PUBLIC SUMMARY DOCUMENT

Product: Clobetasol Propionate, shampoo, 500 microgram per mL, 125mL
Sponsor: Galderma Australia Pty Ltd
Date of PBAC Consideration: November 2013

1. Purpose of Application

To request a Restricted benefit listing for the treatment of adults with moderate to severe scalp psoriasis who are not adequately controlled with either a vitamin D analogue or potent corticosteroid monotherapy.

2. Background

This drug had not been considered by PBAC previously.

3. Registration Status

Clobetasol propionate was TGA registered on 21 March 2013 and is indicated for topical treatment of moderate to severe scalp psoriasis in adults.

4. Listing Requested and PBAC's View

Restricted benefit
Moderate to severe scalp psoriasis in adults who are not adequately controlled with either a vitamin D analogue or potent topical corticosteroid monotherapy.

Listing was requested on the basis of a cost minimisation claim with combination betamethasone dipropionate plus calcipotriol gel.

The PBAC considered that as clobetasol propionate (CP) is the first very potent (Group IV) topical corticosteroid available in Australia, and there is potential for off-label in use in indications including lichen planus and eczema, an Authority required listing was more appropriate.

The PBAC considered that the listing should allow use in patients whose condition is inadequately controlled by either combination vitamin D analogue/potent topical corticosteroid therapy, or monotherapy with the individual agents.

The PBAC noted that the majority of the trials presented in the submission were in patients aged 18 years or older. The PBAC considered that specifying that patients be 18 years or older (rather than 'adults') in the restriction was appropriate.

In consideration of the requested maximum quantity and repeats, the PBAC noted that a single bottle of CP shampoo contained approximately 13 applications (9.2 mL per application). The PBAC noted the advice of the consultant dermatologist during the sponsor's hearing that a single bottle tends to last one month, as the rapid response achieved

from treatment means that most patients won't need 28 days' supply, and will use CP shampoo 'on and off'. The PBAC therefore considered that the requested maximum quantity of 1 bottle with 1 repeat was appropriate, noting that prescribers would be able to request increased maximum quantities for patients requiring them at the time of Authority application.

5. Clinical Place for the Proposed Therapy

Clobetasol propionate shampoo provides a very potent topical corticosteroid formulation for patients with moderate to severe scalp psoriasis who are not adequately managed on first line topical corticosteroids or vitamin D analogues.

The submission stated that CP shampoo will not change the current treatment algorithm for scalp psoriasis but will provide an additional second-line topical treatment.

The PBAC noted the Economics Sub-Committee (ESC) advice that the October 2012 National Institute of Health and Care Excellence (NICE) guidelines placed very potent corticosteroid therapy ,as fourth-line therapy for scalp psoriasis, after failure of combined betamethasone plus calcipotriol. The PBAC further noted the advice of the clinical expert during the sponsor's hearing that the requested listing for clobetasol, for patients whose condition is not adequately controlled with either a vitamin D analogue or potent corticosteroid monotherapy, reflected the most likely use of CP shampoo in Australian clinical practice.

6. Comparator

The submission nominated combination betamethasone dipropionate gel/calcipotriol (Daivobet® 50/500; DBET).

The PBAC accepted this as the appropriate comparator.

7. Clinical Trials

No head-to-head trials of CP shampoo and betamethasone plus calcipotriol (Daivobet®, DBET) gel were presented in the submission.

The submission presented a primary indirect comparison based on:

- Two randomised trials (Trial 2638, Trial 2591) comparing CP shampoo to calcipotriol (Daivonex®) monotherapy (DNEX) in a total of 181 patients with scalp psoriasis;
- Three randomised trials comparing Daivobet (DBET) to DNEX (Kragballe et al 2009; Jemec et al 2008; van de Kerkhof et al 2009) in a total of 1,979 patients with scalp psoriasis.

One unpublished, randomised investigator blinded study (NCT01195831), excluded by the submission, comparing DBET to DNEX in 244 patients was included during the evaluation.

The submission also presented a supplementary indirect comparison based on:

- Three randomised trials comparing CP shampoo to vehicle (Trial 2665, Trial

18075, Trial 18076) in a total of 373 patients with scalp psoriasis;

- Two randomised studies comparing DBET to vehicle (Jemec et al 2008; Tyring et al 2010) in a total of 854 patients with scalp psoriasis.

