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

NICE TA Guidance	Guselkumab for treating moderate to severe plaque psoriasis (TA 521)		
Available at			
Date of issue	13th June 2018	**Implementation deadline**	CCGs are required to comply with the recommendations within 3 months. (13th September 2018) However, because guselkumab has been recommended through the fast track appraisal process, commissioners have agreed to provide funding to implement this guidance 30 days after publication. (14th July 2018)

Medicine details[1,2]	
Name, brand name	Guselkumab (Tremfya®) Mechanism of action **www.medicines.org.uk** Guselkumab is a human IgG1λ monoclonal antibody (mAb) that binds selectively to the interleukin 23 (IL-23) protein with high specificity and affinity. IL-23, a regulatory cytokine, affects the differentiation, expansion, and survival of T cell subsets, (e.g., Th17 cells and Tc17 cells) and innate immune cell subsets, which represent sources of effector cytokines, including IL-17A, IL-17F and IL-22 that drive inflammatory disease. In humans, selective blockade of IL-23 was shown to normalize production of these cytokines. Levels of IL-23 are elevated in the skin of patients with plaque psoriasis. In in vitro models, guselkumab was shown to inhibit the bioactivity of IL-23 by blocking its interaction with cell surface IL-23 receptor, disrupting IL-23-mediated signaling, activation and cytokine cascades. Guselkumab exerts clinical effects in plaque psoriasis through blockade of the IL-23 cytokine pathway.
Manufacturer	Janssen
Licensed indication	Guselkumab (Tremfya®) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
Formulation	Pre-filled syringe contains 100 mg of guselkumab in 1 mL solution.
Usual dosage	The recommended dose of guselkumab (Tremfya®) is 100 mg by

	subcutaneous injection at weeks 0 and 4, followed by a maintenance dose every 8 weeks. Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment.
NICE recommended dosage/schedule	As above

Disease and potential patient group

Brief description of disease[3]

Psoriasis is a common condition where there is inflammation of the skin. It typically develops as patches (plaques) of red, scaly skin. Once it develops 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. It cannot be passed 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		78,672
Prevalence of psoriasis	1.75	1,377
Proportion with plaque psoriasis	90	1,239
People eligible for biologic treatments	2.55	32

Potential patient numbers per 100,000 is unknown but guselkumab is another treatment option for Psoriasis. Currently there are 3 lines of treatment (after standard systemic treatments) available in the psoriasis pathway.
Choices are from 10 drugs with 5 different mechanisms of action. Specialists should choose a drug with a different mode of action with each line of treatment.

SUMMARY

NICE recommendation www.nice.org.uk

1. Recommendations
   1.1. Guselkumab 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 and
   - the disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A

radiation), or these options are contraindicated or not tolerated and
- the company provides the drug according to the commercial arrangement.

1.2. Stop guselkumab at 16 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. If patients and their clinicians consider guselkumab to be one of a range of suitable treatments, including ixekizumab and Secukinumab, the least costly (taking into account administration costs and commercial arrangements) should be chosen.

1.6. These recommendations are not intended to affect treatment with guselkumab 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.

Why the committee made these recommendations

Guselkumab is proposed as an alternative to other biological therapies already recommended by NICE for treating severe plaque psoriasis in adults. Evidence from clinical trials and indirect comparisons show that guselkumab is more effective than TNF-alpha inhibitors (that is, adalimumab, etanercept and infliximab) and ustekinumab. It also suggests that guselkumab is likely to provide similar health benefits to ixekizumab and secukinumab. For the cost comparison, it is appropriate to compare guselkumab with ixekizumab and secukinumab. Taking into account how many people continue treatment (which affects the cost to the NHS), guselkumab provides similar health benefits to ixekizumab and secukinumab at a similar or lower cost. It is therefore recommended as an option for treating plaque psoriasis in the NHS.

Cost implications*

Cost of product:

The list price of guselkumab is £2,250 per pre-filled syringe (excluding VAT; British National Formulary online; accessed March 2018). The commercial arrangement brings guselkumab in line with other treatments available within the Psoriasis treatment pathway.

Annual cost per patient:

Year 1:
Injections at 0 & 4 weeks (induction) and then 8 weekly thereafter (7 injections) = £15,750 (if provided via homecare then VAT not applicable
Year 2:
8 weekly injections (total 6 injections) = £13,500

Availability of PAS and details (if appropriate): www.nice.org.uk

The company has a commercial arrangement. This makes Guselkumab available to the NHS with a discount. The size of the discount is commercial in confidence. It is the

company's responsibility to let relevant NHS organisations know details of the discount.

