**
 - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements for COSENTYX® (secukinumab)
- ▶ **Check that the following information is accurate and complete:**
 - Patient and insurance information (name, address, DOB, insurance information, etc)
 - Prescriber information (name, address, specialty, office contact, NPI, etc)
- ▶ **Document the treatment strength, frequency, quantity, and estimated length of therapy, including the appropriate NDC code**
- ▶ **Attach relevant clinical documentation supporting treatment with COSENTYX, such as:**
 - Relevant medical records and clinical notes that support treatment with COSENTYX
 - Diagnosis including the appropriate *ICD-10-CM* code and date of diagnosis
 - Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
 - Appropriate clinical information from the Prescribing Information for COSENTYX
 - Disease-specific criteria, including information such as the following:
 - Tuberculosis (TB) test results
 - Plaque psoriasis (PsO) or hidradenitis suppurativa (HS)-specific information from the sample letter examples
 - If appropriate, include examples from the rheumatology checklist that apply to your patient
 - List of previous therapies used, duration of therapy, and reason for discontinuation
- ▶ **For patients with PsO and PsA, be sure to include relevant information from appropriate letters**



- ▶ **Reach out** to your dedicated Novartis Access and Reimbursement Manager (ARM)—they can help you understand plan requirements and coverage criteria



- ▶ **For support** throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support



Click here to download a customizable PA letter for your office in Word doc format.



Click here for a list of *ICD-10-CM* codes.

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*Applies to plaque psoriasis in patients 6 years and older and adult patients with HS.

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

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

► **Check that the following information is accurate and complete:**

- Patient and insurance information (name, address, DOB, insurance information, etc)
- Prescriber information (name, address, specialty, office contact, NPI, etc)

► **For IV formulation,* a predetermination can be used to check with the plan what is required for successful reimbursement**

► **Document the treatment strength, frequency, quantity, and estimated length of therapy, including the appropriate NDC code**

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

- Relevant medical records and clinical notes that support treatment with COSENTYX
 - Diagnosis including the appropriate *ICD-10-CM* code and date of diagnosis
- Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
- Appropriate clinical information from the Prescribing Information for COSENTYX
- Disease-specific criteria, including information such as the following:
 - TB test and Lab results (eg, hsCRP, ESR, or HLA-B27)
 - PsA, AS, or nr-axSpA-specific information from the sample letter examples
 - If appropriate, include assessment of disease severity (eg, PASI score)
 - For adult patients with PsA, AS, or nr-axSpA prescribed COSENTYX for IV use, be sure to include documentation of medical necessity for IV administration
 - List of previous therapies used, duration of therapy, and reason for discontinuation



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DOB, date of birth; ESR, erythrocyte sedimentation rate; HLA, human leukocyte antigen; hsCRP, high-sensitivity C-reactive protein; *ICD-10-CM*, *International Statistical Classification of Diseases, Tenth Revision*; NPI, National Provider Identifier; PASI, Psoriasis Area and Severity Index.

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Submitting an Exception

If the patient's health plan has placed restrictions on COSENTYX® (secukinumab) such as higher tier placement or formulary exclusion, you will need to submit an exception request to ensure coverage.



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 NDC blocks if COSENTYX is excluded from the formulary of your patient's health plan.

Tips



► **Conduct** a benefits verification of your patient's health plan to help determine the specific coverage criteria for COSENTYX



► **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** an **Exception Request/Tiering Exception Request** or **Formulary Exception Request** if your patient's health plan previously approved COSENTYX but has since changed its formulary to exclude or move COSENTYX to a higher tier without grandfathering in current patients



► **Consider** asking your patient to write their own exception request letter that is signed by the physician



► **Click here** to view a checklist with helpful tips for your patient when writing to their health plan



► If your office uses an **electronic PA submission site**, check to see if you can submit an appeal via the platform

See the following pages for helpful exception request checklists.

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Exception Request Checklist

Submission checklist for dermatology*

Consider the following points when preparing to submit an exception request. The checklist below is provided to help ensure your exception request is as complete as possible when communicating with health plans. The checklist is intended to provide examples of what information is usually required.