Details are presented in the table below.

Trials and associated reports presented in the submission

Trial ID/ First author	Protocol title/ Publication title	Publication citation
Common reference DNEX		
CP Shampoo		
Trial 2638	Reygagne P, Mroweitz U et al. 2005. Clobetasol propionate shampoo 0.05% and calcipotriol solution 0.005%: A randomized comparison of efficacy and safety in subjects with scalp psoriasis. Clinical study report 2638. 2001. Parallel group comparison of 4-week treatment with clobetasol 17-propionate 0.05% shampoo versus calcitriol solution 0.005% (Dovonex/Daivonex™) An efficacy and safety study in subjects with scalp psoriasis.	Journal of Dermatological Treatment 2005; 16: 31-36.
Trial 2591	Clinical study report 2591. 2000. Parallel group comparison of a 3-week treatment with clobetasol propionate 0.05% shampoo following different application patterns – a pilot study in patients with scalp psoriasis.	
DBET gel		
Kragballe 2009	Kragballe K et al. 2009. Efficacy and safety of calcipotriol plus betamethasone dipropionate scalp formulation compared with calcipotriol scalp solution in the treatment of scalp psoriasis: a randomized controlled trial. Ortonne J et al. 2009. Quality of life in patients with scalp psoriasis treated with calcipotriol/betamethasone dipropionate scalp formulation: a randomized controlled trial.	British Journal of Dermatology 2009; 161: 159. Journal of the European Academy of Dermatology and Venereology 2009; 23: 919.
Jemec 2008	Jemec G et al. 2008. A new scalp formulation of calcipotriol plus betamethasone compared with its active ingredients and the vehicle in the treatment of scalp psoriasis: A randomized, double-blind, controlled trial.	Journal of the American Academy of Dermatology 2008; 59(3): 455.
Van de Kerkhof 2009	Van de Kerkhof P et al. 2009. A new scalp formulation of calcipotriol plus betamethasone dipropionate compared with each of its active ingredients in the same vehicle for the treatment of scalp psoriasis: a randomized, doublé-blind, controlled trial.	British Journal of Dermatology 2009; 160: 170.
NCT01195831	Publication or clinical study report not available	Clinicaltrials.gov
Common reference vehicle		
CP Shampoo		

Trial ID/ First author	Protocol title/ Publication title	Publication citation
Trial 2665	Clinical study report 2665. 2002. Efficacy and safety of clobetasol propionate 0.05% shampoo as compared to its vehicle and clobetasol propionate 0.05% gel (Dermoval™ gel) in the treatment of subjects with scalp psoriasis.	
Trial 18075	Clinical study report 18075. 2002. A randomized, double-blind, parallel group evaluation of clobetasol propionate shampoo, 0.05% versus its vehicle – an efficacy and safety study in subjects with scalp psoriasis.	
Trial 18076	Clinical study report 18076. 2002. A randomized, double-blind, parallel group evaluation of clobetasol propionate shampoo, 0.05% versus its vehicle – an efficacy and safety study in subjects with scalp psoriasis. Jarrat M et al. 2004. Clobetasol shampoo 0.05%: a new option to treat patients with moderate to severe scalp psoriasis.	Journal of Drugs in Dermatology 2004; 3(4): 367.
DBET gel		
Tyring 2010	Tyring S et al. 2010. A calcipotriol/ betamethasone dipropionate two-compound scalp formulation in the treatment of scalp psoriasis in Hispanic/Latino and Black/African American patients: results of a randomized, 8-week, double-blind phase of a clinical trial.	International Journal of Dermatology 2010; 49: 1328.

The sponsor requested a hearing for this item. The PBAC noted the perspective of the consultant dermatologist's presentation in relation to the clinical positioning of CP shampoo, impact of the disease on Quality of Life (QoL), and benefits of treatment given the short contact time in relation to improved compliance and increased efficacy, and other matters in response to the Committee's questions.

8. Results of Trials

With regards to comparative effectiveness, the results for the outcome of proportion of patients with "response" according to the investigator global assessment (IGA) are summarised in the tables below.

