Authorization and appeals kit: Ankylosing spondylitis

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.

Click here for additional Important Safety Information.

Click here for full Prescribing Information, including Medication Guide.

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

Cosentyx® (secukinumab)

NOVARTIS PHARMACEUTICALS

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.

Click on number/field to jump to that section.

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.

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

Cosentyx® (secukinumab)

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.

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.

Sample outline of prior authorization request letter when

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 ankylosing spondylitis [ICD-10 Dx code].

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

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
- Patient global assessment of disease activity, total spinal pain assessment data, Bath Ankylosing Spondylitis Functional Index scores, inflammation scores, Bath Ankylosing Spondylitis Disease Activity Index scores, Bath Ankylosing Spondylitis Metrology Index scores, 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.

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

Sample outline of prior authorization request letter when

patient **is** 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 ankylosing spondylitis [ICD-10 Dx 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 ankylosing spondylitis 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.)

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

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
- Patient global assessment of disease activity, total spinal pain assessment data, Bath Ankylosing Spondylitis Functional Index scores, inflammation scores, Bath Ankylosing Spondylitis Disease Activity Index scores, Bath Ankylosing Spondylitis Metrology Index scores, 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.

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

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

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.)

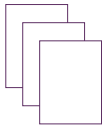
2 Suggestions for writing a Prior Authorization Appeals Letter

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**

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.

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

Cosentyx® (secukinumab)

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 ankylosing spondylitis [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
- Patient global assessment of disease activity, total spinal pain assessment data, Bath Ankylosing Spondylitis Functional Index scores, inflammation scores, Bath Ankylosing Spondylitis Disease Activity Index scores, Bath Ankylosing Spondylitis Metrology Index scores, 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

patient **is** 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 ankylosing spondylitis [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:

*May be required by some plans.

- Document that patient does not have active tuberculosis*
- Medical records indicating the patient's diagnosis and the date of diagnosis
- Patient global assessment of disease activity, total spinal pain assessment data, Bath Ankylosing Spondylitis Functional Index scores, inflammation scores, Bath Ankylosing Spondylitis Disease Activity Index scores, Bath Ankylosing Spondylitis Metrology Index scores, 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

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

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

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.)

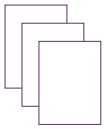
3 Suggestions for writing a Letter of Medical Necessity

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**

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.

Sample outline of letter of medical necessity when

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:

I am writing on behalf of my patient, [patient name], to support the coverage of COSENTYX for treatment of ankylosing spondylitis [ICD-10 Dx 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]. 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:

*May be required by some plans.

- Documentation the patient does not have tuberculosis*
- Medical records indicating the patient's diagnosis and the date of diagnosis
- Patient global assessment of disease activity, total spinal pain assessment data, Bath Ankylosing Spondylitis Functional Index scores, inflammation scores, Bath Ankylosing Spondylitis Disease Activity Index scores, Bath Ankylosing Spondylitis Metrology Index scores, 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

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

Sample outline of letter of medical necessity when

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

[Date]
[Medical Director]
[Insurance Company]
[Address]
[City, State, Zip]

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

To whom it may concern:

I am writing on behalf of my patient, [patient name], to support the coverage of COSENTYX for treatment of ankylosing spondylitis [ICD-10 Dx 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]. 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**. 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:

- Documentation the patient does not have tuberculosis*
- Medical records indicating the patient's diagnosis and the date of diagnosis
- Patient global assessment of disease activity, total spinal pain assessment data, Bath Ankylosing Spondylitis Functional Index scores, inflammation scores, Bath Ankylosing Spondylitis Disease Activity Index scores, Bath Ankylosing Spondylitis Metrology Index scores, high-sensitivity C-reactive protein levels (hs-CRP)
- Comprehensive list of previous treatment therapies used
- Confirmation the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Additional clinical support for the appeal, including patient response to COSENTYX if the patient is already on drug
- 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,

_____

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

Encl: Medical records

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

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.

Sample outline of formulary exception request letter when

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

[Date]
[Formulary Director]
[Insurance Company]
[Address]
[City, State, Zip]

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

To whom it may concern:

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

If this is a **2nd- or 3rd-level appeal**, after the first sentence, insert additional text from page 17.

I have been diagnosed with [insert diagnosis] and my doctor has prescribed COSENTYX [strength]. Dr. [insert physician name] practices in the medical specialty of [insert medical specialty] 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]

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,

[Patient name and signature]

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

Encl: Medical records
Letter of medical necessity

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

Sample outline of formulary exception request letter when

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

[Date]
[Formulary Director]
[Insurance Company]
[Address]
[City, State, Zip]

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

To whom it may concern:

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

If this is a **2nd- or 3rd-level appeal**, after the first sentence, insert additional text from page 17.