- ▶ **Fill out the health plan's exception request form, if required**
 - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements
- ▶ **Complete a Letter of Medical Necessity with relevant patient information and clinical support, which can include information such as:**
 - Patient's name, date of birth, health plan information (policy number)
 - A statement of the exception you are requesting for the patient and the reason for the request
 - Diagnosis and corresponding *ICD-10-CM* code(s)
 - [Click here](#) for a list of *ICD-10-CM* codes
 - Rationale for choosing COSENTYX® (secukinumab)
 - Summary of the patient's current condition and relevant treatment history
 - If appropriate, a statement of the patient's financial hardship
- ▶ **Attach relevant clinical documentation:**
 - Relevant medical records and clinical notes that support treatment with COSENTYX
 - Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
 - Appropriate clinical information from the Prescribing Information for COSENTYX
 - Disease-specific criteria, including information such as the following:
 - TB test results
 - PsO- or HS-specific information from the sample letter examples
 - List of previous therapies used, duration of therapy, and reason for discontinuation
 - If appropriate, include examples from the rheumatology checklist that apply to your patient
- ▶ **For patients with PsO and PsA, be sure to include relevant information from appropriate letters**

 [Click here](#) to view sample **Letter(s) of Medical Necessity** for your office.



- ▶ Reach out to your dedicated Novartis Access and Reimbursement Manager (ARM)—they can help you understand plan requirements and coverage criteria



- ▶ For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

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Exception Request Checklist

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*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.

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Submitting an Appeal

If the patient's PA or exception request for COSENTYX® (secukinumab) has been denied, you can consider an appeal. Your patient's health plan will provide a written explanation and include information about how to request an appeal. Review the health plan's guidelines on the appeals process to ensure the appeal is as complete as possible.

Tips



► **Conduct a benefits verification** of your patient's health plan to help determine the specific coverage criteria for COSENTYX



► **Promptly submit the appeal** upon receipt of the denial before the health plan's deadline



► **Clearly address the plan's specific reason(s)** for denial when writing the appeal letter



► **Review the appeals process** for your patient's health plan



► **Always refer to the health plan's website** to locate their appeal form or information for submitting your own document

- Many health plans will allow **up to 3 levels of appeal of PA denials**; the third level of appeal may include a review by an independent, non-insurance-affiliated 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



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Appeal Submission Checklist

Submission checklist for dermatology*

Consider the following points when preparing to submit an appeal. The checklist below is provided to help ensure your appeal submission is as complete as possible when communicating with health plans. The checklist is intended to provide examples of what information is usually required.

- ▶ **Fill out an Appeal Form in response to the denial, if required by the health plan**
 - Conduct a benefits verification 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, such as:**
 - Patient's name, date of birth, health plan information (policy number)
 - Denial date and denial reference number
 - Summary of patient's diagnosis and corresponding *ICD-10-CM* code(s)
 - [Click here](#) for a list of *ICD-10-CM* codes
 - A statement clearly addressing the plan's specific reason(s) for denial
 - Summary of patient's treatment history
 - Detail why each of the health plan's suggested alternative therapies are not appropriate for your patient
 - Rationale for choosing COSENTYX® (secukinumab)
- ▶ **Attach relevant clinical documentation, such as:**
 - Relevant medical records and clinical notes that support treatment with COSENTYX
 - Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
 - Appropriate clinical information from the Prescribing Information for COSENTYX
 - TB test results
 - PsO- or HS-specific information from the sample letter examples
 - If appropriate, include examples from the rheumatology checklist that apply to your patient
 - List of previous therapies used, duration of therapy, and reason for discontinuation
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- ▶ For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

 [Click here](#) to view sample **Letter(s) of Appeal** for your office.

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Appeal Submission Checklist

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 - If appropriate, include assessment of disease severity (eg, PASI score)
 - For adult patients with PsA, AS, or nr-axSpA prescribed COSENTYX for IV use, be sure to include documentation of medical necessity for IV administration
 - List of previous therapies used, duration of therapy, and reason for discontinuation



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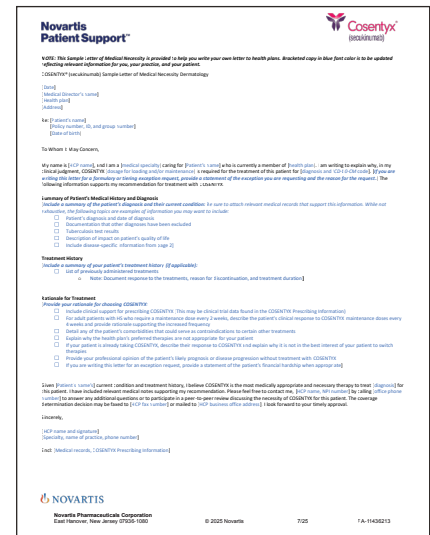
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Click the links below to view sample letters for your office:



Sample Appeal Letter (Rheumatology[†])



Example of Letter of Medical Necessity (Dermatology)

Click the links below to view patient resources for your office:



Patient Letter Checklist



Example of Patient Letter Checklist

†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.

