Authorization and Appeals Kit

Psoriatic arthritis

Resources for healthcare providers

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 adult patients with active psoriatic arthritis.

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

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

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.

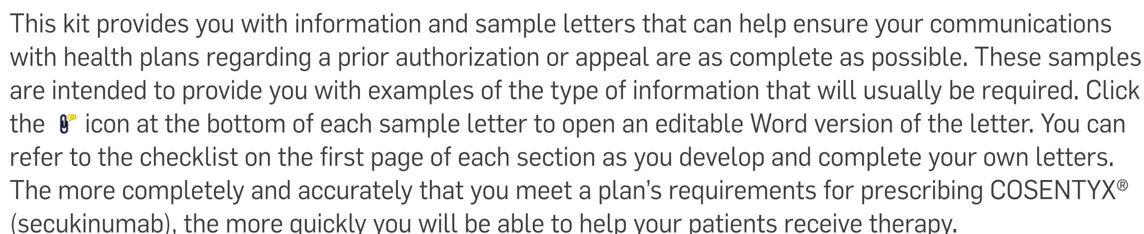
Click here for additional Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

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

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.

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. Click the icon at the bottom of each sample letter to open an editable Word version of the letter. 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® (secukinumab), the more quickly you will be able to help your patients receive therapy.

Click on number/field to jump to that section.

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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 appeal guidelines, which are often available on their website.

If there is a denial after multiple levels of appeal: In line with your standard office practice, you may refer the patient to charitable foundation programs to explore eligibility for financial assistance.

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ICD-10=International Classification of Diseases, Tenth Revision; NDC=National Drug Code.

Click here for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Suggestions for Writing a Prior Authorization Request Letter*

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

Click the icon at the bottom of each sample letter to open an editable Word version of the letter.

Tips

All COSENTYX® (secukinumab) PA forms should be completed and submitted to the plan by your office.

Your Field Reimbursement Manager (FRM) may be able to provide you with PA requirements for specific plans and pharmacy benefit managers. Benefits verifications performed by COSENTYX® Connect Support Program and specialty pharmacies can also identify PA, step-therapies, and form requirements.

Fax the PA request to the health plan.

Fax the service request form (SRF) to the COSENTYX® Connect Support Program at 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. That appeal should generally include a Letter of Medical Necessity.
Click here for a sample Letter of Medical Necessity.

Many payers will allow up to 3 levels of appeal of PA 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.

Checklist

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

- ☐ **Include the patient's name, policy number, and date of birth**
- ☐ **Confirm and document that all PA requirements of the plan have been met**
- ☐ **Confirm and document that the patient has satisfied any step-therapy requirements**
- ☐ **When appropriate, attach a photo or x-ray of the affected area**
- ☐ **Review suggested letter formats that follow for additional guidance**
- ☐ **Refer to the health plan's website to locate their PA form. Your FRM may also be able to assist you in identifying the payer's PA form or PA requirements**

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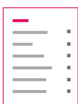
See sample letters on following pages.



Click here for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Sample Prior Authorization Request Letter

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

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Patient Name]
[Policy Number]
[DOB]

To Whom it May Concern:

This letter is being submitted for the prior authorization of COSENTYX® (secukinumab) for [patient name, ID, and group number], for the treatment of psoriatic arthritis [*ICD-10* code].

If appealing a step-edit requirement, consider inserting an explanation like that shown in the pink shaded box to detail why step-therapies are not appropriate for this patient.

The plan currently requires a trial of the following therapies before COSENTYX 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.

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

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX. Examples of information you may want to include are:

- Tuberculosis test and results
- Patient's diagnosis and the date of diagnosis
- Clinical documentation with up-to-date notes
- 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)
- When appropriate, photo or x-ray of the affected area
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Impact on quality of life
- Summary of recommendation]

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].

NPI=national provider identifier.

Sincerely,

____

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

Double-click to open a Word version of this letter.

