

5.15 COAL TAR PREPARED

2% (20 mg/g), foam aerosol; 100 g;

Scytera[®] Foam; Dr Reddy's Laboratories Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission sought PBS listing of coal tar foam (Scytera[®]) as an Unrestricted Benefit for the treatment of psoriasis. Coal tar lotion (Exorex[™]) is currently available on the PBS as an Unrestricted Benefit.

2 Requested listing

- 2.1 The submission sought the following new listing:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Manufacturer	Name and
COAL TAR PREPARED Coal tar prepared 2% (20 mg/g) foam, 100 g	1	2	Scytera [®]	

Unrestricted Benefit

3 Background

- 3.1 Scytera[®] Foam was TGA registered on 10 April 2013 for use in the relief of symptoms of psoriasis.
- 3.2 Scytera[®] Foam had not been considered by PBAC previously.

4 Comparator

- 4.1 The minor submission nominated the PBS-listed topical coal tar preparation for psoriasis Exorex[™] (coal tar prepared 1% (10 mg/g) lotion, 100 mL.)

5 Consideration of evidence

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 5.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

- 5.3 There are no randomised controlled studies comparing Scytera[®] foam with Exorex[™] lotion, or comparing other coal tar foams and lotions. The submission presented case studies to demonstrate the value of Scytera[®] to some patients, including use as monotherapy or in combination with a topical corticosteroid.

Published clinical case studies of Scytera prepared coal tar foam 2%

Trial ID	Case presentation	Treatment	Results
Frankel, Zeichner et al. (2010)	<ul style="list-style-type: none"> • 59 year old Caucasian women. • Long-standing plaque-type psoriasis. • Affecting bilateral elbows, palms, soles. • Otherwise healthy, no signs or symptoms of arthritis. 	<p>Treatment regimen:</p> <ul style="list-style-type: none"> • Scytera coal tar 2% foam administered twice daily to elbows for 2 weeks. • Clobetasol propionate 0.05% emollient foam administered twice daily to elbows for 2 weeks. <p>Maintenance regimen:</p> <ul style="list-style-type: none"> • Scytera coal tar 2% foam administered twice daily to elbows Monday to Friday • Clobetasol propionate 0.05% emollient foam administered twice daily to elbows on Saturday and Sunday. 	<ul style="list-style-type: none"> • Plaques significant improved at week 8 follow-up. • Patient satisfied with treatment: “no complaints”. • No adverse effects observed by the clinician.
Zeichner (2010)	<ul style="list-style-type: none"> • 31 year old Caucasian man • Long-standing plaque-type psoriasis • Affecting bilateral elbows, knees, palms, axillae (6% of his body) and finger nail pitting • Major complaint: palms and axillae psoriasis • Otherwise healthy, no signs or symptoms of arthritis 	<p>Past treatment:</p> <ol style="list-style-type: none"> 1. Topical steroids, Vitamin D analogues <ul style="list-style-type: none"> • Efficacious on elbows and knees • Stopped treatment of palms due to dislike of ointment vehicle. 2. Topical calcineurin inhibitors: <ul style="list-style-type: none"> • i.e. pimecrolimus, tacrolimus • Discontinued due to burning at application site. <p>Treatment with Scytera coal tar 2% foam:</p> <ul style="list-style-type: none"> • Administered twice daily on palms and axillae for 8 weeks. 	<ul style="list-style-type: none"> • At week 8 the plaques were significantly improved (see below) • Axillae were clear with residual hyperpigmentation and palms were almost clear. • Patient had no complaints with treatment. • No reported staining of clothing or skin from the coal tar foam.

Trial ID	Case presentation	Treatment	Results
Zeichner (2010)	<ul style="list-style-type: none"> • 50 year old Indian woman • Lifelong history of plaque-type psoriasis. • Erythematous plaques with silvery white scale on bilateral extensor elbows, knees and trunk. • Plaques on >10% of her scalp. • Most distressed by scalp involvement – visibility and pruritus. • No associated arthritis, otherwise healthy 	<p>Past/current treatment of body lesions:</p> <ul style="list-style-type: none"> • Combination of betamethasone ointment with calcipotriene ointment. • Treatment successful for body lesions and patient wished to continue this. <p>Past treatment of scalp lesions:</p> <ul style="list-style-type: none"> • Using intralesional corticosteroid injection, topical steroids and salicylic acid gels and shampoos for several years. • Scalp disease had not successfully responded to treatment. <p>New treatment of scalp lesions:</p> <ul style="list-style-type: none"> • Scytera coal tar 2% foam twice daily for 2 weeks, then twice daily on weekdays. • Clobetasol foam twice daily for 2 weeks, then twice daily on weekends. 	<ul style="list-style-type: none"> • At week 4 the plaques were significantly improved with decreased erythema, scale and plaque thickness. • At week 6 improvements had continued and there was no evidence of hair staining. • The patient reported improvement in pruritus on the scalp. • Patient had no complaints with the use of coal tar foam or clobetasol foam.