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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 health care 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 health care services, and the associated costs and payments
- ▶ **Formulary:** A list of prescription medications covered by an insurer/health plan
- ▶ **National Drug Code (NDC):** Universal product identifier with a unique set of numbers used for human drugs in the US
- ▶ **Preferred drug:** A medication designated as a valuable, cost-effective treatment option. In a multi-tier plan, preferred drugs are assigned to a lower tier than non-preferred 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
- ▶ **Tiers:** Most health plans' formularies are divided into different categories, called tiers, with increasingly scaled co-payments. Tiers are commonly based on brand or generic medications, preferred or non-preferred medications, and traditional or specialty medications

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Indications and Important Safety Information

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.

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.



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WARNINGS AND PRECAUTIONS (cont)

Infections (cont)

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.

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.



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

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Indications and Important Safety Information (cont)

WARNINGS AND PRECAUTIONS (cont)

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

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NOTE: This Sample Letter of Medical Necessity is provided to help you write your own letter to health plans. Bracketed copy in blue font color is to be updated reflecting relevant information for you, your practice, and your patient.

COSENTYX® (secukinumab) Sample Letter of Medical Necessity Dermatology

[Date]

[Medical Director's name]

[Health plan]

[Address]

Re: [Patient's name]

[Policy number, ID, and group number]

[Date of birth]

To Whom It May Concern,

My name is [HCP name], and I am a [medical specialty] caring for [Patient's name] who is currently a member of [health plan]. I am writing to explain why, in my clinical judgment, COSENTYX [dosage for loading and/or maintenance] is required for the treatment of this patient for [diagnosis and ICD-10-CM code]. [If you are writing this letter for a formulary or tiering exception request, provide a statement of the exception you are requesting and the reason for the request.] The following information supports my recommendation for treatment with COSENTYX:

Summary of Patient's Medical History and Diagnosis

[Include a summary of the patient's diagnosis and their current condition: Be sure to attach relevant medical records that support this information. While not exhaustive, the following topics are examples of information you may want to include:

- ☐ Patient's diagnosis and date of diagnosis
- ☐ Documentation that other diagnoses have been excluded
- ☐ Tuberculosis test results
- ☐ Description of impact on patient's quality of life
- ☐ Include disease-specific information from page 2]

Treatment History

[Include a summary of your patient's treatment history (if applicable):

- ☐ List of previously administered treatments
 - o Note: Document response to the treatments, reason for discontinuation, and treatment duration]

Rationale for Treatment

[Provide your rationale for choosing COSENTYX:

- ☐ Include clinical support for prescribing COSENTYX (This may be clinical trial data found in the COSENTYX Prescribing Information)
- ☐ For adult patients with HS who require a maintenance dose every 2 weeks, describe the patient's clinical response to COSENTYX maintenance doses every 4 weeks and provide rationale supporting the increased frequency
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Explain why the health plan's preferred therapies are not appropriate for your patient
- ☐ If your patient is already taking COSENTYX, describe their response to COSENTYX and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with COSENTYX
- ☐ If you are writing this letter for an exception request, provide a statement of the patient's financial hardship when appropriate]

Given [Patient's name's] current condition and treatment history, I believe COSENTYX is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient. I have included relevant medical notes supporting my recommendation. Please feel free to contact me, [HCP name, NPI number] by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of COSENTYX for this patient. The coverage determination decision may be faxed to [HCP fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP name and signature]

[Specialty, name of practice, phone number]

Encl: [Medical records, COSENTYX Prescribing Information]

The following lists of topics are examples of disease-specific information you may want to include in your summary of the patient's diagnosis and their current condition:

If your patient has **PsO**, use these examples and delete the other disease lists:

- ☐ [Psoriasis Area and Severity Index (PASI)]
- ☐ Percentage of body surface area (BSA) currently affected
- ☐ Investigator's Global Assessment (IGA) score
- ☐ Nail, scalp, and/or joint involvement (if any)
- ☐ Indication of persistent troublesome areas of the body to treat (if any)]

