

Pharmaceutical Benefits Scheme

Post-market Review

The use of biologics in the treatment of severe chronic plaque
psoriasis

Report to PBAC

Background

FINAL REPORT

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Abbreviations

Abbreviation	Full Name / Wording
CPP	chronic plaque psoriasis
DLQI	Dermatology Life Quality Index
DUSC	Drug Utilisation Sub-Committee
PASI	Psoriasis Area and Severity Index
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PMR	Post-Market Review
RACGP	Royal Australian College of General Practitioners
RG	Reference Group
ToR	term of reference

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Membership listed in Appendix A – Reference Group Members

Report Structure

This Report is presented in several parts, as briefly outlined below. The Report has been structured in this way to address the Terms of Reference (ToR) of the Review.

Background

Provides the context for the Review, a brief description of chronic plaque psoriasis (CPP); the listing history for Pharmaceutical Benefits Scheme (PBS) listed biologics for psoriasis; and the research questions supporting the Review's ToRs.

Section 1 – ToR 1: Reviews current clinical guidelines for the treatment of severe CPP and compares them to the PBS restrictions for use of biologics in this indication from previous sponsor submissions.

Section 2 – ToR 2: Reviews and evaluates recent clinical evidence on the efficacy and safety of biologics used in the treatment of severe CPP and compares to the evidence considered by the Pharmaceutical Benefits Advisory Committee (PBAC) in previous sponsor submissions.

Section 3 – ToR 3: Reviews the utilisation of PBS-listed biologics for the treatment of CPP and compares the patient response in practice to those observed in the clinical trial evidence considered by the PBAC.

Section 4 – ToR 4: Summarises the evidence considered in ToR 1-3 and presents options for the PBAC to consider when determining if a cost-effectiveness review is required.

Background

B.1 Post-market monitoring

The Post-Market Review (PMR) program is a systematic approach to monitoring medicines subsidised by the PBS. PMRs were initiated under the 2011-12 Budget measure 'Improving sustainability of the PBS through enhanced post-market surveillance'.

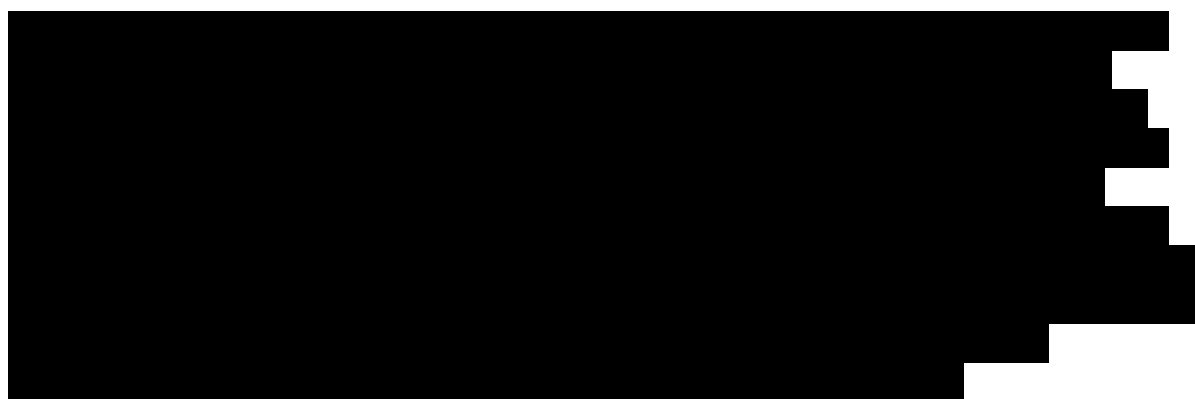
PMRs are established under the quality use of medicines objective of the National Medicines Policy framework; promoting the safe and effective use of medicines, with the aim to improve health outcomes for all Australians.

The PMR program contributes to the following:

- Improved patient safety through better understanding of adverse events and medicine-related harms, including hospitalisations;
- A more sustainable PBS through better targeting of medicines, and avoidance of preventable wastage, or inappropriate prescribing;
- A better knowledge base to understand medicines utilisation, to validate the intended clinical benefit which will inform medicines evaluation processes; and
- A strengthened approach to medicine pricing management, including through better management of clinical and economic uncertainty.

Post-market reviews can be initiated when concerns related to the quality use of a medicine, cost-effectiveness, clinical effectiveness, higher than predicted utilisation and/or international differences are raised. A full post-market review will only proceed following PBAC agreement and Ministerial approval.

B.2 Context of the Review



In March 2013, the PBAC considered a submission seeking an extension of the adalimumab restriction to include moderate CPP. While the submission sought listing for patients with PASI or DLQI >10 in patients who have failed to respond to at least two non-biologic therapies, the Pre-Sub-Committee Response amended the restriction so that the only difference from the previous restriction was the change from PASI of > 15 to >10.

