

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Equality and health inequality impact assessment

**Sirolimus gel for treating facial
angiofibroma from tuberous sclerosis
complex in people 6 years and older
[ID6757]**

Scoping

1 Have any potential equality issues been identified during the scoping process? If so, what are they?

Yes. Stakeholders noted that it is anticipated that this treatment will have a disproportionate impact for people with autism spectrum disorder (ASD). ASD is highly prevalent in people with TSC-associated facial angiofibroma. ASD and TSC are driven by the same genetic defect (mutations in the TSC1 or TSC2 gene). This consideration is particularly relevant when it comes to invasive and sensory comparator procedures (laser or photodynamic therapy) due to increased risk of sensory-sensitivity problems. The psychosocial burden of facial angiofibromas, impact on mental health, impacts on the caregiver and wider family unit, and socioeconomic status were also identified as potential equality issues.

In TA972, which this topic is reviewing, the following equalities issues were raised during the first round of scoping consultation and workshop (November 2022):

1. Previous dermatology appraisals noted that assessment tools for severity & response to treatment (specifically the Psoriasis Area and Severity Index (PASI) and Freckles Area and Severity Index (FASI)) may not be sensitive enough in people with darker skin pigmentation.

2. Previous dermatology appraisals also noted that physical, psychological, sensory or learning disabilities, or communication difficulties could affect responses to DLQI (Dermatology Life Quality Index). Other tuberous sclerosis complex topics also highlighted that a large proportion of people with the condition have neuropsychiatric disorders of varying severity.

3. At the scoping workshop it was highlighted that the DLQI may not be useful in younger children but can be useful in young people.

2 Have any potential health inequality issues been identified during the scoping process? If so, what are they?

3 Yes. Stakeholders identified educational impacts and variation in access due to geography and funding pathways as potential health inequality issues. What is the preliminary view as to what extent the committee needs to address the potential issues set out in questions 1 and 2?

Because autism spectrum disorder (ASD) is prevalent in people with tuberous sclerosis complex, and this comorbidity could impact on the choice of available treatments (due to sensory issues), the committee will take into account any presented potential uncaptured benefits of sirolimus gel for people with autism spectrum disorder.

In relation to severity and response assessment in people with darker skin. Clinical experts at the scoping workshop explained that the angiofibroma tends to be pigmented in darker skin, which makes it more visible. So, it is unlikely that a different assessment of severity or response will occur in people with darker skin pigmentation. Also, the FASI and PASI tools are validated but not systematically used in facial angiofibroma. However, the committee should ensure it considers whether the tools used within the company submission are suitable for all skin pigmentations.

In relation to the appropriateness of DLQI and whether the tools used are capable of measuring disease-specific quality of life in children, these issues should be considered by committee during the appraisal.

Where appropriate, the committee will consider the impact the recommendations may have for people with protected characteristics.

The committee will consider any factors presented that may contribute to health inequalities caused by the condition and the availability of the technology, such as those identified above.

4 Has any change to the draft scope been agreed to highlight the potential equality or health inequality issues set out in questions 1 and 2 following the scope consultation?

No.

5 Has the stakeholder list been updated as a result of additional equality or health inequality issues identified during the scoping process?

No.

Approved by senior responsible officer: Elizabeth Bell

Date: 02/06/2026