Encl: Medical records
COSENTYX clinical trial data

Click here for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Sample Prior Authorization Request Letter

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

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Patient Name]
[Policy Number]
[DOB]

To Whom it May Concern:

This letter is being submitted for the prior authorization of COSENTYX® (secukinumab) for [patient name, ID, and group number], for the treatment of psoriatic arthritis [*ICD-10* code]. The authorization requested is for the current date of [insert date] through the date of [insert future date].

(Include information outlining the severity of psoriatic arthritis symptoms **at the time of COSENTYX prescription**. Historical medical records may need to be pulled to capture the information relevant to COSENTYX treatment at an earlier date.)

If appealing a step-edit requirement, consider inserting an explanation like that shown in the pink shaded box to detail why step-therapies are not appropriate for this patient.

The plan currently requires a trial of the following therapies before COSENTYX 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.

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

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX. Examples of information you may want to include are:

- Tuberculosis test and results
- Patient's diagnosis and the date of diagnosis
- Clinical documentation with up-to-date notes
- 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)
- When appropriate, photo or x-ray of the affected area
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for continuation of COSENTYX, documenting clinical benefits
- Impact on quality of life
- Summary of recommendation]

Supporting references:

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

NPI=national provider identifier.

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,

Double-click to open a Word version of this letter.

____

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

Encl: Medical records
COSENTYX clinical trial data

Click here for Important Safety Information.

Please see full Prescribing Information, including Medication Guide.

Physician Letter 2

Suggestions for Writing a Prior Authorization Appeals Letter*

This type of letter can be used when a prior authorization (PA) 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 **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.

Click the icon at the bottom of each sample letter to open an editable Word version of the letter.

Checklist

- ☐ **Include the patient's name, policy number, date of birth, PA denial reference number and date of denial**
- ☐ **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)

  When appropriate, attach a photo or x-ray of the affected area
- ☐ **Document severity of condition**

  Familiarize yourself with the severity scoring methods preferred by the health plan
- ☐ **List of 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® (secukinumab) package insert.
- ☐ If required, attach a **Letter of Medical Necessity**
  Click here for a sample Letter of Medical Necessity.

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.

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See sample letters on following pages.

Click here for Important Safety Information.

Please see full Prescribing Information, including Medication Guide.

Sample Prior Authorization Appeals Letter

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

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Patient Name]
[Policy Number]
[DOB]
[PA Denial Reference # and Date]

To Whom it May Concern:

I have read and acknowledge your policy for the responsible management of drugs in this category.

If this is a 2nd- or 3rd-level appeal, consider including an explanation like the one in the shaded pink box.

This is a [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.

I am writing to request that you reconsider your denial of coverage of COSENTYX® (secukinumab) for the treatment of psoriatic arthritis [*ICD-10* code]. The reason given for the denial was [state reason from insurer's letter]. After reviewing the denial letter, I maintain that COSENTYX [dose, frequency] is the appropriate therapy. Listed below is a summary of the relevant clinical history.

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

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX. Examples of information you may want to include are:

- Tuberculosis test and results
- Patient's diagnosis and the date of diagnosis
- Clinical documentation with up-to-date notes
- 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)
- When appropriate, photo or x-ray of the affected area
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Impact on quality of life
- Summary of recommendation]

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.

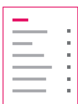
Sincerely,

____

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

Encl: Medical records
Letter of denial
COSENTYX clinical trial data

Double-click to open a Word version of this letter.



Click here for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Physician Letter 2

Sample Prior Authorization Appeals Letter

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

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Patient Name]
[Policy Number]
[DOB]
[PA Denial Reference # and Date]

To Whom it May Concern:

I have read and acknowledge your policy for the responsible management of drugs in this category.

If this is a 2nd- or 3rd-level appeal, consider including an explanation like the one in the shaded pink box.

This is a [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.

I am writing to request that you reconsider your denial of coverage of COSENTYX® (secukinumab) for the treatment of psoriatic arthritis [*ICD-10* code]. The reason given for the denial was [state reason from insurer's letter]. After reviewing the denial letter, I maintain that COSENTYX [dose, frequency] is the appropriate therapy. Listed below is a summary of the relevant clinical history.

