

Authorization and appeals kit: Moderate to severe plaque psoriasis coexisting with psoriatic arthritis

Resources for healthcare providers

INDICATIONS

COSENTYX® is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis.

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients.

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Information and sample letters to help ensure that your communications with health plans are as complete as possible.



Cosentyx[®]
(secukinumab)

How to use this kit

This kit provides you with information and sample letters that can help ensure your communications with health plans regarding a prior authorization or appeal are as complete as possible. These samples are intended to provide you with examples of the type of information that will usually be required. You can refer to the checklist on the first page of each section as you develop and complete your own letters. The more completely and accurately that you meet a plan's requirements for prescribing COSENTYX®, the more quickly you will be able to help your patients receive therapy.

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If an initial appeal is rejected: There can be multiple levels of appeal. Each of the appeal letters can be adapted for higher level appeals. After a second-level appeal, additional adjudication may include review by an independent noninsurance-affiliated external review board or hearing. Please refer to the plan's specific appeals guidelines, which are often available on their website.

If there is a denial after multiple levels of appeal: The patient may be referred to charitable foundation programs for financial assistance.

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1 Suggestions for writing a Prior Authorization Request Letter

Many plans require prior authorization for biologics and will have their own prior authorization (PA) forms available on their websites. This section provides general guidance on submitting a PA form and provides sample letters.

Tips

All COSENTYX® prior authorization forms should be completed and submitted to the plan by your office.

Your Novartis Strategic Account Manager or Patient Services Liaison may be able to provide you with PA requirements for specific plans and pharmacy benefit managers (PBMs). Benefits verifications performed by the Customer Engagement Center (CEC) and specialty pharmacies can also identify prior authorization requirements, step therapies, and form requirements.

Fax the prior authorization request to the health plan.

Fax the service request form (SRF) to the CEC at [1-844-666-1366](tel:1-844-666-1366).

Many specialty pharmacies have the ability to submit a test claim to a payer to confirm coverage of COSENTYX.

If the physician anticipates that a step therapy specified by the plan will not be well tolerated by the patient, an appeal to bypass that requirement may be submitted to the payer. [Click here for a sample Letter of Medical Necessity \[3\]](#).

Many payers will allow up to three levels of appeal of prior authorization denials. The third level of appeal may include review by an independent noninsurance-affiliated external review board or hearing. [Click here for a sample Prior Authorization Appeals Letter \[2\]](#).

Checklist

- Include the patient's name, policy number, and date of birth
- Document that all PA requirements of the plan have been met
- Document that the patient has satisfied any step-therapy requirements. For step-therapy exception requests, add wording included on page 6
- Review suggested letter formats that follow for additional guidance
- Refer to the health plan's website to locate their PA form. Your Strategic Account Manager or Patient Services Liaison may also be able to assist you

Note: Some plans may require the use of their own letter templates for prior authorization requests.

See sample letters on following pages.

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patient is **not** already taking COSENTYX® (secukinumab)

[Date]

[Medical Director]

[Insurance Company]

[Address]

[City, State, Zip]

Re: [Patient Name]

[Policy Number]

[DOB]

To whom it may concern:

This letter is being submitted for the prior authorization of COSENTYX for [patient name, ID and group number] for the treatment of coexisting moderate to severe plaque psoriasis [ICD-10 Dx code] and psoriatic arthritis [ICD-10 Dx code].

Patient's history, diagnosis, current condition and symptoms:

- Document that patient does not have active tuberculosis*
- Medical records indicating the patient's diagnosis and the date of diagnosis
- Percentage body surface area (BSA) currently affected (including the percentage involving sensitive areas, PASI severity scores, and photos of the plaque psoriasis, if available)
- 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's assessment of pain, patient global assessment, physician global assessment, Health Assessment Questionnaire Disability Index, high-sensitivity C-reactive protein levels (hs-CRP)
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Summary of recommendation

If you are appealing a **step edit requirement**, insert additional text here from page 6.

*May be required by some plans.

Supporting References:

(Provide clinical support for your recommendation. This can be clinical trial data from the COSENTYX package insert.)

The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #], or mailed to [physician business office address]. Please also send a copy of the coverage determination decision to [patient name].

Sincerely,

[Physician name and signature]

[Name of practice]

[Phone #]

[Patient name and signature]

Encl: Medical records

COSENTYX clinical trial data

PASI = Psoriasis Area and Severity Index.



