Suggestions for Writing

A Medical Exception Request Letter

A resource 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.

Checklist and sample letter 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)

Suggestions for Writing a Medical Exception Request Letter*

This checklist and the accompanying letter can help to support a medical exception request if COSENTYX® (secukinumab) has been excluded from coverage by a health plan or pharmacy benefit manager without the grandfathering in of current patients.

Plans may provide a form on their website that can be used to apply for a medical exception. Plans will often ask that, in addition, you fax a supporting letter that provides your rationale for the request. Check with the plan or your Field Reimbursement Manager (FRM) to learn more.

This checklist and the sample letter template on the following page are provided as a suggested framework that may be helpful as you write your own letters.

This letter should come from the physician.

Checklist

The following information may be helpful as you prepare a Medical Exception Request letter:

- ☐ **Patient's name, policy number, date of birth, and a copy of the notification letter from the plan**
- ☐ **Patient history, diagnosis, and current condition**
  - How has patient responded to the therapy? Are they currently controlled and stable?
  - How long have they been on COSENTYX?
  - What is their current health status?
  - Description of the severity of the condition prior to treatment with COSENTYX
  - Patient's level of satisfaction with COSENTYX
- ☐ **Your rationale for maintaining the patient on COSENTYX. Consider including reasons such as:**
  - Clinical support for COSENTYX
  - Considerations related to COVID-19
  - Potential impact a nonmedical switch could have on office time and resources
- ☐ **Copies of relevant medical records**
- ☐ **List of prior medications, their duration, and dates of use**
- ☐ **Fax supporting documentation to the plan**

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See sample letter on following page.

Sample Medical Exception Request Letter

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

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

To Whom it May Concern:

My patient, [insert name], has received a notice from [Plan or PBM] that COSENTYX® (secukinumab) will no longer be covered under their health plan and that they will have to switch to [another preferred medication]. Otherwise, they will have to pay the full price for COSENTYX or cease taking an effective therapy.

This patient has been under my care for the treatment of [insert one or more diagnosis] for [x] years. I do not consider the nonmedical switching of this patient to another medication to be good medical practice and I request an exception to the policy for the reasons I have listed below [INSERT THE REASONS FOR YOUR REQUEST FOR A MEDICAL EXCEPTION TO THE POLICY]:

- [Description of how the patient has responded to current COSENTYX therapy]
- [How long patient has been on COSENTYX?]
- [List of prior therapies and dates of treatment if known]
- [Rationale for maintaining patient on COSENTYX ie, reasons why other therapies may not be appropriate]
- [Clinical considerations, such as lack of trials that establish comparable efficacy]
- [Considerations related to COVID-19]
- [Potential impact on office time and resources]

For the reasons cited above, I believe that COSENTYX is the appropriate treatment for this patient and I request a medical exception to your policy.

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

Sincerely,

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

[Encl: Medical records]

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

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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 5.

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 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 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 4.

Please see full Prescribing Information, including Medication Guide.

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