(Include information outlining the severity of the patient's symptoms **at the time of COSENTYX prescription**. Historical medical records may need to be pulled to capture the information relevant to COSENTYX treatment at an earlier date.)

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

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX. Examples of information you may want to include are:

- Tuberculosis test and results
- Patient's diagnosis and the date of diagnosis
- Clinical documentation with up-to-date notes
- 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)
- When appropriate, photo or x-ray of the affected area
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for continuation of COSENTYX, documenting clinical benefits
- Impact on quality of life
- Summary of recommendation]

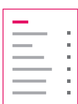
Please contact my office by calling [insert phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Sincerely,

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

Double-click to open a Word version of this letter.

Encl: Medical records
Letter of denial
COSENTYX clinical trial data



Click here for Important Safety Information.

Please see full Prescribing Information, including Medication Guide.

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® (secukinumab) over agents that are on formulary.
Click here for a sample Prior Authorization Appeals Letter.

Click the icon at the bottom of each sample letter to open an editable Word version of the letter.

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.
Click here for a sample Tiering Exception Request Letter.

Checklist

- ☐ **Include the patient's name, policy number, date of birth, and, if appropriate, prior authorization denial reference number and date of denial**
- ☐ **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)

  When appropriate, attach a photo or x-ray of the affected area
- ☐ **Document severity of condition**

  Familiarize yourself with the severity scoring methods preferred by the health plan
- ☐ **List of 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**

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See sample letters on following pages.

Sample Letter of Medical Necessity

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

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Patient Name]
[Policy Number]
[DOB]
[Optional: PA Denial Reference # and Date]

To Whom it May Concern:

I am writing on behalf of my patient, [patient name], to support the coverage of COSENTYX® (secukinumab) for treatment of psoriatic arthritis [*ICD-10* code]. I have read and acknowledge your policy for the responsible management of drugs in this category. In this letter, I provide my rationale for the use of COSENTYX [dose, frequency] and explain why, in my clinical judgment, it is required for the appropriate management of this patient. I have also included a brief description of the patient's medical history, a review of previous therapies, and the patient's severity score.

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

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX. Examples of information you may want to include are:

- Tuberculosis test and results
- Patient's diagnosis and the date of diagnosis
- Clinical documentation with up-to-date notes
- 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)
- When appropriate, photo or x-ray of the affected area
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Impact on quality of life
- Summary of recommendation]

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.

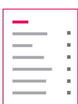
Sincerely,

____

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

Encl: Medical records
COSENTYX clinical trial data

Double-click to open a Word version of this letter.



Click here for Important Safety Information.

Please see full Prescribing Information, including Medication Guide.

Sample Letter of Medical Necessity

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

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Patient Name]
[Policy Number]
[DOB]
[Optional: PA Denial Reference # and Date]

To Whom it May Concern:

I am writing on behalf of my patient, [patient name], to support the coverage of COSENTYX® (secukinumab) for treatment of psoriatic arthritis [*ICD-10* code]. I have read and acknowledge your policy for the responsible management of drugs in this category. In this letter, I provide my rationale for the use of COSENTYX [dose, frequency] and explain why, in my clinical judgment, it is required for the appropriate management of this patient. I have also included a brief description of the patient's medical history, a review of previous therapies, and the patient's severity score.

(Include information outlining the severity of the disease and the patient's symptoms **at the time of COSENTYX prescription**. Historical medical records may need to be pulled to capture the information relevant to COSENTYX treatment at an earlier date.)

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

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX. Examples of information you may want to include are:

- Tuberculosis test and results
- Patient's diagnosis and the date of diagnosis
- Clinical documentation with up-to-date notes
- 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)
- When appropriate, photo or x-ray of the affected area
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for continuation of COSENTYX, documenting clinical benefits
- Impact on quality of life
- Summary of recommendation]

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.

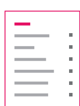
Sincerely,

____

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

Double-click to open a Word version of this letter.

