

Ingenol TAG summary recommendations July 2013

The enclosed policies represent DRAFT recommendations to CCGs. It is proposed that individual CCGs consider the summaries and policies enclosed within their relevant decision making groups and respond to the CCG with a decision regarding adoption/amendment of the policy – please use the attached form. Further advice on the contents of the draft policies can be sought from the contacts list at the end of the document.

Ingenol mebutate gel (Picato, Leo laboratories Ltd)

Recommendation: Ingenol mebutate is recommended as a first line treatment option for the management of actinic keratosis.

Key points which were discussed include:

- Ingenol mebutate gel is a macrocyclic diterpene ester licensed for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.
- The pooled analyses showed ingenol mebutate gel to be an effective topical, field directed treatment for actinic keratosis.
- The comparator in these studies was placebo. There are no published studies comparing it against other active treatments.
- There is currently an absence of clinical data concerning the repeated use of this gel after recurrence of lesions.
- This gel only has to be applied for 2-3 days dependent on the area of the body affected which should improve compliance and reduce adverse effects compared to the alternatives.
- Actinic keratosis field changes can often affect a much larger area than the 25cm² single treatment area specified for ingenol mebutate gel.
- Prescribing data suggests that the majority of prescribing is with 3% diclofenac gel with hyaluronic acid which is more expensive than ingenol mebutate gel.
- CCGs may wish to review the referral pathway to make sure only severe cases or patients at risk of skin cancer are referred to secondary care.