I have been diagnosed with [insert diagnosis] and my doctor has prescribed COSENTYX [strength]. Dr. [insert physician name] practices in the medical specialty of [insert medical specialty] 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]

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,

[Patient name and signature]

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

Encl: Medical records
Letter of medical necessity

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

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.

Sample outline of tiering exception request letter when

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

[Date]
[Formulary Director]
[Insurance Company]
[Address]
[City, State, Zip]

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

To whom it may concern:

I am requesting a tier exception for the drug COSENTYX prescribed to me by [insert physician name and specialty] for the diagnosis of [insert diagnosis and ICD-10 Dx code]. [If prior insurance covered COSENTYX on a preferred tier, describe this previous coverage.] The drug is delivered by [insert route of administration] in a strength of [insert strength of drug]. The initial requested length of tier exception approval is for [insert requested length of initial approval].

If this is a **2nd- or 3rd-level appeal**, after the first sentence, insert additional text from page 21.

I have attached medical records and a letter of medical necessity from my physician outlining why COSENTYX is needed for my medical care over other drugs listed as preferred on my formulary. [Describe why low-tiered formulary drugs would not be as effective.] 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 hinders 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 [insert diagnosis]. 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,

[Patient name and signature]

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

Encl: Medical records
Letter of medical necessity

Sample outline of tiering exception request letter when

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

[Date]
[Formulary Director]
[Insurance Company]
[Address]
[City, State, Zip]

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

To whom it may concern:

I am requesting a tier exception for the drug COSENTYX prescribed to me by [insert physician name and specialty] for the diagnosis of [insert diagnosis and ICD-10 Dx code]. [If prior insurance covered COSENTYX on a preferred tier, describe this previous coverage.] The drug is delivered by [insert route of administration] in a strength of [insert strength of drug]. The initial requested length of tier exception approval is for [insert requested length of initial approval].

If this is a **2nd- or 3rd-level appeal**, after the first sentence, insert additional text from page 21.

I have attached medical records and a letter of medical necessity from my physician outlining why COSENTYX is needed for my medical care over other drugs listed as preferred on my formulary. [Insert copies of medical records **dating to the initial prescription of COSENTYX**.] [Insert a summary of reason(s) why low-tiered formulary drugs would not be as effective.] 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 [insert diagnosis]. 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,

[Patient name and signature]

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

Encl: Medical records
Letter of medical necessity

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

6 Suggestions for writing a Dosage Appeals Letter

Some plans may not approve loading doses of COSENTYX® for ankylosing spondylitis unless an appeal is submitted by the patient. 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**.

Checklist

- ☐ **Include the patient's name, policy number, and date of birth**
- ☐ **Explain why you are requesting approval to initiate therapy in your patient with a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4**
- ☐ **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** (familiarize yourself with the severity scoring methods preferred by the health plan)
- ☐ **Provide clinical support for your recommendation**
- ☐ **To close the letter, summarize your recommendation, 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 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 letter on the following page.

Sample outline of loading dose appeals letter when

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:

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

This letter is being submitted for approval to initiate COSENTYX for the treatment of ankylosing spondylitis [ICD-10 Dx code] with a 5-week loading dose for [patient name, ID and group number]: 150 mg at Weeks 0, 1, 2, 3, and 4.

My physician has provided the following:

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
- Patient global assessment of disease activity, total spinal pain assessment data, Bath Ankylosing Spondylitis Functional Index scores, inflammation scores, Bath Ankylosing Spondylitis Disease Activity Index scores, Bath Ankylosing Spondylitis Metrology Index scores, high-sensitivity C-reactive protein levels (hs-CRP)
- Comprehensive list of previous treatment therapies used
- Rationale for initiating COSENTYX with a 5-week loading dose followed by 150 mg every 4 weeks

*May be required by some plans.

Insert clinical support.

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,

[Patient name and signature]

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

Encl: Medical records
Letter of medical necessity
COSENTYX clinical trial data

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

Possible AS ICD-10-CM Codes	Descriptor
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
M45.2	Ankylosing spondylitis of cervical region
M45.3	Ankylosing spondylitis of cervicothoracic region
M45.4	Ankylosing spondylitis of thoracic region
M45.5	Ankylosing spondylitis of thoracolumbar region
M45.6	Ankylosing spondylitis of lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis of sacral and sacrococcygeal region
M45.9	Ankylosing spondylitis of unspecified sites in spine

M45 code family has the following notations
Includes: Rheumatoid arthritis of spine.
Excludes 1: arthropathy in Reiter's disease (M02.3-) and juvenile (ankylosing) spondylitis (M08.1).
Excludes 2: Behçet's disease (M35.2).

AS=ankylosing spondylitis.

*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.

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

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 26.

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 25.

Bibliography

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

www.cosentyx.com

Click here for full Prescribing Information, including Medication Guide.

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

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Cosentyx® (secukinumab)