Encl: Medical records
COSENTYX clinical trial data



Patient Letter 4

Suggestions for Writing a Formulary Exception Request Letter*

This type of letter can be used when COSENTYX® (secukinumab) is not listed on a formulary or if it has a national drug code (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.

Click the icon at the bottom of each sample letter to open an editable Word version of the letter.

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

Checklist

- ☐ **Include your name, policy number, date of birth, and, if appropriate, the denial reference number from a previous appeal and the date of denial**
- ☐ **Your diagnosis**
- ☐ **List of your previous therapies**
- ☐ **The main reasons that support your request for a formulary exception for COSENTYX**
- ☐ **Relevant medical records**
- ☐ **If this is a 2nd-level or 3rd-level formulary exception appeal,** include the letter of denial and your physician's medical notes in response to the denial
- ☐ If required, attach a **Letter of Medical Necessity** from your physician
Click here for a sample Letter of Medical Necessity.

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.

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See sample letters on following pages.

Sample Formulary Exception Request Letter

when you are **not** already taking COSENTYX® (secukinumab)

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Your Name]
[Policy Number]
[DOB]
[Optional: Denial Reference # and Date]

To Whom it May Concern:

I am a member of [enter name of health plan]. Currently, COSENTYX® (secukinumab) is not listed on my formulary, and according to my doctor, my medical condition necessitates the use of this drug.

If this is a 2nd- or 3rd-level appeal, consider including an explanation like the one in the shaded purple box.

Be sure to include a copy of the original letter of denial along with your doctor's specific medical notes in response to the denial.

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.

I am requesting an exception to your formulary so that I am able to fill my prescription for COSENTYX. I request that it be available to me as a preferred drug and that any applicable NDC blocks be removed.

I have been diagnosed with psoriatic arthritis and my doctor has prescribed COSENTYX [strength]. Dr [insert physician name], [insert medical specialty], practices at [insert physician address]. My past treatments have included [list previous treatments and drugs]. I have enclosed my medical records and a Letter of Medical Necessity from my physician supporting my request for the formulary exception approval of COSENTYX.

The main reasons that I am requesting this exception are:

[Insert main medical necessity points]

NDC=National Drug Code.

These reasons are supported by the information that I have included. My physician can be contacted at [insert phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of COSENTYX in the treatment of my medical condition.

Sincerely,

Be sure to have your physician sign the letter.

Enclose your medical records along with a Letter of Medical Necessity from your physician.

[Patient name and signature]

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

Encl: Medical records
Letter of Medical Necessity

Double-click to open a Word version of this letter.

Click here for Important Safety Information.

Please see full Prescribing Information, including Medication Guide.

Sample Formulary Exception Request Letter

when you **are** already taking COSENTYX® (secukinumab)

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Your Name]
[Policy Number]
[DOB]
[Optional: Denial Reference # and Date]

To Whom it May Concern:

I am a member of [enter name of health plan]. Currently, COSENTYX® (secukinumab) is not listed on my formulary, and according to my doctor, my medical condition necessitates the use of this drug.

If this is a 2nd- or 3rd-level appeal, consider including an explanation like the one in the shaded purple box.

Be sure to include a copy of the original letter of denial along with your doctor's specific medical notes in response to the denial.

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.

I am requesting an exception to your formulary so that I am able to fill my prescription for COSENTYX. I request that it be available to me as a preferred drug and that any applicable NDC blocks be removed.

I have been diagnosed with psoriatic arthritis and my doctor has prescribed COSENTYX [strength]. Dr [insert physician name], [insert medical specialty], practices at [insert physician address]. My past treatments have included [list previous treatments and drugs]. I have enclosed my medical records and a Letter of Medical Necessity from my physician supporting my request for the formulary exception approval of COSENTYX. (Note: medical records should include the records from the **date COSENTYX was first prescribed to the patient** and should also include disease severity indicators.)

The main reasons that I am requesting this exemption are:

[Insert main medical necessity points]

NDC=National Drug Code.