If your patient has **HS**, use these examples and delete the other disease lists:

- ☐ [Relevant comorbidities (eg, metabolic syndrome, depression, or arthritis)]
- ☐ Hurley stage
- ☐ HISCR
- ☐ Number of scars and/or draining tunnels
- ☐ Location of areas affected
- ☐ Flare frequency
- ☐ Patient's numeric rating scale of pain]

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COSENTYX® (secukinumab) Sample Letter of Medical Necessity Rheumatology

[Date]

[Medical Director's name]

[Health plan]

[Address]

Re: [Patient's name]

[Policy number, ID, and group number]

[Date of birth]

To Whom It May Concern,

My name is [HCP name], and I am a [medical specialty] caring for [Patient's name] who is currently a member of [health plan]. I am writing to explain why, in my clinical judgment, COSENTYX [dosage for loading and/or maintenance] is required for the treatment of this patient for [diagnosis and ICD-10-CM code]. *[If you are writing this letter for a formulary or tiering exception request, provide a statement of the exception you are requesting and the reason for the request.]* The following information supports my recommendation for treatment with COSENTYX:

Summary of Patient's Medical History and Diagnosis

[Include a summary of the patient's diagnosis and their current condition: Be sure to attach relevant medical records that support this information. While not exhaustive, the following topics are examples of information you may want to include:

- ☐ Patient's diagnosis and date of diagnosis
- ☐ Documentation that other diagnoses have been excluded
- ☐ Tuberculosis test results
- ☐ Other relevant test results (eg, hsCRP, ESR, or HLA-B27)
- ☐ When appropriate, description of photos, x-rays, or MRI evidence
- ☐ Description of impact on patient's quality of life
- ☐ Include disease-specific information from page 2]

Treatment History

[Include a summary of your patient's treatment history:

- ☐ List of previously administered treatments
 - o Note: Document response to the treatments, reason for discontinuation, and treatment duration

Rationale for Treatment

[Provide your rationale for choosing COSENTYX:

- ☐ Include clinical support for prescribing COSENTYX (This may be clinical trial data found in the COSENTYX Prescribing Information)
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Explain why the health plan's preferred therapies are not appropriate for your patient. For adult patients with PsA, AS, or nr-axSpA prescribed COSENTYX for intravenous use, provide rationale supporting this dosage form (ie, the patient is unable or unwilling to self-inject)
- ☐ If your patient is already taking COSENTYX, describe their response to COSENTYX and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with COSENTYX
- ☐ If you are writing this letter for an exception request, provide a statement of the patient's financial hardship when appropriate]

Given [Patient's name's] current condition and treatment history, I believe COSENTYX is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient. I have included relevant medical notes supporting my recommendation. Please feel free to contact me, [HCP name, NPI number] by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of COSENTYX for this patient. The coverage determination decision may be faxed to [HCP fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP name and signature]

[Specialty, name of practice, phone number]

Encl: [Medical records, COSENTYX Prescribing Information]

The following lists of topics are examples of disease-specific information you may want to include in your summary of the patient's diagnosis and their current condition. NOTE: COSENTYX[®] (secukinumab) for intravenous use is indicated for adult patients with PsA, AS, or nr-axSpA.

If your patient has **PsA**, use these examples and delete the other disease lists:

- ☐ [Number of areas of tenderness or pain other than in a joint (ie, enthesitis)]
- ☐ Number of entire fingers or toes with swelling (ie, dactylitis)
- ☐ Patient assessment of pain, patient global assessment, physician global assessment, Health Assessment Questionnaire Disability Index (HAQ-DI)
- ☐ If patient has concomitant moderate to severe PsO, include percentage of body surface area (BSA) currently affected and indication of persistent troublesome areas of the body to treat (if any)]

If your patient has **juvenile PsA or ERA**, use these examples and delete the other disease lists:

- ☐ [Patient's current age and age of onset]
- ☐ Active joints (swelling or with limitation of movement)
- ☐ Number of areas of tenderness or pain other than in a joint (ie, enthesitis)
- ☐ Number of entire fingers or toes with swelling (ie, dactylitis)
- ☐ For juvenile PsA, description of psoriasis lesions
- ☐ For juvenile PsA, description of any fingernail abnormalities (eg, nail pitting or onycholysis)
- ☐ For ERA, digestive tract involvement
- ☐ Acute anterior uveitis
- ☐ Axial involvement
- ☐ Physician global assessment, Juvenile Arthritis Disease Activity Score (JADAS), Childhood Health Assessment Questionnaire (CHAQ)]

