



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 Surrey & North West Sussex Area Prescribing Committee (APC) on NICE Technology Appraisals: Local implementation

NICE TA Guidance	Risankizumab (Skyrizi) for treating moderate to severe plaque psoriasis (TA596)		
Available at	https://www.nice.org.uk/guidance/ta596/resources/risankizumab-for-treating-moderate-to-severe-plaque-psoriasis-pdf-82607267096773		
Date of issue	21 st August 2019	Implementation deadline	Fast Track appraisal process (30 days implementation) as agreed by NHS England and NHS commissioners. 20 th September 2019.

Medicine details^{1,2}	
Name, brand name	Risankizumab (Skyrizi) Mechanism of action – Interleukin (IL) 23 cytokine
Manufacturer	Abbvie
Licensed indication	Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
Formulation	Each pre-filled syringe contains 75 mg risankizumab in 0.83 ml solution.
Usual dosage	The recommended dose is 150 mg (two 75 mg injections) administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter. Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment. Some patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks.
NICE recommended dosage/schedule	As above

Disease and potential patient group	
Brief	

<p>description of disease³</p>	<p>https://patient.info/skin-conditions/psoriasis-leaflet</p> <p>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.</p>															
<p>Potential patient numbers per 100,000</p>	<p>www.nice.org.uk Resource impact template</p> <table border="1" data-bbox="424 775 1402 1140"> <thead> <tr> <th>Population</th> <th>NICE assumption (%)</th> <th>Number of people</th> </tr> </thead> <tbody> <tr> <td>Adult population per 100,000</td> <td></td> <td>78,666</td> </tr> <tr> <td>Prevalence of psoriasis</td> <td>1.75</td> <td>1,377</td> </tr> <tr> <td>Proportion with plaque psoriasis</td> <td>90</td> <td>1,239</td> </tr> <tr> <td>People eligible for biologic treatments</td> <td>2.55</td> <td>32</td> </tr> </tbody> </table> <p>Risankizumab will be another treatment option for Psoriasis.</p> <p>Currently there are 3 lines of treatment (after standard systemic treatments) available in the psoriasis pathway in line with national guidance.</p> <p>Choices are from 12 drugs (13 drugs with risankizumab) with 7 different mechanisms of action. Specialists should choose a drug with a different mode of action with each line of treatment.</p>	Population	NICE assumption (%)	Number of people	Adult population per 100,000		78,666	Prevalence of psoriasis	1.75	1,377	Proportion with plaque psoriasis	90	1,239	People eligible for biologic treatments	2.55	32
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SUMMARY

NICE recommendation www.nice.org.uk

1. Recommendations

1.1. Risankizumab 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 treatments, including ciclosporin, methotrexate and phototherapy, or these options are

contraindicated or not tolerated and

- the company provides the drug according to the commercial arrangement (see section 2).

1.2. Stop risankizumab treatment 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. If patients and their clinicians consider risankizumab to be one of a range of suitable treatments, including guselkumab, secukinumab and ixekizumab, the least expensive should be chosen (taking into account administration costs, dosage, price per dose and commercial arrangements)

1.4. 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.

1.5. 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.

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

Risankizumab is proposed as an alternative to other biological therapies already recommended by NICE for treating severe plaque psoriasis in adults. Evidence from clinical trials shows that risankizumab is more effective than adalimumab and ustekinumab. Indirect comparisons suggest that risankizumab is likely to provide similar health benefits compared with guselkumab, and better PASI response rates compared with many other biologicals.

For the cost comparison, it is appropriate to compare risankizumab with guselkumab. The total costs associated with risankizumab are similar to or lower than those associated with guselkumab.

Therefore, risankizumab is recommended as an option for use in the NHS for severe plaque psoriasis that has not responded to systemic non-biological treatments, or if these are contraindicated or not tolerated.

Cost implications*

Cost of product:

£3326.09 per 150mg (2 x 75mg pre-filled syringe (excluding VAT, British national formulary online; accessed, July 2019). The company has a **commercial arrangement.**

Annual cost per patient:

Year 1:

Injections (150mg (2 injections)) at 0 & 4 weeks (induction) and then every 12 weeks thereafter (10 injections) = £16,630 (if provided via homecare then VAT not applicable)

Year 2:

12 weekly injections (total 8 injections) = £13,304

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

The company has a commercial arrangement. This makes risankizumab 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):

Home care service is available (Alcura, Healthcare at Home or Healthnet (www.sps.nhs.uk) accessed in July 2019

**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 APC may reconsider the commissioning status.*

Alternative treatments available with the psoriasis pathway**TNF-Alpha inhibitors**

- adalimumab, etanercept, infliximab & certolizumab

Fumaric Acid Ester

- dimethyl fumarate

Phosphodiesterase (PDE4) inhibitor

- apremilast

Interleukin 17RA inhibitor

- brodalumab

Interleukin 17 inhibitor

- secukinumab & izekizumab

Interleukin (IL)23 protein

- guselkumab & tildrakizumab - & risankizumab

Interleukin (IL)12/23 inhibitor

- ustekinumab

Clinical effectiveness: www.nice.org.uk

The committee accepted that the results of these trials showed that risankizumab was more effective than adalimumab and ustekinumab.

Impact to patients

- An additional treatment option for plaque psoriasis would be valued by patients.

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 risankizumab 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
<ul style="list-style-type: none"> • The initiation, administration and on-going treatment is managed by secondary care. • Homecare arrangements will be managed by the trust. • 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
<ul style="list-style-type: none"> • The technology is commissioned by clinical commissioning groups (CCGs). • Providers are NHS hospital trusts. • Risankizumab 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 APC discussion
Implementation
<ul style="list-style-type: none"> • NICE TA implementation must be within 30 days (Fast track appraisal process) 20th September 2019 • Blueteq forms to be developed
Recommendation to PCN
<p>APC to consider</p> <ul style="list-style-type: none"> • RED TRAFFIC LIGHT STATUS – 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

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Declaration of Interest:

None

Date: 22nd August 2019