National Institute for Health and Clinical Excellence Centre for Health Technology Evaluation

Pro-forma Response

Executable Model

Alitretinoin for the treatment of chronic eczema of the hand, refractory to steroids

A joint response from the SKIN CARE CAMPAIGN* and NATIONAL ECZEMA SOCIETY**:

*The Skin Care Campaign is the umbrella body providing a collective voice for all skin conditions. Together, the SCC and its member organisations work to improve the quality of life for more than 15 million people in the UK with skin conditions.

The Skin Care Campaign:

> Campaigns for the improvement of healthcare for people with skin conditions

> Educates and informs the public, healthcare staff and the government about skin conditions and their treatment

> Works alongside other influential organisations in order to achieve these objectives

**The National Eczema Society:

> is the UK's leading eczema patient support organisation, offering help and information to everyone affected by eczema

> as a charity supports and funds research into eczema

> is committed to making life easier for the 1 in 5 children and 1 in 12 adults who suffer from eczema.

i) Do you consider that all of the relevant evidence has been taken into account?

The Skin Care Campaign (SCC) and National Eczema Society (NES) would like the committee to further consider the following information re:

RELEVENT and TIMELY ACCESS TO TREATMENT and COST EFFECTIVENESS

1.3, 4.1, 4.4 and 4.15

"Only dermatologists with specialist experience in managing severe hand eczema should start and monitor treatment with alitretinoin."

Patients are treated by a multi-disciplinary team, inc: specialist nurses, pharmacists and GPwSIs not just dermatologists.

The SCC and NES suggest the recommendation should be:

"1.3 Only clinicians with specialist experience in managing eczema should start and monitor treatment with alitretinoin."

This will ensure that Patients will get better and faster treatment if all members of the specialist dermatology team – inc. specialist nurses, GPwSIs, PwSIs can prescribe and monitor this treatment.

> PATIENT SAFETY

2.4

"Alitretinoin should not be prescribed if the person's eczema can be adequately controlled by standard measures, including skin protection, avoiding allergens and irritants, and treatment with potent topical corticosteroids."

Topical corticosteroids have several side effects and should be considered alongside Alitretinoin as a second line treatment.

The SCC and NES suggest the recommendation should be:

"Alitretinoin should not be prescribed if the person's eczema can be adequately controlled by standard measures, including skin protection, avoiding allergens and irritants, and treatment with topical emollients."

This will ensure patients get the safest possible treatments.

ii) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence, and that the preliminary views on the resource impact and implications for the NHS are appropriate?

The Skin Care Campaign (SCC) and National Eczema Society (NES) would like the committee to further consider the following information re:

> PATIENT SATISFACTION and HOLISTIC COST EFFECTIVENESS

4.1, 4.2 and 4.12

"The Committee also agreed that the benefits of moving from the health state of severe chronic hand eczema to hands clear or almost clear would be considerable."

Almost clear is not good enough and still results in significant disability.

The SCC and NES suggest the recommendation should be:

"The Committee also agreed that the benefits of moving from the health state of severe chronic hand eczema to hands clear would be considerable."

This would highlight that any form of chronic hand eczema is debilitating and problematic for a person with it. Recent research (Health Talk 2009) has shown that patients with chronic hand eczema clearly benefit from total clearance and nothing less:

- This survey showed that 88% had difficultly in doing everyday things such as cutting up vegetables, gardening, washing up and doing up buttons.
- The same survey showed that 96% found their hand eczema embarrassing.

When asked "what was the worst thing about having hand eczema?" comments included:

- "Not being able to touch the people I love, leaving blood stains on clothes/door handles, constant infection risk"
- "Lost earnings."
- "When it affected my relationship with my baby son because picking him up was so painful"
- "The mad itching, cracking skin, blisters that weep stinging"
- "The redness of my hands they look like an old woman's and I am in my 40's."
- "The constant pain of split and broken weeping and bleeding skin, hurts all the time. It is embarrassing"

iii) Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

The Skin Care Campaign (SCC) and National Eczema Society (NES) would like the committee to further consider the following information re:

> PATIENT SAFETY

1.1 and 4.14

"the disease has not responded to a second-line treatment such as ciclosporin, azathioprine or PUVA (psoralen and long-wave ultraviolet radiation), or the person is intolerant of or has a contraindication to these treatments."

All of these second line treatments have very serious side-effects and have comparatively little evidence to prove their success e.g.: 4.3 "*ciclosporin is associated with an increased risk of lymphoma and skin cancer, and PUVA is known to be carcinogenic.*"

It also seems negligent to prefer unlicensed treatments to licensed ones.

The SCC and NES suggest the recommendation should be:

"Alitretinoin should be included as a second-line treatment as an alternative to ciclosporin, azathioprine and PUVA (psoralen and long-wave ultraviolet radiation)."

This will ensure patients will have a far safer treatment available to them.

This would also be in line with and not contradict recommendation 6.1 for comparative phase III trials.

> PATIENT SAFETY, DISCRIMINATION and COST EFFECTIVENESS

1.2, 4.1 and 4.15

"Alitretinoin treatment should be stopped:

• if the eczema does not show an adequate response (defined as hands clear or almost clear) within 12 weeks **or**

• as soon as an adequate response (hands clear or almost clear) has been achieved."

This does not allow for a long enough period to properly achieve clear hands and will lead to some patients not properly benefiting from this treatment and money being wasted on not allowing enough treatment time to properly assess success.

'almost' is too subjective and would cause discrimination for some patients.

The SCC and NES suggest the recommendation should be:

"1.2 Alitretinoin treatment should be stopped:

• if the eczema does not show an adequate response (defined as hands clear) within 24 weeks or

• as soon as a successful response (hands clear) has been achieved."

This will allow enough time to see any benefits and leave no level of doubt / discrimination about 'almost clear'.

iv) Are there any equality related issues that need special consideration that are not covered in the ACD?

The Skin Care Campaign (SCC) and National Eczema Society (NES) would like the committee to further consider the following information re:

> DISCRIMINATION and INEQUITY

1.1 and 4.13

"the person has severe disease, as defined by the physicians global assessment (PGA) and a dermatology life quality index (DLQI) score of 15 or more"

- this is a relatively high score and creates an inequitable comparison for the DLQI score of >10 that people with psoriasis need to get biologic treatments

The SCC and NES suggests the recommendation should be

"the person has severe disease, as defined by the physicians global assessment (PGA) and a dermatology life quality index (DLQI) score of 10 or more,"

This will provide equity with other skin diseases and an appropriate DLQI score to access this treatment.





Skin Care Campaign

National Eczema Society

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