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Janssen's Response to the Appraisal Consultation Document

Ustekinumab for treating active psoriatic arthritis (rapid review of technology appraisal guidance 313) [ID819]

Please find below Janssen's response to the Appraisal Consultation Document (ACD) for ustekinumab.

We are very pleased to hear that the Appraisal Committee has recommended ustekinumab for active psoriatic arthritis (PsA) for those patients for whom a TNF-alpha inhibitor is contraindicated, and also for those who have had treatment with 1 or more TNF-alpha inhibitors. The Committee's recommendation supports Janssen's view that ustekinumab offers value-for-money to the NHS as well as being clinically valuable. We are delighted that patients living with this condition will soon have access to another treatment option beyond currently available TNF-alpha inhibitors.

For those patients for whom TNF-alpha inhibitor is not suitable

As stated in our patient access scheme (PAS) submission (August 2014) and also noted in the ACD, there is a considerable unmet need in patients for whom TNF-alpha inhibitors are unsuitable. Whilst contraindication to a TNF-alpha inhibitor is clearly an important factor, there are other reasons why TNF-alpha inhibitor may not be suitable for some patients with active PsA. For such patients, a more frequent dosing regimen with a TNF-alpha inhibitor may not be suitable and these patients may benefit from ustekinumab's infrequent 12 weekly regimen. Examples of such patients include:

- those who are needlephobic,
- those who are unable to self-inject due to arthritis in fingers,
- those who have difficulties complying with a more frequent dosing regimen due to their co-morbid physical or mental condition, or due to their professional requirement (e.g. frequent travel).

It must be noted that the nurse-led homecare service, provided free-of-charge to the NHS, ensures that any nervous or concerned patients can receive ustekinumab treatment safely, and supports their adherence to treatment. As far as we are aware, a similar nurse-led homecare service is not provided by manufacturers of TNF-alpha inhibitors.

In summary, we believe there are a small number of patients for whom a TNF-alpha inhibitor may not strictly be contraindicated, yet is otherwise unsuitable, and thus may benefit from having ustekinumab as a treatment option.

Costs associated with the implementation and operation of the PAS

Paragraph 3.31 of the ACD states: "The company estimated the additional costs associated with the patient access scheme to be £33 per patient; it considered these costs irrelevant and did not include them in the economic analyses." We would like to clarify this point as

the additional costs associated with the PAS are clearly relevant to the economic analyses. However, as we stated in our PAS submission, the cost (£31 per ustekinumab patient) is very small and therefore can be considered immaterial. Since incremental QALY gains for ustekinumab is 1 or above in most of the incremental analyses, the impact of the PAS-related costs on the ICER is £30 per QALY gained or below, and therefore is inconsequential to the Committee's decision-making.