These reasons are supported by the information that I have included. My physician can be contacted at [insert phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of COSENTYX in the treatment of my medical condition.

Sincerely,

Be sure to have your physician sign the letter.

Enclose your medical records along with a Letter of Medical Necessity from your physician.

[Patient name and signature]

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

Encl: Medical records
Letter of Medical Necessity

Double-click to open a Word version of this letter.

Click here for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Suggestions for Writing a Tiering Exception Request Letter*

This type of letter can be used when COSENTYX® (secukinumab) is on formulary but is on a tier with a high co-pay. Based on medical necessity, you 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 out-of-pocket expense 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**.

Click the icon at the bottom of each sample letter to open an editable Word version of the letter.

Checklist

- ☐ **Include your name, policy number, date of birth, and, if appropriate, the denial reference number from a previous appeal and the date of denial**
- ☐ **Your diagnosis**
- ☐ **Include a statement of financial hardship**
- ☐ **List of your previous therapies**
- ☐ **Relevant medical records**
- ☐ **If this is a 2nd-level or 3rd-level tiering exception appeal,** include the letter of denial and your physician's medical notes in response to the denial
- ☐ If required, attach a **Letter of Medical Necessity** from your physician
  Click here for a sample Letter of Medical Necessity.

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.

*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.

See sample letters on following pages.

Click here for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Patient Letter 5

Sample Tiering Exception Request Letter

when you are **not** already taking COSENTYX® (secukinumab)

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Your Name]
[Policy Number]
[DOB]
[Optional: Denial Reference # and Date]

To Whom it May Concern:

I am requesting a tier exception for the drug COSENTYX® (secukinumab) prescribed to me by [insert physician name and specialty] for the diagnosis of psoriatic arthritis. [If prior insurance covered COSENTYX on a preferred tier, describe this previous coverage.]

If this is a 2nd- or 3rd-level appeal, consider including an explanation like the one in the shaded purple box.

Be sure to include a copy of the original letter of denial along with your doctor's specific medical notes in response to the denial.

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.

The initial requested length of tier exception approval is for [insert requested length of initial approval].

I have attached medical records and a Letter of Medical Necessity from my physician outlining why COSENTYX is needed for my medical care. Past treatments and drugs that have been unsuccessful in achieving control of my symptoms include [insert list of past treatments and drugs]. My current symptoms are [insert complete list of symptoms].

My current treatment is [list current treatments].

I am requesting a tier exception because the current assigned tier for COSENTYX is a burden on my finances and would hinder my ability to utilize a drug that will assist with the treatment of my diagnosis.

In summary, my physician believes that COSENTYX is the best choice for my health and treatment of psoriatic arthritis. My physician may be reached to answer any additional questions or to participate in a peer-to-peer review by calling [insert physician's phone number].

Sincerely,

Be sure to have your physician sign the letter.

Enclose your medical records along with a Letter of Medical Necessity from your physician.

[Patient name and signature]

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

Encl: Medical records
Letter of Medical Necessity

Double-click to open a Word version of this letter.

Click here for Important Safety Information.

Please see full Prescribing Information, including Medication Guide.

Sample Tiering Exception Request Letter

when you **are** already taking COSENTYX® (secukinumab)

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Your Name]
[Policy Number]
[DOB]
[Optional: Denial Reference # and Date]

To Whom it May Concern:

I am requesting a tier exception for the drug COSENTYX® (secukinumab) prescribed to me by [insert physician name and specialty] for the diagnosis of psoriatic arthritis. [If prior insurance covered COSENTYX on a preferred tier, describe this previous coverage.]

If this is a 2nd- or 3rd-level appeal, consider including an explanation like the one in the shaded purple box.

Be sure to include a copy of the original letter of denial along with your doctor's specific medical notes in response to the denial.

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.

The initial requested length of tier exception approval is for [insert requested length of initial approval].

I have attached medical records and a Letter of Medical Necessity from my physician outlining why COSENTYX is needed for my medical care. [Insert copies of medical records **dating to the initial prescription of COSENTYX.**] Past treatments and drugs that have been unsuccessful in achieving control of my symptoms include [insert list of past treatments and drugs.]

