Policy for dose escalation of Ustekinumab in psoriasis or psoriatic arthritis

INTRODUCTION

The purpose of this policy is to ensure that WCCG funds treatment only for clinically effective interventions delivered to the right patients at the right place and time.

This policy has been developed to support the decision making process associated with the allocation of resources for commissioning. It will be used to support the development of effective, efficient and ethical agreements with provider organisations. In creating this policy WCCG has reviewed this treatment and the clinical conditions for which it is prescribed. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

BACKGROUND

Use of ustekinumab for psoriasis is approved via the NICE technology appraisal (TA) TA455[1] (July 2017) and for use in psoriatic arthritis via the NICE TA340[2]. On occasion some patients are treated with these drugs at doses that are not included in these TAs and may also be outside of the license. In order to ensure that our patients across Wiltshire CCG are dealt with in an equitable manner, this policy will provide clarity to acute provider trusts on how to deal with patients where dose escalation is being considered with ustekinumab for psoriasis or psoriatic arthritis.

PRINCIPLES

Dose escalation of Ustekinumab to 8 weekly regimens is not routinely commissioned for psoriasis or psoriatic arthritis.

Funding may be considered on an individual patient basis, if there is evidence of clinical exceptional circumstances.

Exceptionality means ‘a person to which the general rule is not applicable’. The over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:

• Significantly different to the general population of patients with the condition in question

and as a result of that difference

• They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

Description of Epidemiology and Need:

- **Ustekinumab 45mg 8 weekly (Off-label): IFR required**

The 90mg vial is the same cost as the 45mg vial, therefore if a pt fails to respond to the 45mg every 12 weeks, it would not cost more to increase them to the 90mg dose every 12 weeks. This is not within the license for pts under 100kg. Such a dose change will not affect the cost-effectiveness, hence this would be the recommended dose strategy for pts not responding to the 45mg dose rather than changing to 45mg 8 weekly, only if the patient and consultant agree to use of an off-license dosing schedule, (as per British Association of Dermatologists (BAD) guidance[3] for psoriasis patients). BaNES/Swindon/Wiltshire CCGs do not commission the use of the 45mg 8 weekly regimen. An increase from 45mg 12 weekly dosing to 8 weekly dosing, would increase the total number of injections from 4 to 6 per year. This would in turn increase the total cost per year by over £4000. The NICE cost-effectiveness analysis was based on 4 injections per year. Any patients on this regimen currently should be switched to the 90mg 12 weekly regimen and if this is not thought to be suitable, an IFR would need to be completed or consideration of switching to a different biologic if they fit NICE criteria.

- **Ustekinumab 90mg 8 weekly (Off-label): IFR required**

For pts over 100kg, an increase from 90mg 12 weekly dosing to 8 weekly dosing, would increase the total number of injections from 4 to 6 per year., This would in turn increase the total cost per year by over £4000. The NICE cost-effectiveness analysis was based on 4 injections per year. For psoriasis patients, there is some evidence from PHOENIX-2[4] that this is a clinically-effective strategy & is supported by BAD but no cost-effectiveness evidence is available. BaNES/Swindon/Wiltshire CCGs do not commission the use of the 90mg 8 weekly regimen. As this regimen is not supported by NICE, any patients who this is being considered for would need an IFR to the patients CCG only if the patient and consultant agree to the use of an off-license dosing schedule, (as per British Association of Dermatologists (BAD) guidance for psoriasis patients). Or alternatively, consideration of switching to a different biologic if they fit NICE criteria.

Clinical evidence review

NICE TA455 and TA340 do not consider off-label 8 weekly regimens. British Association of Dermatologists (BAD) 2017 biologic guidance does however recommend them if the local CCG commissions them.
No equivalent clinical consensus guidance for psoriatic arthritis could be found to support the use of an 8 weekly off-label regimen (e.g. in EULAR[5] or GRAPPA[6] guidance) for psoriatic arthritis patients.

NHS Funds

Clinical Commissioning Groups (CCGs) buy healthcare on behalf of the local population. The money for this comes from a fixed budget. By law, we are required to keep within this budget.

Demand for healthcare is greater than we are able to fund from this fixed budget. This isn't just a problem in Wiltshire, it is a nationwide issue. Unfortunately, this means that some healthcare which patients might wish to receive and which consultants, doctors and other health professionals might wish to offer cannot be funded. It has always been the situation, ever since the start of the NHS in 1948, that the NHS is not able to fund every treatment.

Assessing what the overall population needs most

This means we have to prioritise what we spend, so NHS Wiltshire CCG residents have availability to the healthcare treatments which are needed most.

This assessment of need is made across the whole population and wherever possible, on the basis of best evidence about effectiveness. We also aim to do this in a way that is fair, so that different people with equal need have equal opportunity to access services. This approach is not new and it is not only happening in Wiltshire, it is consistent with other NHS organisations who buy healthcare for their local populations.

PRIVATE FUNDING

If patients choose to privately fund a drug or intervention that is not normally funded by NHS Wiltshire CCG, they will continue to retain their entitlement to all other elements of NHS care available to a Wiltshire resident.
However, when patients are privately funding an intervention, they are responsible for all the costs associated with that intervention, including any Consultant costs or diagnostics. They are, therefore, unable to receive a mixture of privately funded and NHS funded care within the same appointment or intervention - they cannot 'top up' an NHS funded appointment or intervention by paying for an additional intervention to be provided or monitored during the same consultation within the same episode of care.
We do not expect NHS providers to offer this intervention privately.

MANAGING EXCEPTIONS

In their dealings with patients and the public, providers should, if necessary, make it clear that the decision by NHS Commissioners to consider treatments or procedures to be of low priority under this policy is a considered decision. This is made against their responsibility to seek the greatest health advantage possible for local populations, using the resources allocated to them. It is necessary for NHS Commissioners to make decisions regarding the investment of resources in interventions which achieve the greatest health gain for the local population.

Where individual patient circumstances require the escalation of their care please refer to the Individual Funding Requests Policy.

IMPLEMENTATION

NHS Wiltshire CCG will require secondary care service providers to embrace and abide by the policy and advise patient's accordingly.

MONITORING THE POLICY

NHS Wiltshire CCG will monitor the adherence to this policy through the contractual process, using contractual levers where breaches of the Policy are identified.

Referrals to secondary care that are outside of this policy will be routinely monitored by the Commissioning Management and the Contracts Management Teams of the NHS Commissioners.

References

1. Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people. NICE TA TA455 (July 2017): https://www.nice.org.uk/guidance/ta455
2. Ustekinumab for treating active psoriatic arthritis. NICE TA340 (June 2015): https://www.nice.org.uk/guidance/ta340
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4. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 52-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 2). K A Papp et al. Lancet. 2008 May 17;371(9625):1675-84. doi: 10.1016/S0140-6736(08)60726-6. https://www.ncbi.nlm.nih.gov/pubmed/18486740
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6. Coates L C et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. Arthritis Rheumatol 2016 May;68(5):1060-71. https://www.ncbi.nlm.nih.gov/pubmed/26749174