Results of proportion of patients with "response" according to the IGA at Week 4 across the randomised trials using DNEX as the common reference

	CP shampoo trials					***DBET gel trials***				
Trial ID	***Treatment effect OR (95% CI)***	***Treatment effect RR (95% CI)***	***Treatment effect RD (95% CI)***	***CP n/N (%)***	***DNEX n/N (%)***	***DNEX n/N (%)***	***DBET n/N (%)***	***Treatment effect OR (95% CI)***	***Treatment effect RR (95% CI)***	***Treatment effect RD (95% CI)***
Trial 2638	***2.57 (1.31, 5.05)***	***1.79 (1.17, 2.74)***	***0.22 (0.07, 0.37)***	*38/76 (50.0%)*	*21/75 (28.4%)*	-	-	-	-	-
Trial 2591	*7.00 (0.71, 69.49)*	*5.00 (0.66, 37.85)*	*0.27 (0, 0.54)*	*5[b]/15 (33.3%)*	*1[b]/15 (6.7%)*	-	-	-	-	-
Kragballe	-	-	-	-	-	*19/105*	*114/207*	***5.55***	***3.04***	***0.37***

2009						*(18.1%)*	*(55.1%)*	***(3.15, 9.78)***	***(1.99, 4.66)***	***(0.27, 0.47)***
Jemec 2008	-	-	-	-	-	*64/272 (23.5%)*	*362/541 (66.9%)*	***6.57 (4.71, 9.17)***	***2.84 (2.28, 3.55)***	***0.43 (0.37, 0.50)***
Van de Kerkhof 2009	-	-	-	-	-	*74/286 (25.9%)*	*311/567 (54.9%)*	***3.47 (2.54, 4.74)***	***2.12 (1.72, 2.61)***	***0.29 (0.22, 0.35)***
NCT0119 5831	-	-	-	-	-	*63/124 (50.8%)*	*105/120 (87.5%)*	***6.78 (3.55, 12.92)***	***1.72 (1.43, 2.07)***	***0.37 (0.26, 0.47)***
Pooled[a]	***2.79 (1.46, 5.32)***	***1.87 (1.23, 2.83)***	***0.23 (0.10, 0.36)***	*43/91 (47.3%)*	*22/90 (24.4%)*	*157/663*[c] *(23.7%)*	*787/1315*[c] *(59.8%)*	***4.95 (3.18, 7.72)***[c]	***2.56 (2.03, 3.22)***[c]	***0.36 (0.27, 0.46)***[c]
						220/787[d] *(28.0%)*	*892/1435*[d] *(62.2%)*	***5.24 (3.61, 7.59)***[d]	***2.31 (1.75, 3.04)***[d]	***0.36 (0.29, 0.44)***[d]
Indirect estimate of effect (*Excluding Trial NCT011958 submission*								*0.56 (0.26, 1.23)*	*0.73 (0.45, 1.18)*	*-0.13 (-0.29, 0.03)*
Indirect estimate of effect (*Including Trial NCT0119583*								*0.53 (0.25, 1.12)*	*0.81 (0.49, 1.33)*	*-0.13 (-0.28, 0.02)*

Abbreviations: CI = confidence interval; CP = clobetasol proprionate; DBET = Daivobet® (calcipotriol/betamethasone); DNEX = Daivonex® (calcipotriol); IGA = investigators' global assessment; ITT = intention to treat; LOCF = last observation carried forward; n = number with event; N = number in group; OR = odds ratio; RD = risk difference; RR = relative risk.

Bold typography indicates statistically significant differences

[a] *pooled using the random effects model*

[b] *outcome measured at week 3*

[c] *Excluding Trial NCT01195831 as in the submission*

[d] *Including Trial NCT01195831*

Results of proportion of patients with "response" according to the IGA at Week 4 across the randomised trials using 'vehicle' as the common reference