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patient is already taking COSENTYX® (secukinumab)

[Date]
 [Medical Director] Re: [Patient Name]
 [Insurance Company] [Policy Number]
 [Address] [DOB]
 [City, State, Zip]

To whom it may concern:

This letter is being submitted for the prior authorization of COSENTYX for [patient name, ID and group number] for the treatment of coexisting moderate to severe plaque psoriasis [ICD-10 Dx code] and psoriatic arthritis [ICD-10 Dx code]. The authorization requested is for the current date of [insert date] through the date of [insert future date].

If you are appealing a **step edit requirement**, insert additional text here from page 6.

(Include information outlining the severity of symptoms **at the time of COSENTYX prescription**. Medical records may need to be pulled from past dates to capture the information relevant to COSENTYX treatment started at an earlier date.)

Patient's history, diagnosis, current condition, and symptoms:

- Document that patient does not have active tuberculosis*
- Medical records indicating the patient's diagnosis and the date of diagnosis
- Percentage body surface area (BSA) currently affected (including the percentage involving sensitive areas, PASI severity scores, and photos of the plaque psoriasis, if available)
- 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's assessment of pain, patient global assessment, physician global assessment, Health Assessment Questionnaire Disability Index, high-sensitivity C-reactive protein levels (hs-CRP)
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments

Supporting references:

(Provide clinical support for your recommendation. This can be clinical trial data from the COSENTYX package insert.) Also include a summary of recommendations and how COSENTYX has helped treat the patient's diagnosis.)

The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #] or mailed to [physician business office address]. Please also send a copy of the coverage determination decision to [patient name].

Sincerely,

 [Physician name and signature]
 [Name of practice]
 [Phone #]

 [Patient name and signature]

Encl: Medical records
 COSENTYX clinical trial data

*May be required by some plans.



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if you are appealing a **step edit requirement**, add this after first paragraph of letters on preceding pages.

The plan currently requires a trial of the following therapies before COSENTYX® (secukinumab) is prescribed: [insert required step therapies]. Included please find a statement explaining why these step therapies are not feasible. We request that the step therapy requirement be eliminated.

(Physician: Provide statement explaining why step therapies are not appropriate for this patient.)



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2

Suggestions for writing a Prior Authorization Appeals Letter

This type of letter can be used when a prior authorization request has been denied. There can be multiple levels of appeal. Please refer to the plan's specific appeals guidelines.

This letter comes from the **patient** and the **physician**. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity. [Click here for a sample Letter of Medical Necessity](#) [3].

Checklist

- Include the patient's name, policy number, and date of birth**
- Acknowledge that you are familiar with the company's policy and state the reason for the denial**

Patient's medical records



Patient history, diagnosis, current condition, and symptoms

Include copies of relevant medical records (payers may want to see if any infections, allergies, or comorbidities are present)

Document severity of condition

For each condition, familiarize yourself with the severity scoring methods preferred by the health plan



When appropriate, attach a photo of the affected area

List previous therapies

Explain why each therapy was discontinued, and specify the duration of therapy for each agent

Explain why formulary preferred agents are not appropriate (if they have not already been listed as previous therapies)

Provide clinical support for your recommendation

This can be clinical trial data from the COSENTYX® package insert

If required, attach a Letter of Medical Necessity

[Click here for a sample Letter of Medical Necessity](#) [3].

Note: At each stage of appeal, health plans may require that their own forms (or the universal forms that are required by some states) be submitted along with your letter.

See sample letters on following pages.

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patient is **not** already taking COSENTYX® (secukinumab)

[Date]

[Medical Director]

[Insurance Company]

[Address]

[City, State, Zip]

Re: [Patient Name]

[Policy Number]

[DOB]

To whom it may concern:

We have read and acknowledge your policy for the responsible management of drugs in this category. We are writing to request that you reconsider your denial of coverage of COSENTYX for the treatment of coexistent moderate to severe plaque psoriasis [ICD-10 Dx code] and psoriatic arthritis [ICD-10 Dx code]. The reason given for the denial was [state reason from insurer's letter]. After reviewing the denial letter, we continue to feel that COSENTYX [dose, frequency] is appropriate therapy. Listed below is a summary of the relevant clinical history.

If this is a 2nd- or 3rd-level appeal, after first sentence, insert additional sentence from page 10.

Patient's history, diagnosis, current condition, and symptoms:

- Document that patient does not have active tuberculosis*
- Medical records indicating the patient's diagnosis and the date of diagnosis
- Percentage body surface area (BSA) currently affected (including the percentage involving sensitive areas, PASI severity scores, and photos of the plaque psoriasis, if available)
- 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's assessment of pain, patient global assessment, physician global assessment, Health Assessment Questionnaire Disability Index, high-sensitivity C-reactive protein levels (hs-CRP)
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Additional clinical support for the appeal
- Summary of recommendation

*May be required by some plans.

