Secukinumab (Cosentyx) - Full Clinical Guideline

Reference no.: CG-RHEUM/2017/008

Prescribing Schedule for secukinumab (Cosentyx)

1. Purpose

To ensure that patients are receiving secukinumab according to National Guidelines and in a safe and effective manner.

Secukinumab is a fully human IgG1k monoclonal antibody to interleukin-17A

2. Guidelines

Indications for treatment

The National Institute for Clinical Effectiveness has developed guidelines for use in ankylosing spondylitis.

Secukinumab is recommended as an option for treating active ankylosing spondylitis in adults whose disease has responded inadequately to conventional therapy (non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors).

Assessments prior to therapy

These are undertaken by trained rheumatology nurses

- Patients with AS should have their BASDAI and spinal VAS measured. A BASDAI of 4 or more units and VAS of at least 4cm on 0-10cm scale indicates active disease eligible for treatment.
- Patients should be screened for TB as per the protocol (CXR +/- skin or blood testing).
- Patients should be screened for hepatitis B and C
- Patients should have blood tests (FBC, U&E, LFT, CRP, ESR) within 1 week of commencing treatment and results checked.
- Urinalysis should be checked at screening visit.

Contraindications

- Clinically important active infection (including active TB)
- Hypersensitivity to the active substance or any of the excipients including latex allergy.

Treatment schedule

Initiation of therapy should be by Consultant Rheumatologist only. Secukinumab is given as a subcutaneous injection of 150mg. This is given at weeks 0,1,2,3 and 4 followed by monthly maintenance dosing. Treatment is initiated on the Rheumatology day case unit and patients are taught how to self-administer the injections. Patients will usually have the initial injections

dispensed from the hospital pharmacy. Further supplies will be delivered to the patient's home.

Adverse effects and precautions:

Infections
Secukinumab may increase risk of infection. Caution should be exercised when considering the use of secukinumab in patients with chronic infection or a history of recurrent infection. Patients should be instructed to seek medical advice if signs or symptoms of infection occur. Secukinumab should not be given during an infection.
Secukinumab should not be given to patients with active TB. Treatment for latent TB should be initiated before starting treatment.

Crohn's disease
Caution should be exercised when prescribing secukinumab to patients with Crohn's disease as exacerbations of Crohn's disease, in some cases serious, have been reported.

Vaccinations
Live vaccines should not be given concurrently with secukinumab. Influenza (by injection) and pneumococcal vaccinations are recommended.

Pregnancy
There are no studies of secukinumab in pregnant women. Women of childbearing potential should use an effective method of contraception during treatment and for at least 20 weeks after treatment. Breast-feeding should be avoided.

Other adverse events
Oral candidiasis (uncommon), oral herpes (common), neutropenia (uncommon), conjunctivitis (uncommon), diarrhoea (common), anaphylaxis (rare).

Subsequent Assessment of Disease
Blood monitoring should be carried out in line with other biologic drugs.
Patients should be formally assessed at 16 weeks as per NICE guidance.
Failure to respond should lead to withdrawal of treatment

3. References

1. NICE technology appraisal guidance ta407. Secukinumab for treating active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or anti-TNF alpha inhibitors. September 2016

2. NICE technology appraisal guidance ta383. TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis. February 2016

3. Cosentyx SPC eMC updated May 2016

4. Documentation Controls

Development of Guideline:	Dr Sheila O'Reilly, Consultant Rheumatologist
Consultation with:	Rheumatology
Approved By:	8/11/16 Rheumatology 15/11/16 Drugs and Therapeutics 31/01/17 Medical Division
Date of Upload:	23/03/17
Review Date:	March 2020
Key Contact:	Dr Sheila O'Reilly, Consultant Rheumatologist