- The PBAC rejected the submission on the basis of highly uncertain cost-effectiveness.
- The PBAC was concerned about the use of monoclonal antibodies in larger patient populations to treat milder forms of disease.
- The PBAC considered that there was a risk that adalimumab would be used in a proportion of patients with mild disease (i.e. PASI < 10).

In June 2014, the DUSC utilisation review of PBS-listed biologics for CPP found that:

- the number of prescriptions dispensed had increased progressively between 2006 and 2013
- approximately 500 new patients started treatment each year since 2006
- close to 3,500 patients received an Authority approval for a biological for psoriasis in 2013
- treatment continuation was high, with 86% of patients receiving a fourth Authority approval for a biological
- ustekinumab was the most commonly used biologic, followed by adalimumab.

In March 2015, the PBAC in considering the submission for secukinumab for severe CPP noted that etanercept was the main comparator for the PBS-listed biologics for psoriasis, including ustekinumab. There is emerging evidence of variations in response to TNF-alfa inhibitors in psoriasis, with etanercept appearing to be less effective than other agents. The PBAC recommended to the Minister that a post-market review of the biologics for chronic plaque psoriasis be undertaken.

B.3 Review Process

B.3.1 Purpose of the Review

The Review has the overall aim of continuing safe and cost-effective access to biologic medicines used in the treatment of severe CPP.

B.3.2 Review Reference Group

A Reference Group is formed to assist in the review of the evidence and information for each of the Review's terms of reference, and to ensure that the perspectives of stakeholders are considered in its preparation of the final report to the PBAC. The Reference Group may provide the PBAC with options to address key findings. Members of the Reference Group are appointed as either individuals or organisational representatives. Representation includes clinical experts, health economists and representatives of relevant health professional and consumer organisations. The Reference group for the Review was appointed on 3 February 2017. A full list of Reference Group members is provided in the final report published on the PBS website at Appendix A – Reference Group Members.

B.3.3 Review Terms of Reference

The Review's draft Terms of Reference (ToR) were open to public consultation from 2 May 2016 to 18 May 2016. Three submissions were received through this consultation process:

two from pharmaceutical companies and one from a health professional peak body. Except where requested otherwise, public comments were published on the Review's website.

The PBAC considered the draft ToR and comments from stakeholders in August 2016. In November 2016, the Minister for Health approved the final ToR. Research questions relating to the ToR were developed to guide the technical review, and were discussed and further refined by the RG at their first meeting on 18 May 2017. The final ToR and research questions, approved by the RG Chair, are listed below.

Term of reference 1

ToR 1: Review current clinical guidelines for the treatment of severe CPP and compare to the PBS restrictions for use of biologics in this indication.

Q1. Examine whether the PBS restrictions are consistent with the clinical guidelines recommended in Australia for the treatment of severe CPP. Include consideration of the following:

- a) Do the PBS restrictions reflect the clinical treatment algorithms recommended in Australian or other relevant international clinical guidelines?
- b) Are the discontinuation criteria in the PBS restrictions consistent with those recommended in Australian or other relevant international clinical guidelines?
- c) Are the recommendations for switching between biologic agents described in Australian or other relevant clinical guidelines? If so, are these recommendations consistent with PBS restrictions?
- d) Examine the criteria in the PBS restrictions for treating patients with biologics who have: pre-existing disease (e.g. viral infection); recent vaccination; or who are pregnant. Are these criteria consistent with Australian and other relevant international clinical guidelines?

Q2. Review the most commonly recommended clinical assessment measures used to evaluate the severity of CPP or stages for disease progression.

Term of reference 2

ToR 2: Review and evaluate recent clinical evidence on the efficacy and safety of biologics used in the treatment of severe CPP and compare to the evidence considered by the PBAC in previous sponsor submissions.

Q1. Undertake a systematic literature review to identify any new randomised trials or large observational studies (cross-sectional, cohort, case-control or longitudinal) that compare the efficacy and safety of the PBS listed biologics for severe CPP.

This systematic review will focus on:

- a) comparing efficacy and safety of all PBS listed biologics for CPP and meta-analysis of results where appropriate
- b) comparing new evidence with that already considered by PBAC for each class of medicine
- c) comparing evidence on the efficacy and safety of biologics for CPP in mild-moderate disease versus severe disease
- d) considering any evidence on the effectiveness of biologics for CPP on other comorbidities such as psoriatic arthritis

- e) considering evidence on comparative effectiveness of classes of biologic agents in populations with hand/face/feet psoriasis
- f) identifying and describing any recent findings concerning safety associated with longer term use of biologics
- g) including a quality assessment and description of the limitations of included trials or observational studies
- h) including studies measuring outcomes previously accepted by PBAC, and any other relevant clinical outcomes reported in more recent studies.