Please contact my office by calling [insert phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Sincerely,

[Patient name and signature]

[Physician name and signature]

[Name of practice]

[Phone #]

Encl: Medical records
Letter of medical necessity

PASI = Psoriasis Area and Severity Index.



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patient **is** already taking COSENTYX® (secukinumab)

[Date]
[Medical Director] Re: [Patient Name]
[Insurance Company] [Policy Number]
[Address] [DOB]
[City, State, Zip]

To whom it may concern:

We have read and acknowledge your policy for the responsible management of drugs in this category. We are writing to request that you reconsider your denial of coverage of COSENTYX for the treatment of coexisting moderate to severe plaque psoriasis [ICD-10 Dx code] and psoriatic arthritis [ICD-10 Dx code]. The reason given for the denial was [state reason from insurer's letter]. After reviewing the denial letter, we continue to feel that COSENTYX [dose, frequency] is appropriate therapy. Listed below is a summary of the relevant clinical history.

If this is a **2nd- or 3rd-level appeal**, after first sentence, insert additional sentence from page 10.

(Include information outlining the severity of the patient's symptoms **at the time of COSENTYX prescription**. Medical records may need to be pulled from past dates to capture the information relevant to COSENTYX treatment that was started at an earlier date.)

Patient's history, diagnosis, current condition, and symptoms:

- Document that patient does not have active tuberculosis*
- Medical records indicating the patient's diagnosis and the date of diagnosis
- Percentage body surface area (BSA) currently affected (including the percentage involving sensitive areas, PASI severity scores, and photos of the plaque psoriasis, if available)
- 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's assessment of pain, patient global assessment, physician global assessment, Health Assessment Questionnaire Disability Index, high-sensitivity C-reactive protein levels (hs-CRP)
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Additional clinical support for the appeal
- Summary of recommendation

*May be required by some plans.

Please contact my office by calling [insert phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Sincerely,

[Patient name and signature]

[Physician name and signature]

[Name of practice]

Encl: Medical records
Letter of medical necessity

[Phone #]

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If this is a **2nd- or 3rd-level appeal**, add this after first sentence of letters on the preceding pages.

This is my [Insert level of request] prior authorization appeal. A copy of the most recent denial letter is included along with medical notes in response to the denial.

For 2nd-level and 3rd-level appeals, be sure to include:

- The original letter of denial
- Specific medical notes in response to the denial

(A third level of appeal may include review by an independent noninsurance-affiliated external review board or hearing.)



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3 Suggestions for writing a Letter of Medical Necessity

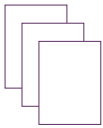
Some plans require that a Letter of Medical Necessity be submitted along with a Prior Authorization Appeal to support the choice of COSENTYX® over agents that are on formulary. Click here for a sample Prior Authorization Appeals Letter [2](#).

You may find that this checklist and the sample letters that follow are a helpful guide to preparing that letter. A Letter of Medical Necessity should also accompany a Formulary Exception Request Letter as well as a Tiering Exception Request Letter. Click here for a sample Formulary Exception Request Letter [4](#). Click here for a sample Tiering Exception Request Letter [5](#).

Checklist

Include the patient's name, policy number, and date of birth

Support your recommendation with the following:



Patient history, diagnosis, current condition, and symptoms

Include copies of relevant medical records (payers may want to see if any infections, allergies, or comorbidities are present)

Document severity of condition

For each condition, familiarize yourself with the severity scoring methods preferred by the health plan



When appropriate, attach a photo of the affected area

List previous therapies

Explain why each therapy was discontinued, and specify the duration of therapy for each agent

Explain why formulary preferred agents are not appropriate
(if they have not already been listed as previous therapy)

Provide clinical support for your recommendation

This can be clinical trial data from the COSENTYX package insert

To close the letter, summarize your recommendation, and provide a phone number should any additional information be required

See sample letters on following pages.

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4

Suggestions for writing a Formulary Exception Request Letter

This type of letter can be used when COSENTYX® is not listed on a formulary or if it has an NDC block. While the plan may provide a form on its website that can be used to apply for an exception, you can refer to the sample provided in this kit to see the type of information that is typically required.

This letter comes from the **patient** and is also signed by the **physician**. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity. [Click here for a sample Letter of Medical Necessity](#) [3].

