19th Expert Committee on The Selection and Use of Essential Medicines

April 8-12 2013

Expert peer review on application for the review of section on psoriasis: coal tar

1. Assessment of efficacy
a. Have all relevant studies on efficacy been included
   Yes ✓

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   The use of tar is a well-established modality for treating psoriasis, although newer treatment options have reduced its popularity. The precise mechanism of action of tar is not known, it has an apparent antiproliferative effect. Tar can be helpful as an adjunct to topical corticosteroids, but there are no commercially available corticosteroid/tar combinations.

   In a Cochrane review, vitamin D performed better than coal tar.


   A preparation of 1 percent tar in a fatty-acid based lotion may be superior to conventional 5 percent tar products and appears to have efficacy similar to that of calcipotriene.


   c. Please provide any additional relevant information with reference

   A recent systematic review found that corticosteroids are highly effective and safe in psoriasis when used continuously for up to 8 weeks and intermittently for up to 52 weeks. Coal tar and retinoids were of limited benefit.


2. Assessment of safety
a. Have all relevant studies on safety been included
   Yes ✓
b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

The main side effect of coal tar is skin irritancy although it may also be a photosensitiser.

There has been concern expressed over potential carcinogenicity of the application of tar –based products based on experimental animal studies. Coal tar products containing coal tar above a concentration of 5% are listed by the World Health Organisation as carcinogenic. Reviews of the literature have however been unable to uncover evidence of increased risk of cancer in those treated with medical formulations of coal tar. Studies of patients receiving long term treatment with coal tar have also not found evidence of an increased risk of cancer. A recent in depth analysis of patients receiving tar based anti-psoriasis treatment compared with alternative medications found no evidence of an increased risk of skin cancer associated with tar.

c. Please provide any additional relevant information with reference

NA

3. Assessment of cost and availability

a. Have all relevant data on cost been provided

No ✓

The cost data of specific products have not been submitted.

b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

There has been one cost effectiveness study comparing tar treatments for psoriasis with calcipotriol. The coal tar treatment produced greater improvement in severity (PASI) score (58.2%) at less cost ($0.92 per 1% improvement in PASI, or “PASI-1”) than calcipotriol treatment (36.5% at $35.42 per PASI-1) after 12 weeks of treatment. After treatment and 6 weeks of follow-up (at week 18), the cost of PASI-1 was $1.01 in the coal tar group and $58.11 in the calcipotriol group because the coal tar group maintained PASI improvement (52.5%), while PASI in the calcipotriol group significantly worsened (to 22.2%). Furthermore, the expected costs for achieving PASI-50 and PASI-75 with each therapy choice were also less for coal tar than for calcipotriol.


c. Please provide any additional relevant information with reference

According to a recent pharmacoeconomic analysis, potent corticosteroids, used alone or in combination with vitamin D are most cost-effective for patients with psoriasis of the trunk and limbs. Potent or very potent corticosteroids are most cost-effective for patients with scalp psoriasis.


Coal tar review
d. Is the product available in several low and middle income countries?
   Yes

4. Assessment of public health need
a. Please provide the public health need for this product (1-2 sentences)

Psoriasis is a common chronic skin disorder. The prevalence of psoriasis is relatively high in the general population, ranging between 0.6% and 4.8%, mainly as a result of chronicity and the absence of a cure. Numerous topical and systemic therapies are available for the treatment of psoriasis. Treatment modalities are chosen on the basis of disease severity, relevant comorbidities, patient preference (including cost and convenience), efficacy, and evaluation of individual patient response. With the current treatment options the primary goal of treatment is control of the disease rather than cure.


b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable
   Yes (e.g. UK, Canada, NZ)

5. Are there special requirements for use or training needed for safe/effective use?
   No

6. Is the proposed product registered by a stringent regulatory authority?
   Yes ✓

7. Any other comments
   NA

8. What is your recommendation to the committee (please provide the rationale)

Coal tar products are of established efficacy, although the trial data of today’s standard are even more scarce than for dithranol. The products are relatively cheap, easily available and easy and safe to use. The maximum concentration of coal tar preparations should not exceed 5%.

The Committee is recommended to maintain for now the current listing of coal tar.