**East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG, Surrey Heath CCG, Crawley CCG, Horsham & Mid-Sussex CCG**

# Briefing Paper for Prescribing Clinical Network on NICE Technology Appraisals: Local implementation

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|---|---|---|---|
| **NICE TA Guidance** | Ixekizumab for treating moderate to severe plaque psoriasis<br>NICE Technology appraisal guidance 442 | | |
| **Available at** | https://www.nice.org.uk/guidance/ta442 | | |
| **Date of issue** | 26 April 2017 | **Implementation deadline** | 26 July 2017 |

| **Medicine details** | |
|---|---|
| **Name, brand name and manufacturer** | Ixekizumab (Taltz)<br>Eli Lilly<br><br>**www.medicines.co.uk**<br><br>**Mechanism of action**<br>Ixekizumab is an IgG4 monoclonal antibody that binds with high affinity (< 3 pM) and specificity to interleukin 17A (both IL-17A and IL-17A/F). Elevated concentrations of IL-17A have been implicated in the pathogenesis of psoriasis by promoting keratinocyte proliferation and activation. Neutralisation of IL-17A by ixekizumab inhibits these actions.<br><br>For information, Ixekizumab's mode of action is the same as secukinumab where both neutralize IL-17A |
| **Licensed indication** | Ixekizumab (Taltz) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. |
| **Formulation** | Ixekizumab (Taltz) solution for injection in pre-filled syringe |
| **Usual dosage** | The recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg (one injection) at Weeks 2, 4, 6, 8, 10, and 12, then maintenance dosing of 80 mg (one injection) every 4 weeks.<br><br>Consideration should be given to discontinuing treatment in patients who have shown no response after 16 to 20 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 20 weeks.<br><br>This is the current dose considered by NICE as part of the NICE evaluation. Subsequent changes in the license following NICE publication will need to be considered by the Prescribing Clinical Network and will not be routinely funded by local commissioners. |

## Disease and potential patient group

**Brief description of disease**

www.patient.co.uk

What is psoriasis?

Psoriasis is a common condition where there is inflammation of the skin. It typically develops as patches (plaques) of red, scaly skin. Once you develop psoriasis it tends to come and go throughout life. A flare-up can occur at any time. The frequency of flare-ups varies. There may be times when psoriasis clears for long spells. However, in some people the flare-ups occur often. Psoriasis is not due to an infection. You cannot pass it on to other people and it does not turn into cancer.

The severity of psoriasis varies greatly. In some people it is mild with a few small patches that develop and are barely noticeable. In others, there are many patches of varying size. In many people the severity is somewhere between these two extremes.
However, with an early diagnosis and appropriate treatment, it's possible to slow down the progression of the condition and minimise or prevent permanent damage to the joints.

**Potential patient numbers per 100,000**

www.nice.org.uk Resource impact template

| **Population** | **NICE assumption(%)** | **Number of people** |
|---|---|---|
| Adult population per 100,000 | | 78,674 |
| Prevalence of psoriasis | 1.75 | 1,377 |
| Proportion with plaque psoriasis | 90 | 1,239 |
| People eligible for biologic treatments | 2.55 | 32 |
| People estimated to be treated with ixekizumab over time (5 years) | 10 | 3 |

## SUMMARY

**Guidance** www.nice.org.uk

1. Recommendations
   1.1. Ixekizumab is recommended as an option for treating plaque psoriasis in adults, only if:
   - the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10
   - the disease has not responded to standard systemic therapies, for example, ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation), or these treatments are contraindicated or the person cannot tolerate them, and
   - the company provides the drug with the discount agreed in the patient access scheme.

   1.2. Stop ixekizumab treatment at 12 weeks if the psoriasis has not responded adequately. An adequate response is defined as:
      - a 75% reduction in the PASI score (PASI 75) from when treatment started or
      - a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.

   1.3. When using the PASI, healthcare professionals should take into account skin colour

and how this could affect the PASI score, and make the clinical adjustments they consider appropriate.