	CP shampoo trials					***DBET gel trials***				
Trial ID	***Treatment effect OR (95% CI)***	***Treatment effect RR (95% CI)***	***Treatment effect RD (95% CI)***	***CP n/N (%)***	***Vehicle n/N (%)***	***Vehicle n/N (%)***	***DBET n/N (%)***	***Treatment effect OR (95% CI)***	***Treatment effect RR (95% CI)***	***Treatment effect RD (95% CI)***
Trial 18075	***3.94 (1.29, 12.05)***	***3.15 (1.17, 8.50)***	***0.18 (0.06, 0.30)***	*26/97*[c] *(26.8%)*	*4/47*[c] *(8.5%)*			-	-	-
Trial 18076 (Jarratt 2004)	***23.61 (3.11, 179.25)***	***15.83 (2.23, 112.23)***	***0.32 (0.22, 0.43)***	*32/93*[c] *(34.4%)*	*1/46*[c] *(2.2%)*			-	-	-
Jemec 2008	–	–	–			*20/136 (14.7%)*	*362/541 (66.9%)*	***11.73 (7.06, 19.48)***	***4.55 (3.02, 6.85)***	***0.52 (0.45, 0.59)***
Tyring 2010	–	–	–			*17/42*[b] *(40.5%)*	*97/135*[b] *(71.9%)*	***3.75 (1.82, 7.72)***	***1.78 (1.21, 2.60)***	***0.31 (0.15, 0.48)***
Pooled[a]	***7.97 (1.33, 47.81)***	***5.79 (1.11, 30.13)***	***0.26 (0.12, 0.39)***	*58/190 (30.5%)*	*5/93 (5.4%)*	*37/178 (20.8%)*	*459/676 (67.9%)*	***6.84 (2.23, 20.96)***	***2.83 (1.05, 7.64)***	***0.43 (0.23, 0.64)***
Indirect estimate of effect (95% CI) *Including all trials*								*1.17 (0.14, 9.64)*	*2.05 (0.30, 14.04)*	*-0.17 (-0.42, 0.08)*
Indirect estimate of effect (95% CI): *Sensitivity analysis excluding*								*0.68 (0.11, 4.37)*	*1.27 (0.23, 6.97)*	***-0.26 (-0.41, -0.11)***

Tyring 2010					

Abbreviations: CI = confidence interval; CP = clobetasol proprionate; DBET = Daivobet® (calcipotriol/betamethasone); DNEX = Daivonex® (calcipotriol); IGA = investigators' global assessment; ITT = intention to treat; LOCF = last observation carried forward; n = number with event; N = number in group; OR = odds ratio; RD = risk difference; RR = relative risk.

Bold typography indicates statistically significant differences.

[a] *pooled using the random effects model. The submission stated that the results are pooled using the random effects model but the submission's results are actually pooled using the fixed effects model*

[b] *outcome measured at Week 8 time point*

[c] *global assessment of improvement as per investigator of clear or almost clear, a secondary outcome. It is not explained why the submission did not use the primary outcome of success rate defined as the % with a global severity score of clear or minimal. The DBET studies used the investigator's global assessment of disease severity.*

No significant differences between CP shampoo and DBET gel were observed in the indirect analysis irrespective of whether the vehicle or DNEX was used as the common comparator. However, the PBAC noted that the submission did not nominate non-inferiority margins or minimally important clinical differences.

With regards to comparative harms, the PBAC noted that the main adverse events that differed by greater than or equal to 5% in Trial 2638 were dermatitis/eczema, followed by erythema which occurred significantly more frequently in the DNEX arm compared to the CP shampoo arm. A burning sensation was significantly more common in the DNEX group compared to CP shampoo (p=0.04 for burning on the scalp, p=0.005 for burning on the face, p=0.01 for burning on the neck).

The proportion of patients with lesional/perilesional adverse events was significantly lower in the DBET group than in the DNEX group. Pruritus appeared to be a significant adverse event that was reported in all DBET trials, which occurred significantly more frequently in the DNEX arm compared to DBET. Application-site burning occurred significantly more frequently in the DNEX arm (4.8%) compared to DBET (0.5%) in Kragbelle et al (2009).

A summary of the key adverse events in the randomised trials in the primary indirect comparison is presented in the table below.

Summary of key adverse events in the randomised trials – primary indirect comparison

