**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

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|---|---|---|---|
| **NICE TA Guidance** | Ustekinumab for treating moderately to severely active ulcerative colitis<br>Technology appraisal guidance - TA633 | | |
| **Available at** | https://www.nice.org.uk/guidance/ta633 | | |
| **Date of issue** | 17 June 2020 | **Implementation deadline** | September 2020 |

## Medicine details

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|---|---|
| **Name, brand name** | ustekinumab (Stelara) |
| **Manufacturer** | Janssen-Cilag Ltd |
| **Licensed indication** | Ulcerative Colitis<br>Ustekinumab has a marketing authorisation that includes the following indication: 'treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies'. |
| **Formulation iv** | **STELARA 130 mg Concentrate for solution for infusion SmPC accessed July 2020.** |
| **Usual dosage iv** | STELARA treatment is to be initiated with a single intravenous dose based on body weight. The infusion solution is to be composed of the number of vials of STELARA 130 mg as specified:<br>Initial intravenous dosing of STELARA |

| Body weight of patient at the time of dosing | Recommended dose Approx. 6 mg/kg | Number of 130 mg STELARA Vials |
|---|---|---|
| ≤ 55 kg | 260 mg | 2 |
| > 55 kg to ≤ 85 kg | 390 mg | 3 |
| > 85 kg | 520 mg | 4 |

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| **Formulation sc** | **STELARA solution for injection in pre-filled syringe SmPC.accessed July 2020** |
| **Usual dosage sc** | The first subcutaneous administration of 90 mg STELARA should take place at week 8 after the intravenous dose. After this, dosing every 12 weeks is recommended.<br>Patients who have not shown adequate response at 8 weeks after the first subcutaneous dose, may receive a second subcutaneous dose at this time.<br>Patients who lose response on dosing every 12 weeks may benefit from an increase in dosing frequency to every 8 weeks.<br>Patients may subsequently be dosed every 8 weeks or every 12 weeks according to clinical judgment. |

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| | Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit 16 weeks after the IV induction dose or 16 weeks after switching to the 8-weekly maintenance dose. |
| **NICE recommended dosage/schedule** | NICE TA 633 indicates the dosage schedule as available in the summary of product characteristics. |

## Disease and potential patient group

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|---|---|
| **Brief description of disease** | Ulcerative Colitis (UC) is a condition that causes inflammation and ulceration of the inner lining of the colon and rectum (the large bowel). In UC, ulcers develop on the surface of the bowel lining and these may bleed and produce mucus.<br>UC is one of the two main forms of Inflammatory Bowel Disease, (IBD). The other main form of IBD is Crohn's Disease.<br>UC is a chronic condition. This means that it is ongoing and lifelong, although there may be long periods of good health known as remission, as well relapses or flare-ups when symptoms are more active.<br>At present there is no cure for UC, but drugs, and sometimes surgery, can give long periods of relief from symptoms. |
| **Potential patient numbers per 100,000** | NICE resource impact assessment provides an estimate of the numbers eligible for non-conventional DMARDs for each ICP<br>Crawley: 24<br>East Surrey: 40<br>Guildford and Waverly: 46<br>Horsham and Mid-Sussex: 52<br>North West Surrey: 75<br>Surrey Downs: 63<br>Surrey Heath: 21<br>The proportion of these in whom ustekinumab will be chosen is unknown. NICE places ustekinumab after an anti-TNF unless an anti-TNF is not suitable for the patient. |

## SUMMARY

**NICE recommendation**

Ustekinumab is recommended as an option for treating moderately to severely active ulcerative colitis in adults when conventional therapy or a biological agent cannot be tolerated, or the disease has responded inadequately or lost response to treatment, only if:

- a tumour necrosis factor-alpha inhibitor has failed (that is the disease has responded inadequately or has lost response to treatment) or
- a tumour necrosis factor-alpha inhibitor cannot be tolerated or is not suitable,