1.4. When using the DLQI, healthcare professionals should take into account any physical, psychological, sensory or learning disabilities, or communication difficulties, that could affect the responses to the DLQI and make any adjustments they consider appropriate.

1.5. These recommendations are not intended to affect treatment with ixekizumab that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

**Summary of appraisal committees key conclusions:**

**What is the position of the treatment in the pathway of care for the condition:**
Ixekizumab is likely to be primarily offered to patients whose disease has not responded to a previous biological treatment and to patients who cannot have other biological treatments.

**Cost implications**

**Cost:**
The list price is £1,125 for 80mg and £2,250 for 2 x 80mg

**Annual cost per patient:**
The estimated annual cost of treatment in the year 1 (with induction) is £18,000 (Via homecare so no VAT and without PAS).

Year 2 onwards estimated cost of treatment will be £13,500 (80mg x 12 injections)

**Availability of PAS and details (if appropriate): www.nice.org.uk**
The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of ixekizumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS

**Availability of homecare service (if appropriate):**
Yes

**Alternative treatments and cost per patient per year**

**Other NICE recommended products:**
Based on the list price:

1st year (including loading dose) (All via homecare so no VAT except infliximab which is given by intravenous infusion in hospital where a day care tariff will be applied and Apremilast which is an oral treatment, not provided via homecare)

**TNF-alpha inhibitors**
Adalimumab (Humira) - **£9,115**
Etanercept (Enbrel) - **£9,295** (there has been a recent discount applied to this product)
Etanercept (Benepali – Biosimilar) – **£8,528**
Infliximab (Remicade, Inflectra, Remsima) (weight based dosing average adult weight 76kg) – **(£14.5k - £20k inclusive of VAT)**

**Interleukin inhibitors**
Secukinumab (Cosentyx -IL17a) - **£9,750**
Ustekinumab (Stelara – IL23a) - **£10,735**

**Phosphodiesterase Type- 4 Inhibitor (PDE4)**

Apremilast (Otezla) - **£6,600** (excluding VAT and without PAS).

**Options not reviewed by NICE but used in standard practice:**
N/A

**Impact to patients**

- An additional treatment option for psoriasis would be valued by patients.
- Ixekizumab is available under a homecare service so will be delivered directly to the patient. This reduces the number of hospital appointments to those required for review and/or monitoring.

**Impact to primary care prescribers**

- This is a PbRe drug and is commissioned by CCGs for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving ixekizumab in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care.
- Information on treatment should be added to the patient's notes so that they are available to view,(but not prescribe) by the primary care prescriber

**Impact to secondary care**

- The initiation, administration and on-going treatment is managed by secondary care.
- Homecare arrangements will be managed by the trust.
- Ixekizumab is available on homecare and patients will only require appointments for review and/or monitoring.
- An additional treatment option for psoriasis would be valued by clinicians.

**Impact to CCGs**

- The technology is commissioned by clinical commissioning groups (CCGs).
- Providers are NHS hospital trusts.

**Implementation**

- NICE TA implementation must be within 90 days of publication – 26th July 2017
- Blueteq forms to be developed
- Trusts to initiate homecare
- Revision to psoriasis treatment pathway has been made at consultation with local dermatologists.

**Recommendation to PCN**

**PbRe:** Y

**Recommended traffic light status:**
**RED**

**Additional comments:**

**Prepared by:**

Clare Johns (Lead Commissioning Technician)

Declaration of Interest: None.

Date: 31/05/2017

**Reviewed by:**

Declaration of Interest:

Sarah Watkin (Head of Strategic Pharmaceutical Commissioning)

Declaration of Interest: None

Date: 15/06/2017

**VERSION CONTROL SHEET**

| Version | Date | Author | Status | Comment |
|---|---|---|---|---|
| 1 | 31/05/2017 | Clare Johns | Draft | Peer review pending. |
| 2 | 15/06/2017 | Sarah Watkin | Draft | Peer review |
| 3 | 15/06/2017 | Clare Johns | Draft | Out for wider consultation with treatment pathway |
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