The difference in my health status after [insert length of time] of COSENTYX therapy compared with my status before starting COSENTYX confirms that COSENTYX is medically necessary for treating my condition. [Insert specifics on improvements in symptoms since taking COSENTYX].

I am requesting a tier exception because I am not able to afford the [select co-pay or coinsurance] for COSENTYX without financial relief.

In summary, my physician believes that COSENTYX is the best choice for my health and treatment of psoriatic arthritis. My physician may be reached to answer any additional questions or to participate in a peer-to-peer review by calling [insert physician's phone number].

Sincerely,

Be sure to have your physician sign the letter.

Enclose your medical records along with a Letter of Medical Necessity from your physician.

[Patient name and signature]

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

Encl: Medical records
Letter of Medical Necessity

Double-click to open a Word version of this letter.

Click here for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

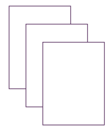
Suggestions for Writing a Dosage Appeals Letter*

Some plans may not approve loading doses of COSENTYX® (secukinumab) for psoriatic arthritis unless an appeal is submitted by the patient. And for patients with psoriatic arthritis without coexisting moderate to severe plaque psoriasis who continue to have active disease, plans may also require an appeal for use of the 300-mg dose. This section provides general guidance on submitting an appeal for an alternate dosing regimen. This letter comes from the **patient** and is also signed by the **physician**.

Click the icon at the bottom of each sample letter to open an editable Word version of the letter.

Checklist

- ☐ **Include your name, policy number, date of birth, and, if appropriate, the denial reference number from a previous appeal and the date of denial**
- ☐ **Your diagnosis**
- ☐ **Explain why you are requesting approval to initiate therapy with a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4**
- ☐ **Explain why a monthly dosage of 300 mg is warranted**
- ☐ **Support your appeal with the following:**



Your patient history, diagnosis, current condition, and symptoms

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

- ☐ **Describe the severity of your condition**
- ☐ **Ask your physician to provide clinical support for this request**
- ☐ **To close the letter, summarize the recommendation from your physician and provide a phone number should any additional information be required**
- ☐ If required, attach a **Letter of Medical Necessity**
  Click here for a sample Letter of Medical Necessity.

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.

*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.

See sample letters on following pages.

Sample Loading Dose Appeals Letter

when you are **not** already taking COSENTYX® (secukinumab)

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Your Name]
[Policy Number]
[DOB]
[Optional: Denial Reference # and Date]

To Whom it May Concern:

I am a member of [enter name of health plan]. I have been approved for initiation of COSENTYX® (secukinumab) without a loading dose. According to my doctor, my condition warrants initiation with a loading dose.

I am submitting this letter to request approval to initiate COSENTYX for the treatment of psoriatic arthritis with a 5-week loading dose: 150 mg at weeks 0, 1, 2, 3, and 4.

My physician has provided my patient history, diagnosis, current condition, and symptoms

[Include relevant medical information to support your request.
Examples of information you may want to include are:

- Tuberculosis test and results
- Medical records describing my diagnosis and the date of diagnosis
- Number of areas of tenderness or pain other than in a joint (ie, enthesitis); number of entire fingers or toes with swelling (ie, dactylitis)
- High-sensitivity C-reactive protein levels (hs-CRP)
- Your own description of pain from the condition (you can also include your physician's assessment or the Health Assessment Questionnaire Disability Index)
- Description of the impact of the condition on your quality of life and your ability to perform activities of daily living
- Comprehensive list of previous treatment therapies used
- Rationale for initiating COSENTYX with a 5-week loading dose followed by 150 mg every 4 weeks]

NPI=national provider identifier.

Include clinical support from your physician.

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 me.

Sincerely,

Be sure to have your physician sign the letter.

Enclose your medical records along with a Letter of Medical Necessity from your physician.

[Patient name and signature]

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

Encl: Medical records
Letter of Medical Necessity

Double-click to open a Word version of this letter.