If your patient has **AS**, use these examples and delete the other disease lists:

- ☐ [Patient global assessment of disease activity such as total spinal pain assessment data, Bath Ankylosing Spondylitis Functional Index (BASFI) scores, inflammation scores, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores, and Bath Ankylosing Spondylitis Metrology Index (BASMI) scores]

If your patient has **nr-axSpA**, use these examples and delete the other disease lists:

- ☐ [Description of patient's symptoms such as nocturnal awakenings or continuous chronic back pain with age of onset before age 45 with pain and stiffness that improve with movement]

NOTE: This Sample Letter of Appeal is provided to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

COSENTYX® (secukinumab) Sample Letter of Appeal Dermatology

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name], and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I prescribed COSENTYX [dosage for loading and/or maintenance] for this patient to treat [diagnosis and ICD-10-CM code] and submitted a [Prior Authorization/Formulary Exception Request/Tiering Exception Request] on [date of submission]. The request was denied on [date of denial and reference number] and the reason given was [reason from the health plan's denial letter]. I request a formal appeal of your denial for COSENTYX, based on my review of the patient's diagnosis, care plan, and clinical guidelines for treatment. I maintain that COSENTYX is the appropriate therapy for [Patient's name]. The following information supports my recommendation for treatment with COSENTYX:

Summary of Patient's Medical History and Diagnosis

[Include a summary of the patient's diagnosis and current condition: Be sure to attach relevant medical records that support this information.]

The following topics are examples of information you may want to include:

- ☐ Patient's diagnosis and date of diagnosis
- ☐ Documentation that other diagnoses have been excluded
- ☐ Tuberculosis test results
- ☐ Description of impact on patient's quality of life
- ☐ Include disease-specific information from page 2]

Treatment History

[Include a summary of your patient's treatment history (if applicable):]

- ☐ List of previously administered treatments
 - o Note: Document response to the treatments, reason for discontinuation, and treatment duration]

Rationale for Treatment

[Provide your rationale for choosing COSENTYX:]

- ☐ Include clinical support for prescribing COSENTYX (This may be clinical trial data found in the COSENTYX Prescribing Information)
- ☐ For adult patients with HS who require a maintenance dose every 2 weeks, describe the patient's clinical response to COSENTYX maintenance doses every 4 weeks and provide rationale supporting the increased frequency
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Ensure that you clearly address the health plan's reason(s) for denial. If the plan requires step therapy, provide an explanation indicating why the treatments specified are not appropriate for your patient
- ☐ If your patient is already taking COSENTYX, describe their response to COSENTYX and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with COSENTYX]

Given [Patient's name's] current condition and treatment history, I believe COSENTYX is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient and would appreciate your prompt reconsideration of this denial.

I have included a copy of the denial letter along with relevant medical notes in response to the denial. Please feel free to contact me, [HCP's name, NPI number], by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of COSENTYX for this patient. The appeal decision may be faxed to [fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: Denial letter, Medical records, COSENTYX Prescribing Information

The following lists of topics are examples of disease-specific information you may want to include in your summary of the patient's diagnosis and their current condition:

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- ☐ [Relevant comorbidities (eg, metabolic syndrome, depression, or arthritis)]
- ☐ Hurley stage
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- ☐ Number of scars and/or draining tunnels
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COSENTYX® (secukinumab) Sample Letter of Appeal Rheumatology

[Date]

[Medical Director's name]

[Health plan]

[Address]

Re: [Patient's name]

[Policy number, ID, and group number]

[Date of Birth]

To Whom It May Concern,

My name is [HCP's name], and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I prescribed COSENTYX [dosage for loading and/or maintenance] for this patient to treat [diagnosis and ICD-10-CM code] and submitted a [Prior Authorization/Formulary Exception Request/Tiering Exception Request] on [date of submission]. The request was denied on [date of denial and reference number] and the reason given was [reason from the health plan's denial letter]. I request a formal appeal of your denial for COSENTYX, based on my review of the patient's diagnosis, care plan, and clinical guidelines for treatment. I maintain that COSENTYX is the appropriate therapy for [Patient's name]. The following information supports my recommendation for treatment with COSENTYX:

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- ☐ Ensure that you clearly address the health plan's reason(s) for denial. If the plan requires step therapy, provide an explanation indicating why the treatments specified are not appropriate for your patient
- ☐ For adult patients with PsA, AS, or nr-axSpA prescribed COSENTYX for intravenous use, provide rationale supporting this dosage form (ie, the patient is unable or unwilling to self-inject)
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Sincerely,

[HCP's name and signature]

[Specialty, name of practice, phone number]

Encl: Denial letter, Medical records, COSENTYX Prescribing Information

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- ☐ [Number of areas of tenderness or pain other than in a joint (ie, enthesitis)]
- ☐ Number of entire fingers or toes with swelling (ie, dactylitis)
- ☐ Patient assessment of pain, patient global assessment, physician global assessment, Health Assessment Questionnaire Disability Index (HAQ-DI)
- ☐ If patient has concomitant moderate to severe PsO, include percentage of body surface area (BSA) currently affected and indication of persistent troublesome areas of the body to treat (if any)]

If your patient has **juvenile PsA or ERA**, use these examples and delete the other disease lists:

- ☐ [Patient's current age and age of onset]
- ☐ Active joints (swelling or with limitation of movement)
- ☐ Number of areas of tenderness or pain other than in a joint (ie, enthesitis)
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- ☐ Axial involvement
- ☐ Physician global assessment, Juvenile Arthritis Disease Activity Score (JADAS), Childhood Health Assessment Questionnaire (CHAQ)]

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- ☐ [Patient global assessment of disease activity such as total spinal pain assessment data, Bath Ankylosing Spondylitis Functional Index (BASFI) scores, inflammation scores, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores, and Bath Ankylosing Spondylitis Metrology Index (BASMI) scores]

If your patient has **nr-axSpA**, use these examples and delete the other disease lists:

- ☐ [Description of patient's symptoms such as nocturnal awakenings or continuous chronic back pain with age of onset before age 45 with pain and stiffness that improve with movement]

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COSENTYX® (secukinumab) Sample Prior Authorization Request Letter Dermatology

[Date]

[Medical Director's name]

[Health plan]

[Address]

Re: [Patient's name]

[Policy number, ID, and group number]

[Date of Birth]

To Whom It May Concern,

My name is [HCP's name] and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I am writing to request prior authorization of COSENTYX [dose/frequency] for the treatment of this patient for [diagnosis and ICD-10-CM code(s)]. As per the requirements of the plan, I have tried [required step-therapies] for my patient before prescribing COSENTYX. Included please find a statement explaining why these preferred therapies are not appropriate for my patient. The following information supports my recommendation for treatment with COSENTYX:

I have attached relevant medical records, including the patient's diagnosis, test results, and treatment history.

[Include a summary of the patient's treatment history:

- ☐ Provide a comprehensive list of previous therapies, duration of therapy, and reason for discontinuation
- ☐ Specify which treatments the patient has tried and failed, and confirm that the patient has not received adequate results from any previous treatments
- ☐ Include clinical support for prescribing COSENTYX (This may be clinical trial data found in the COSENTYX Prescribing Information)
- ☐ Detail any comorbidities that could serve as contraindications to certain other treatments]

Given [Patient's name's] current condition and treatment history, I believe COSENTYX should be authorized to treat [diagnosis] for this patient. Please do not hesitate to contact me by calling [office phone number] if you require additional information or would like to discuss this case further.

The prior authorization decision may be faxed to [fax number] or mailed to [HCP business office address]. Thank you for your prompt attention to this matter.

Sincerely,

[HCP's name and signature]

[Specialty, name of practice, phone number]

Encl: Medical records, COSENTYX Prescribing Information

NOTE: This Sample Prior Authorization Request Letter is provided to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

COSENTYX[®] (secukinumab) Sample Prior Authorization Request Letter Rheumatology

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name] and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I am writing to request prior authorization of COSENTYX [dose/frequency] for the treatment of this patient for [diagnosis and ICD-10-CM code(s)]. As per the requirements of the plan, I have tried [required step-therapies] for my patient before prescribing COSENTYX. Included please find a statement explaining why these preferred therapies are not appropriate for my patient. The following information supports my recommendation for treatment with COSENTYX:

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Given [Patient's name's] current condition and treatment history, I believe COSENTYX should be authorized to treat [diagnosis] for this patient. Please do not hesitate to contact me by calling [office phone number] if you require additional information or would like to discuss this case further.

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Encl: Medical records, COSENTYX Prescribing Information