Comparative effectiveness

5.4 Scytera[®] has been designed so that the emollient foam spreads easily and dries quickly into the skin with minimal odour from coal tar. The submission suggested that rapid penetration and disappearance into the skin is a key benefit of foams over other aqueous formulations and would be expected to improve effectiveness, as adherence is more likely with a topical agent that is more easily applied, leaves no residue and is cosmetically acceptable to the patient.

5.5 The submission presented the table below to justify effectiveness of Scytera[®] over other topical coal tar preparations.

Clinical comparison of Scytera[®] 2% foam and other topical coal tar preparations

Cosmetic Area	Scytera (coal tar) Foam 2%	Coal Tar Topicals
Odour	Minimal odour	Strong and unpleasant odour.
Staining	Off-white ('yellowish') colour minimises the potential for staining.	Stains the skin, hair, and clothing. The colour of the stain can vary from mustard to black.
Ease of Application	Spreads easily, penetrates the skin well, and dries quickly.	Difficult to spread and absorb.

Vehicle	Foam and solution based vehicles are preferred by psoriasis patients. Foam for treatment of scalp psoriasis is significantly preferred.	Gels, creams, and ointments are cosmetically unappealing to psoriasis patients.
Versatility to treatment area	Recommended for treatment in challenging areas. Well tolerated by patients.	Not well tolerated by patients in difficult to treat areas.

Source: (Housman, Mellen et al. 2002; Wozel 2008; Frankel, Zeichner et al. 2010; Kircik and Kumar 2010)

Comparative harms

5.6 No comparative harms data were presented in the submission.

Clinical claim

5.7 The submission claimed that Scytera[®] foam will provide patients with the clinical benefits of prepared coal tar (in a demonstrated effective and tolerable strength) in a patient-preferred formulation (foam) which is likely to improve patient adherence to therapy and resultant effectiveness.

Pricing

5.8 Scytera[®] (prepared coal tar 2% w/w) foam may be considered therapeutically equivalent to the comparator Exorex[™] (prepared coal tar 1% w/w) lotion.

5.9 The equi-effective dose for pricing purposes is 1 g of Scytera[®] being equi-effective to 1 mL of Exorex[™]. This is consistent with the listing of 1 mL of calcipotriol scalp lotion being considered equivalent to 1 g of calcipotriol cream. Thus a 100 g can of Scytera provides equivalent treatment to the PBS-listed 100 mL bottle of Exorex[™] lotion.

5.10 The sponsor did not request a higher price for the greater concentration of the active ingredient prepared coal tar in Scytera[®], since both product strengths are within the recommended ranges of therapeutically appropriate topical antipsoriatics.

5.11 A price equivalent to that of the comparator Exorex[™] was requested.

Estimated PBS usage & financial implications

5.12 The submission estimated a net additional cost to the PBS of less than \$10 million per year in year 5 with a cumulative cost of less than \$10 million total in the first 5 years of listing.

5.13 A █████ market growth is assumed following PBS-listing of Scytera[®] based on █████ replacement of Exorex[™] lotion. If replacement of Exorex[™] by Scytera[®] is in fact greater than forecast, a reduced cost to government would occur.

5.14 There were no expected implications from the proposed listing in terms of MBS costs.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of coal tar prepared 2% foam as an unrestricted benefit for the treatment of psoriasis based on the equi-effectiveness of 1 g of Scytera® to 1 mL of Exorex™.
- 6.2 The PBAC recommended that the Safety Net 20 Day Rule should apply for Scytera®.
- 6.3 The PBAC recommended that Scytera® is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners.
- 6.4 The PBAC recommended that coal tar prepared 2% foam should be treated as interchangeable on an individual basis with coal tar prepared 1% lotion according to Section 101 (3BA) advice.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Manufacturer	Name and Manufacturer
COAL TAR PREPARED Coal tar prepared 2% (20 mg/g) foam, 100 g	1	2	Scytera®	Dr Reddy's Laboratories

General Schedule Unrestricted Benefit

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

The sponsor had no comment.