CP shampoo trials	**CP n/N (%)**	**DNEX n/N (%)**	**RR (95% CI)**	**RD (95% CI)**
Trial 2638				
Any AE	8/76 (10.5%)	23/75 (30.7%)	0.34 (0.16, 0.72)	-0.20 (-0.33, -0.08)
Serious AE	0	0	n/a	n/a
Treatment-related AE	1/76 (1.3%)	17/75 (22.7%)	0.06 (0.01, 0.43)	-0.21 (-0.31, -0.12)
AE leading to withdrawal	0	7/75 (9.3%)	0.07 (0, 1.13)	-0.09 (-0.16, -0.02)
Trial 2591				
Any AE	1/15 (6.7%)	4/15 (26.7%)	0.25 (0.03, 1.98)	-0.20 (-0.46, 0.06)
Serious AE	1[a]/15 (6.7%)	0	3.00 (0.13, 68.26)	0.07 (-0.10, 0.23)
Treatment-related AE	0	3/15 (20%)	0.14 (0.01, 2.55)	-0.20 (-0.42, 0.02)
AE leading to withdrawal	0	2/15 (13.3%)	0.20 (0.01, 3.85)	-0.13 (-0.33, 0.06)
DBET gel trials	**DBET n/N (%)**	**DNEX n/N (%)**	**RR (95% CI)**	**RD (95% CI)**
Kragbalie 2009				
Any AE	71/206 (35%)	59/104 (57%)	0.61 (0.47, 0.78)	-0.22 (-0.34, -0.11)
Serious AE	NR	NR	n/a	n/a
Treatment-related AE	7/206 (3.4%)	28/104 (27%)	0.13 (0.06, 0.28)	-0.24 (-0.32, -0.15)
AE leading to withdrawal	2/207 (1.0%)	9/105 (8.6%)	0.11 (0.02, 0.51)	-0.08 (-0.13, -0.02)
Jemec 2008				
Any AE	183/530 (35)	123/266 (46)	0.75 (0.63, 0.89)	-0.12 (-0.19, -0.04)
Serious AE	NR	NR	n/a	n/a

Treatment-related AE	NR	NR	n/a	n/a
AE leading to withdrawal	8/530 (1.5%)	20/266 (7.5%)	0.20 (0.09, 0.45)	-0.06 (-0.09, -0.03)
Van de Kerkhof 2009				
Any AE	218/563 (39)	130/282 (46%)	0.84 (0.71, 0.99)	-0.07 (-0.14, 0)
Serious AE	NR	NR	n/a	n/a
Treatment-related AE	NR	8/282 (2.8%)	n/a	n/a
AE leading to withdrawal	4/563 (0.7%)		0.25 (0.08, 0.82)	-0.02 (-0.04, -0)
NCT01195831				
Any AE	*17/118 (14%)*	*36/124 (29%)*	*0.50 (0.30, 0.83)*	*-0.15 (-0.25, -0.04)*
Serious AE	*2[b]/118 (1.7%)*	*0*	*5.25 (0.25, 108.27)*	*0.02 (-0.01, 0.04)*
Treatment-related AE	*NR*	*NR*	*n/a*	*n/a*
AE leading to withdrawal	*NR*	*NR*	*n/a*	*n/a*

Abbreviations: AE = adverse event; CP = clobetasol proprionate; DBET = Daivobet® (calcipotriol/betamethasone); DNEX = Daivonex® (calcipotriol); *n* = number with event; *N* = number in group; n/a = not applicable; NR = not reported; RD = risk difference; RR = relative risk.
Bold typography indicates statistically significant differences.
[a] considered as definitely unrelated to the study medication.
[b] one limb crushing injury and one ovarian neoplasm.

The PBAC noted that no safety concerns were identified related to 'eye disorders' and 'adrenal disorders for the period 1/9/2012 to 28/2/2013 in the Periodic Safety Update Report.

9. Clinical Claim

The submission claimed that CP shampoo is non-inferior in terms of comparative effectiveness and safety to DBET gel.

Despite the differences between the trials that limited their exchangeability, the PBAC considered that the submission's clinical claim was adequately supported by the indirect comparisons presented in the submission

10. Economic Analysis

The submission undertook a cost-minimisation analysis based on the non-inferiority claim for the outcome of proportion of patients with "response" according to IGA using the indirect comparison via DNEX. The cost minimisation approach did not include additional costs or offsets for administration or for adverse events. The PBAC considered that a cost-minimisation approach was reasonable based on the claim of non-inferiority.

The dosage information from the randomised trials included in the indirect comparison was used to determine the equi-effective doses. The weighted average daily doses for CP shampoo and DBET gel were estimated as 9.2 g and 2.7 g respectively. These were considered appropriate by the PBAC.

Notwithstanding the sponsor's comments in its Pre-PBAC Response in relation to equi-effective dose calculations for the cost-minimisation analysis, in which the calculation of the proposed DPMQ was described as conservative, the PBAC noted that the submission inappropriately conducted the cost-minimisation analysis based on dispensed price for maximum quantity (DPMQ) rather than price to pharmacist (PtP).

