Providing the patient voice

PAPAA has been involved in the appraisals of new therapies with both the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC). As a stakeholder organisation, PAPAA is invited, along with other professional and patient representative groups, to provide the patient perspective. We feel that it is very important that we do this, to provide the lived experience of those affected by psoriasis and/or psoriatic arthritis.

We are also offered the opportunity to nominate individuals to attend the committee meetings as expert patients. This is in order to answer any questions about the conditions and how the proposed therapies are likely to benefit real people or not.

We not only use the organisation's collective knowledge, but draw on the interactions we have had via our information line, correspondence and through attending events. We also use the information provided via our surveys and submissions made to our '*share your story*' website pages. In the past we have been asked to gather specific information about certain aspects of therapies, and are continually grateful to those who respond to our request for input. The processes of treatment appraisal can often be very drawn out and take some significant time, although there are some steps being taken to speed up the process in order to make new therapies available sooner.

In a recent pilot of a new approach to cost-comparison, NICE approved its first treatment under a fast-track appraisal process. The treatment happened to be for severe plaque psoriasis and is called bimekizumab.

As part of the recovery from the COVID-19 pandemic, NICE has been working hard to find new ways to develop and publish guidance affected by the work programme pause in 2020, while also delivering the planned programme for 2021.

To address this, a new approach to the cost-comparison fast-track appraisal process was piloted in the summer for the review of selected low-risk appraisals. The pilot programme worked by using a subset of the appraisal committee to assess low-risk treatments, comparing them to similar therapies that have already been appraised by NICE. This sub-committee was then able to make a recommendation without requiring a full committee meeting. PAPAA provided initial submissions, which were included in the evidence review process.

After an initial recommendation has been made, the guidance is then considered by the entire committee ahead of its release, and a full meeting can be scheduled if any concerns arise. The pilot process does not impact the standard governance or appeal processes.

Clinical trial evidence shows bimekizumab to be more effective at treating the condition than three comparators, which were all previously approved by NICE. The cost-effectiveness estimates are also in line with what is considered to be an acceptable use of NHS resources, so bimekizumab is recommended. Nearly 18,000 people will be eligible for the treatment.

Meindert Boysen, director of the Centre for Health and Technology Evaluation at NICE, said: *"The urgency of the pandemic led to necessary changes to the way NICE prioritised guidance production throughout 2020. As part of our 2021 review into the health technology evaluation process, we are taking this opportunity to introduce new measures to address the impact of the pandemic, including this pilot programme for a limited fast-tracked process.*

"Although our review is still underway, we are pleased to have been able to pilot this new approach to committee decision making to recommend bimekizumab as a treatment option for severe plaque psoriasis.

"It is our hope that we will continue to be able to follow this new process for eligible low-risk appraisals, and release capacity within our committees and the technology evaluation team."

Victoria Barrett, head of HTA & market access policy at the Association of the British Pharmaceutical Industry, said: *"This new approach to ensure some NICE decisions are made in a more efficient way is good news, especially for the patients that stand to benefit. It is important that NICE and its committees have sufficient capacity to issue timely guidance to the NHS, and this is one way to help, given the success of the pilot exercise."*

As well as bimekizumab for severe psoriasis, PAPAA has also contributed to NICE appraisals for secukinumab, which has been recommended as an option for treating plaque psoriasis in children and young people aged 6 to 17 years, and, for psoriatic arthritis, guselkumab, which received a positive recommendation from NICE and the SMC.

Summary of the NICE recommendations and indications as follows:

Bimekizumab: "...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."

Secukinumab: "...the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more 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."

Guselkumab: "...taken with or without methotrexate, for active psoriatic arthritis when disease-modifying antirheumatic drugs (DMARDs) have not worked well enough, or are not tolerated. It is only for adults who have: had 2 conventional DMARDs and at least 1 biological DMARD, peripheral arthritis with 3 or more tender joints and 3 or more swollen joints and moderate to severe psoriasis."

Source:
NICE – www.nice.org.uk
SMC – www.scottishmedicines.org.uk