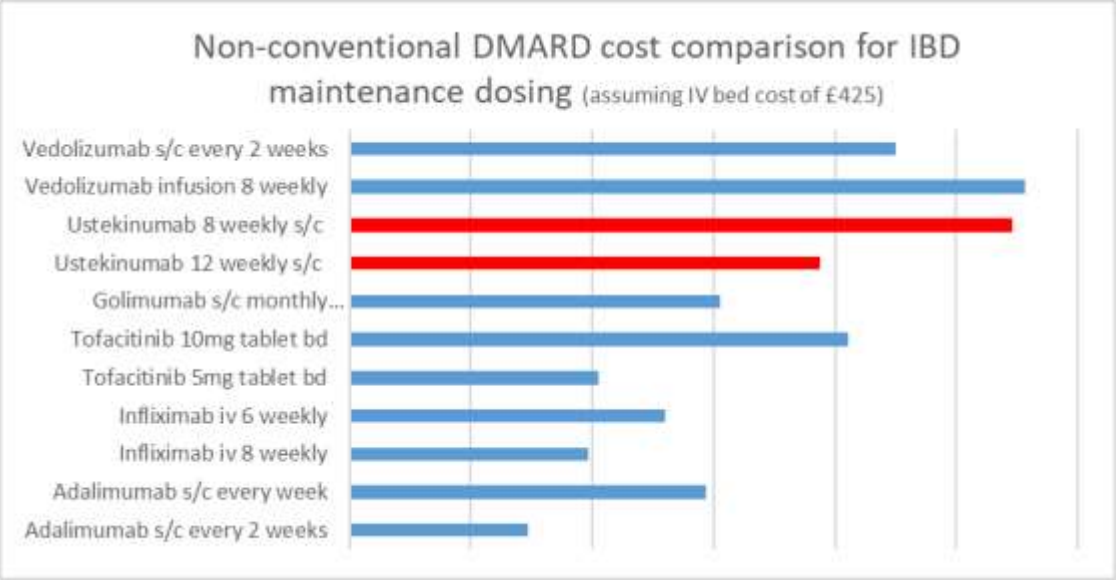
**and** the company provides ustekinumab at the same price or lower than that agreed with the Commercials Medicines Unit.

**Cost implications***

**Cost of product:**
NICE have stated that no significant resource impact is anticipated, they do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations will be less than £5 million per year in England (or £9,000 per 100,000 population).
This is because the technology is a further treatment option and the overall cost of treatment

will be comparable to the current treatment options available. This treatment option is only available to patients when other treatment has failed (that is the disease has responded inadequately or has lost response to treatment), or they have not been able to tolerate or are otherwise inappropriate for a TNF-alpha inhibitor.
The resource impact template provided did not have current or future practice assumptions completed making completion at a local level challenging. There are now several treatment options that are recommended by NICE for moderately to severely active ulcerative colitis. Organisations would need to complete both current and future uptake based on local practice in order to assess the financial impact.
Janssen has agreed a nationally available price reduction for ustekinumab with the Commercial Medicines Unit. The price agreed is commercial in confidence. Some other treatment options have discounts that are commercial in confidence.

**Monthly maintanence cost per patient**




**Has dose escalation been considered as part of the NICE costing template?**
Yes – dose escalation is included in the NICE TA, the company's assumption that 30% of patients have escalated doses of maintenance treatment was accepted by NICE.

**Availability of PAS and details (if appropriate):** Yes currently in use for Crohn's disease
**Availability of homecare service (if appropriate):** Yes currently in use for Crohn's disease

**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 and cost per patient (per year / per month as appropriate)**

**Other NICE recommended products:**
As listed in the cost comparison chart

**Impact to patients**

Provides option of convenience of a 12 weekly sc injection to treat the disease rather than an 8 weekly infusion or 2 weekly sc injection of vedolizumab.

**Impact to primary care prescribers**

No impact to primary care anticipated

**Impact to secondary care**

NHS hospital trusts will be responsible for prescribing and managing care for this therapy. Ustekinumab is already available for use in Crohn's disease in the hospital trusts so minimal impact to adopt this TA.
The addition of ustekinumab to the UC therapy pathway will provide an additional option to IBD teams in secondary care where and anti-TNF has failed or is unsuitable.

**Impact to CCGs**

This technology is commissioned by clinical commissioning groups.

Anticipated minimal cost impact.

**Implementation**

**Place in therapy** – current pathway to be updated to include ustekinumab as an option in UC after an anti-TNF unless an anti-TNF is not suitable for the patient
**Consideration to patients who have already had 3 lines of therapy who may benefit from this therapy** – 4th line therapy has been discussed at IBD network. Proposal to support 4th line therapy in line with RMOC guidance and using the same process as the rheumatology network is brought to the same APC meeting as this paper.
**Documents already on the prescribing advisory database**:
Ulcerative Colitis (Pathway 4) - Biologic Pathway - November 2019
Ustekinumab drug profile on the PAD requires addition of UC treatment in line with this TA
Revised IBD High Cost Immune Modulator pathway submitted to the APC with this paper.
**Blueteq** – Blueteq forms require updating to include ustekinumab treatment for UC after an anti-TNF or where an anti-TNF is not suitable for the patient. Free text will be required to explain the reason if an anti-TNF is deemed unsuitable.

**Recommendation to APC**

**PbRe:** Yes

Colour classification guidelines

**Recommended traffic light status (see attached guidelines):**
RED

**Additional comments:**
A Blueteq form will be developed and made available following APC decision.

**References:**

1 https://www.nice.org.uk/guidance/ta633

**Prepared by:**

Liz Clark | Area Prescribing Committee (APC) Pharmacist

Declaration of Interest:

None

Date: 3rd July 2020

**Reviewed by:**

Name, Designation, Organisation

Declaration of Interest:

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Date: XXXX