Stelara (ustekinumab)

Biologic medications have been used to treat psoriasis in the UK for ten years, and, although those currently in use are thought to be safe, it is important to note that long term safety data is still being compiled by the British Association of Dermatologists Biologics Interventions Register (BDBIR). The National Institute for Health and Care Excellence (NICE) recommends that all patients receiving biologic therapy, who provide their consent, are entered onto this observational study register. For more information on BDBIR, please see the website: www.badbir.org

What is Stelara?
Stelara (also referred to by its generic name, ustekinumab) is a biologic medication approved by the European Medicines Agency (EMEA) and NICE for the treatment of moderate to severe psoriasis. Stelara is also approved for the treatment of active psoriatic arthritis in people who are unsuitable for, or have not had an adequate response from, an anti-TNF biologic (such as adalimumab, etanercept, golimumab or infliximab).

The criteria for individuals who may be eligible to take Stelara is laid out in the ‘Who is it for?’ section on this page, and is published in the NICE Technology Appraisals 180, 313 and 455, available on the NICE website: www.nice.org.uk.

Key Features;
- Approved for treating moderate to severe psoriasis
- After initial doses at week 0 and 4, patients are given an injection under the skin once every 12 weeks
- Patients should be screened for latent (hidden) tuberculosis (TB) and other infections before taking ustekinumab. Patients may also need an annual flu jab.
- If adequate improvement is not seen in 16 weeks, treatment will be stopped

How does it work?
Stelara slows down the activity of interleukin 12 (IL-12) and interleukin 23 (IL-23), chemical ‘messengers’ in the immune system that signal other cells to cause inflammation. This inflammation encourages the development of psoriatic lesions.
Because of the effect Stelara has on the immune system, you will be monitored for infections throughout treatment and you will be tested for TB before treatment commences, because sometimes TB can be reactivated by this treatment. Patients may need an annual flu jab, but should check with a doctor or nurse before having any other vaccinations or taking other medication.

**Who is it for?**
Stelara is prescribed for the treatment of adults, or children over the age of 12, with severe plaque psoriasis who have not responded to, or cannot take or tolerate other systemic treatments including ciclosporin, methotrexate or PUVA.

Stelara may also be prescribed for the treatment of active psoriatic arthritis in adults who are unsuitable for, or have not had an adequate response from, an anti-TNF biologic.

**Who should not take Stelara?**
- People with active serious infections.
- People with a latex allergy, due to the presence of a latex cap on the pre-filled syringe.
- Caution is advised for the elderly, those with an already impaired immune system, and those with a history of cancer
- Pregnant women should not be treated with Stelara and women should not become pregnant for 15 weeks after treatment has stopped

**How is it used?**
Stelara is administered by injection under the skin. The first one or two doses (at weeks 0 and 4) are likely to be administered by a doctor or nurse, but after that Stelara is usually self-administered via a pre-filled ‘pen’ device every 12 weeks. Stelara is designed to be taken continuously to maintain improvement.

Patients taking Stelara will have regular blood tests every three to six months- usually carried out by Dermatology Nurses, or by their own GP- to monitor for infections or other possible effects of the treatment.
What are the side effects?
The most common side effects that have been reported include infections of the throat or airways (this affected more than one in 10 people who used Stelara). Common side effects included depression, feeling dizzy, headache, sore throat, blocked or stuffy nose, diarrhoea, itching, back or muscle pain, feeling tired and redness of the injection site. Inflammation of tissue under the skin is also common and the signs include warmth, swelling, redness and pain. Many side effects reported were mild and did not cause people to stop taking Stelara.

If a serious infection occurs a doctor will most likely stop treatment with Stelara. Although side effects are possible in this, and any, medication, it is important to note that you will be carefully monitored throughout treatment.

How do I get Stelara?
Stelara can only be prescribed by a Dermatologist or Rheumatologist who is responsible for your psoriasis or psoriatic arthritis care. It will only be prescribed for those patients for whom other systemic treatments (including methotrexate, ciclosporin and PUVA) or biologic treatments (where appropriate) have not worked or are not suitable.

For more information, or for a list of resources used in the production of this information sheet, please contact the Psoriasis Association.

July 2017 (Review Date: 03/18)