11. Estimated PBS Usage and Financial Implications

The submission used a market share approach based on the current prescriptions supplied for

DBET gel since September 2011 and an assumption of more regular use than DBET gel. The estimated number of prescriptions dispensed was greater than 200,000 over the first 5 years of listing, at a net cost to the PBS over the first five years of listing of less than $10 million.

The submission assumed a continuing market growth rate of 12.9%. This may underestimate the growth. The introduction of a new and potentially more acceptable product may increase the market but the extent of this is difficult to determine from existing information on PBS listed psoriasis products. The PBAC agreed with the ESC, and the advice of the consultant dermatologist during the sponsor's hearing that CP shampoo will have high patient acceptability and is likely to have large take-up. The quantity applied may vary between patients and should larger quantities be used, the cost to the Commonwealth will increase and the potential harm for patients of larger amounts of high potency steroids being applied is not clear. However, the PBAC also noted the advice of the consultant dermatologist that many patients would be likely to achieve clinical benefit with a shorter course of treatment (less than 4 weeks).

The PBAC agreed with the ESC that the shampoo could replace some use of the less potent products earlier in the treatment regimen.

12. Recommendation and Reasons

The PBAC recommended listing for clobetasol propionate shampoo as an Authority required benefit for treatment of moderate to severe scalp psoriasis in patients aged 18 years or older, whose condition is not adequately controlled by a vitamin D analogue or potent topical corticosteroid as monotherapy or in combination, on a cost-minimisation basis with DBET. The weighted average daily doses for CP shampoo and DBET gel were estimated as 9.2 g and 2.7 g respectively.

The PBAC considered that DBET was the appropriate comparator.

The PBAC noted the ESC advice that the October 2012 NICE guidelines placed very potent corticosteroid therapy as fourth-line therapy for scalp psoriasis, after failure of combined betamethasone plus calcipotriol. The PBAC further noted the advice of the clinical expert during the sponsor's hearing that the requested listing for clobetasol, for patient's whose condition is not adequately controlled with either a vitamin D analogue or potent corticosteroid monotherapy, reflected the most likely use of CP shampoo in Australian clinical practice.

The PBAC noted that no significant differences between CP shampoo and DBET gel were observed in the indirect analysis irrespective of whether the vehicle or DNEX was used as the common comparator. Additionally, the PBAC considered that the evidence presented in the submission supported non-inferiority of CP shampoo compared to DBET. Therefore, the PBAC accepted that the submission's claim that CP shampoo is non-inferior in terms of comparative effectiveness and comparative safety compared to DBET was adequately supported by the indirect comparison presented.

The PBAC considered that the introduction of a new and potentially more acceptable product may increase the market but the extent of this is difficult to determine from existing information on PBS listed psoriasis products. The PBAC agreed with the ESC, and the advice

of the consultant dermatologist during the sponsor's hearing that CP shampoo will have high patient acceptability and is likely to have large take-up. The PBAC also noted that there was potential for use beyond the proposed restriction in other indications including lichen planus and eczema. The PBAC considered that the submission's estimates of usage and financial implications may be underestimated, but it was not possible to determine the extent to which this might be the case. The PBAC recommended usage be reviewed by the Drug Utilisation Sub-Committee (DUSC) after 12-24 months of listing.

The PBAC noted and welcomed the input from the Australasian College of Dermatologists via the Consumer Comments facility on the PBS website in support of the submission for clobetasol propionate shampoo. The input supported the use of CP shampoo as a second line treatment in line with the proposed PBS restriction. It was also stated that experience with CP shampoo has shown high patient acceptance and compliance with the formulation.

The PBAC recommended that clobetasol propionate shampoo was not suitable for prescribing by nurse practitioners.

The Safety Net 20 Day Rule should not apply.

The PBAC advised the Minister that under Section 101 3BA of the *National Health Act*, clobetasol propionate should not be treated as interchangeable on an individual patient basis with any other drug(s) or medicinal preparation(s).

Outcome:
Recommended

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
CLOBETASOL PROPIONATE			Clobex	GA
Clobetasol propionate 0.05 % shampoo, 125 mL	1	1		

Severity:	Moderate to severe
Condition:	scalp psoriasis
Restriction:	Authority Required
Clinical criteria:	The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.
Population criteria:	Patient must be aged 18 years or older.

13. 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.

14. Sponsor's Comment

The sponsor had no comment.