Click here for Important Safety Information.
Please see full Prescribing Information, including Medication Guide.

Patient Letter 6

Sample Loading Dose Appeals Letter

when you **are** already taking COSENTYX® (secukinumab)

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Your Name]
[Policy Number]
[DOB]
[Optional: Denial Reference # and Date]

To Whom it May Concern:

I am a member of [enter name of health plan]. I have been receiving 150 mg of COSENTYX® (secukinumab) every 4 weeks for my psoriatic arthritis. My doctor believes that I would benefit from the 300-mg dose of COSENTYX.

I am submitting this letter to request approval to use COSENTYX 300 mg every 4 weeks for the treatment of psoriatic arthritis. I have been receiving COSENTYX 150 mg every 4 weeks from [insert date] to [insert date] and continue to have active disease.

My physician has provided my patient history, diagnosis, current condition, and symptoms

[Include relevant medical information to support your request.
Examples of information you may want to include are:

- Tuberculosis test and results
- Medical records describing my diagnosis and the date of diagnosis
- Number of areas of tenderness or pain other than in a joint (ie, enthesitis); number of entire fingers or toes with swelling (ie, dactylitis)
- High-sensitivity C-reactive protein levels (hs-CRP)
- Your own description of pain from the condition (you can also include your physician's assessment or the Health Assessment Questionnaire Disability Index)
- Description of the impact of the condition on your quality of life and your ability to perform activities of daily living
- Description of your response to the 150-mg dose
- Rationale for continuing therapy with COSENTYX at the 300-mg dose]

NPI=national provider identifier.

Include clinical support from your physician.

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 me.

Sincerely,

[Patient name and signature]

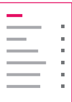
[Physician name and signature]
[Name of practice]
[Phone #]

Encl: Medical records
Letter of Medical Necessity

Be sure to have your physician sign the letter.

Enclose your medical records along with a Letter of Medical Necessity from your physician.

Double-click to open a Word version of this letter.



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

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

PsA=psoriatic arthritis; *ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.*

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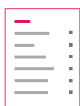

Glossary

COSENTYX® Connect Support Program

A personal support program that provides resources to the practice and patient to help patients get started on COSENTYX.

Dosage Appeals Letter

Some plans may not approve all dosing options that are included on the drug's label. A dosage appeal letter can be used to request approval for a dose that is different from what the plan has approved.

Formulary

List of prescription drugs that are covered by a health plan.

Formulary Exception Request Letter

This type of letter can be sent by the patient to request that a drug, not currently included on the plan's formulary, be approved for the patient.

Letter of Medical Necessity

This letter is written by a physician to present his or her clinical judgment supporting the diagnosis and the need for a specific therapy.

Prior Authorization (PA) Request Letter

Plans may require that a practice submit documentation of certain criteria before they agree to pay for a drug. A PA request letter shows that the patients meets the plan's criteria. It is sent by the physician.

Prior Authorization Appeals Letter

When a prior authorization request is not approved, this type of letter can be used to appeal the decision. It may include more detailed information than what was included in the original PA request. This letter is also sent by the physician.

Tiering Exception Request Letter

When a drug is included on a plan's formulary but has a high copay or coinsurance, this type of letter can be used to appeal that they grant an exception for this patient and place the drug on a lower tier so that the patient has a lower out-of-pocket expense. This letter should be sent by the patient.

National Drug Code (NDC)

Universal product identifier with a unique set of numbers used for human drugs in the US.

Pharmacy Benefits Manager (PBM)

Organizations that administer prescription drug plans on behalf of health insurers and employers.

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 adult patients with active psoriatic arthritis.

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

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

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 page 24.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (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 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.

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.

Please see additional Important Safety Information on page 23.

Reference:

Cosentyx. Prescribing information. Novartis Pharmaceuticals Corp; 2021. Accessed June 11, 2021. www.novartis.us/files/www.novartis.us/files/cosentyx.pdf

www.COSENTYX.com

COSENTYX® Connect

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.readysetcosentyx.com

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