The patient's letter should include:

Checklist

- The patient's name, policy number, and date of birth**
- The patient's diagnosis**
- List of previous therapies**
- The main reasons in support of a formulary exception for COSENTYX for this patient**
- The patient's relevant medical records**
- If this is a 2nd-level or 3rd-level appeal**, include the letter of denial and medical notes in response to the denial
- If required, attach a **Letter of Medical Necessity**
[Click here for a sample Letter of Medical Necessity](#) [3].

Note: At each stage of appeal, health plans may require that their own forms (or the universal forms that are required by some states) be submitted along with your letter.

NDC = National Drug Code.

See sample letters on following pages.

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If this is a **2nd- or 3rd-level appeal**, add this after first sentence of letters on the preceding pages.

This is my [Insert level of request] formulary exception appeal. A copy of the original denial letter is included along with medical notes in response to the denial.

For 2nd-level and 3rd-level appeals, be sure to include:

- The original letter of denial
- Specific medical notes in response to the denial



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5 Suggestions for writing a Tiering Exception Request Letter

This type of letter can be used when COSENTYX® is on formulary but is on a tier with a high co-pay. Based on medical necessity, a patient can appeal to the plan to consider the drug as if it were a preferred branded agent for that patient in order to reduce the co-pay and help alleviate the financial burden. This may be most useful for patients on plans that require coinsurance. This letter comes from the **patient** and is also signed by the **physician**.

Checklist

- Include the patient's name, policy number, and date of birth
- Include the patient's diagnosis
- Patient should include a statement of financial hardship
- List previous therapies
- Include relevant medical records
- If this is a 2nd-level or 3rd-level appeal, include the letter of denial and medical notes in response to the denial
- If required, attach a **Letter of Medical Necessity**
Click here for a sample Letter of Medical Necessity [\[3\]](#).

Note: At each stage of appeal, health plans may require that their own forms (or the universal forms that are required by some states) be submitted along with your letter.

See sample letters on following pages.

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If this is a **2nd- or 3rd-level appeal**, add this after first sentence of letters on preceding pages.

This is my [Insert level of request] tier exception appeal. A copy of the original tier exception denial letter is included along with medical notes in response to the denial.

For 2nd-level and 3rd-level appeals, be sure to include:

- The original letter of denial
- Specific medical notes in response to the denial



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Examples of relevant ICD-10 codes* for COSENTYX® (secukinumab) patients

Possible PsO ICD-10-CM Code	Descriptor
L40.0	Plaque psoriasis

Possible PsA ICD-10-CM Codes	Descriptor
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy

PsO=psoriasis; PsA=psoriatic arthritis.

*These diagnosis code examples are provided for general informational purposes only and are not intended to be directive, a guarantee of coverage, or a substitute for an independent clinical decision.



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INDICATIONS

COSENTYX® is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis.

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Infections

COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in subjects treated with COSENTYX compared to placebo-treated subjects. In placebo-controlled clinical trials in patients 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 patients with psoriatic arthritis and ankylosing spondylitis. The incidence of some types of infections appeared to be dose-dependent in clinical studies.

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, the patient should be closely monitored and COSENTYX should be discontinued until the infection resolves.

Pre-treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX. Do not administer 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. Patients receiving COSENTYX should be monitored closely for signs and symptoms of active TB during and after treatment.

Please see additional Important Safety Information on page 24.



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IMPORTANT SAFETY INFORMATION (cont)

Inflammatory Bowel Disease

Caution should be used when prescribing COSENTYX® (secukinumab) to patients with inflammatory bowel disease. Exacerbations, in some cases serious, occurred in patients treated with COSENTYX during clinical trials in plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. In addition, new onset inflammatory bowel disease cases occurred in clinical trials with COSENTYX. In an exploratory study in 59 patients 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.

Hypersensitivity Reactions

Anaphylaxis and cases of urticaria occurred in patients treated with COSENTYX 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 cap of the COSENTYX Sensoready® pen and the COSENTYX prefilled syringe contains 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.

Vaccinations

Prior to initiating therapy with COSENTYX, consider completion of all age appropriate immunizations according to current immunization guidelines. Patients treated with COSENTYX should not receive live vaccines.

Non-live vaccinations received during a course of COSENTYX may not elicit an immune response sufficient to prevent disease.

MOST COMMON ADVERSE REACTIONS

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

Please see additional Important Safety Information on page 23.

Bibliography

Cosentyx [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2016.

www.cosentyx.com



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COSENTYX® Connect Personal Support Program

You or your patient can call

1-844-267-3689

8:00 AM to 9:00 PM Eastern Time, Monday through Friday, excluding public holidays.

Fax

1-844-666-1366

For additional information, go to

www.cosentyx.com