Availability of homecare service (if appropriate): www.nice.org.uk Janseen funds a homecare service through which the SC injection is administered to patients at home, either by self-injection following nurse training visits over the course of the first 2–3 doses, or by an ongoing nurse administration service for patients who are not suitable for self-injection.

**NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the PCN may reconsider the commissioning status.*

Alternative treatments and cost per patient (per year / per month as appropriate)

Other NICE recommended products:
Based on the list price:

Table 1: 1st year (including loading dose) costs (all via homecare so no VAT except infliximab which is given by intravenous infusion in hospital and a day care tariff will also be applied).

Prices below are before PAS prices have been applied. The prices of all the biosimilars have further reduced recently but these prices are commercially confidential

Drug cost	**Purchase quantity (taken from BNF)**	**Cost taken from BNF.**	**Cost per dose** (after induction)	**Quantity per dose**	**Annual Cost in year 1**
Adalimumab (Humira)	2 pre filled packages : 50 mg/1ml	£704.28	£352.14	50 mg BI weekly	£9,156
Etanercept (biosimilar cost)	4 pre filled packages : 50 mg/1ml	£656.00	£164.00	50 mg once weekly	£5,300
Infliximab (biosimilar cost)	100 mg/1ml	£377.00	£377.00	4 Vials every 8 weeks	£9,802
Ustekinumab (Stelara)	1 pre-filled syringe: 90mg/1ml or 45mg/0.5ml	£2147.00	£2147.00	45mg-90mg every 12 weeks (weight based dosing)	£8,588
Ixekizumab (Taltz)	1 pre filled pen/syringe 80mg/ml	£1125.00	£1125.00	80mg every 4 weeks	£14,625
Secukinumab (Cosentyx)	2 pre-filled pens/ syringes 150mg/1ml	£1218	£1218	300mg every month after induction	£16,770
Apremilast	56x 30mg tablets	£550.00	£9.82	30 mg twice daily	£7,150
Brodalumab	2 pre-filled syringe 210mg/1.5ml	1280	£1140	210mg every 2 weeks after induction	£31,920
Dimethyl Fumarate	90 x 120mg tablets	£190.80	Average maintenance dose up to 480mg/day £8.48	Average maintenance dose up to 480mg (4 tablets per day	£3,086.72

Impact to patients
• An additional treatment option for plaque psoriasis would be valued by patients. • Please note NICE guidance when choosing guselkumab as a 1st line treatment option. Taken directly from NICE guidance '*guselkumab provides substantially greater clinical benefits compared with TNF alpha & ustekinumab, and is likely to provide similar benefit to secukinumab & Ixekizumab'.* By choosing guselkumab 1st line you will be limiting the treatments available to the patient, taking the information on clinical benefit above in consideration.
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 guselkumab and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.
Impact to secondary care
• The initiation, administration and on-going treatment is managed by secondary care. • Homecare arrangements will be managed by the trust. • Janseen funds a homecare service through which the SC injection is administered to patients at home, either by self-injection following nurse training visits over the course of the first 2–3 doses, or by an ongoing nurse administration service for patients who are not suitable for self-injection. • An additional treatment option for plaque psoriasis would be valued by clinicians. • Blueteq forms for initiation and continuation will need to be completed by dermatology specialists.
Impact to CCGs
• The technology is commissioned by clinical commissioning groups (CCGs). • Providers are NHS hospital trusts. • Guselkumab is PbRe and if a patient meets NICE criteria, treatment can be initiated and invoiced to the commissioner (if Blueteq forms have been completed). • Revision of the psoriasis pathway discussed with dermatology specialist teams prior to PCN discussion
Implementation
• NICE TA implementation must be within 90 days of publication – 14th July 2018 • Blueteq forms to be developed
Recommendation to PCN
PbRe: Y **Recommended traffic light status** • **RED –** Blueteq forms for initiation and continuation will be developed for specialists to complete.

References:

1. www.medicines.org
2. NICE www.nice.org.uk
3. What is psoriasis? Patient Platform Ltd. Available at: https://patient.info/health/psoriasis-leaflet
4. Resource impact statement & template www.nice.org.uk
5. NHS choices www.nhs.uk

Prepared by:

Name: **Clare Johns (Lead Commissioning Technician – Pharmaceutical Commissioning (Surrey Downs CCG – Hosted Service)**

Declaration of Interest:

None

Date: 16/07/2018

Reviewed by: Declaration of Interest: None

Date:

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1		*Clare Johns*	*Draft*	*For peer review prior to consultation with specialist teams and PCN*