Term of reference 3

ToR 3: Review the utilisation of PBS biologics for the treatment of CPP and compare the patient response in practice to those observed in the clinical trial evidence considered by the PBAC. Compare the efficacy in practice among the listed biologics in terms of time on treatment and discontinuation of treatment.

- Q1. Summarise the most recent estimates of incidence and prevalence of severe CPP in Australia or other similar populations.
- Q2. Provide any estimates published on the prevalence of patients with psoriatic arthritis within the patient population with CPP.
- Q3. Describe the overall utilisation in terms of prescriptions dispensed and government benefits paid for PBS listed biologics to treat severe CPP using unit record level PBS data.
- Q4. Determine length of treatment or persistence on PBS-listed biologic agents for the treatment of severe CPP. Provide an estimate of the length of treatment by drug and overall continuous length of treatment on any biologic. Present results of patients' individual length of treatment using Kaplan Meier survival techniques.
- Q5. Report on breaks in biologic medicine coverage that could be considered treatment holidays or discontinuation due to sustained remission of the disease.
- Q6. Examine the rate individual patients switch between biologics for the treatment of CPP.
- Q7. Examine the prior use of non-biologic medicines before switching to biologics.
- Q8. Consider to what extent current utilisation of PBS-listed biologics is consistent with clinical guidelines and PBS restrictions.

Term of reference 4

ToR 4 (this technical report): Subject to the findings from ToR 1, 2 and 3, review the cost-effectiveness of biologics for severe CPP.

- Q1. Summarise previous cost-effectiveness analyses for CCP seen by the PBAC.
- Q2. Summarise issues highlighted in ToR 1 to ToR 3 of the report that would need to be addressed using cost-effectiveness analysis.
- Q3. Develop options for cost-effectiveness to be re-established in:
 - a) the population currently accessing PBS biologics for CPP and
 - b) the broader population identified by the reference group.

ToR 4 (possible cost-effectiveness review): Subject to the findings from ToR 1, 2, 3, and 4 of this technical report, review the cost-effectiveness of biologics for severe CPP.

B.3.4 Public submissions

Public submissions to the Review were open from 4 January 2017 to 15 February 2017. This process provided stakeholders with an opportunity to identify relevant issues, evidence or data that may inform the Review. Submissions were received from one individual, one peak body and four pharmaceutical companies. Except where requested otherwise, public submissions were published on the Review's website.

The content of the public submissions was considered in the development of the report and incorporated into the review where appropriate. Overall, the clinical evidence provided in the public submissions was similar to those identified in the reviews of the literature included in the terms of reference.

B.3.5 Stakeholder Forum

A Stakeholder Forum for the Review was held by the Department of Health in Melbourne, on 20 October 2017. Prior to the meeting, attendees were provided with a background discussion paper that included information on the Review's ToR, and identified key issues and questions for the Forum. A brief summary of the clinical evidence and psoriasis medicines utilisation was presented at this Forum. Focus questions were posed at the Forum to prompt discussion and there was also an opportunity for open discussion not related to the focus questions. The discussion from the Stakeholder Forum is summarised in the ToR key findings. A full version of the Stakeholder Forum Summary is available on the Review's website.

B.4 Biologics in the treatment of severe chronic plaque psoriasis

B.4.1 Description of the condition

Chronic Plaque Psoriasis

Psoriasis is a life-long skin condition, commonly characterised by red, scaly areas and patches. The cause is unknown; however evidence suggests that it is a disorder of the immune system.

(1) It is more common in people who have a relative with psoriasis and affects approximately 2% of people worldwide. (1, 2)

Plaque psoriasis occurs in 90% of psoriasis sufferers and has characteristic thick, sharply edged (marginated), red scaly lesions, most commonly on the elbows, knees, lower back and scalp.(1) Psoriasis can also affect the nails and joints and can impact on the emotional and social wellbeing of the affected person.(1) Chronic plaque psoriasis is persistent psoriasis that can be improved with treatment, but is difficult to clear completely.(2) It is characterised by large plaques that may join together to form large areas, and can be localised (e.g. elbows and knees) or generalised (e.g. scalp, trunk and limbs).(2)

B.4.2 Description of the intervention

Biologics (biologic therapies, biologic response modifiers, biopharmaceuticals) are drugs derived from living material (either extracted or semi-synthesised), which interfere with the immune system to treat and prevent immune-mediated inflammatory disorders. (2)

This systematic literature review will focus on all biologics used in the treatment of severe chronic plaque psoriasis that are listed on the PBS. The biologics listed on the PBS are presented in Table B.1 along with their item numbers, and route and frequency of administration.

Table B.1: Biological medicines listed on the PBS for chronic plaque psoriasis

Active ingredient	Brand name & strength	Company/ PBS Item number	Administration
Efalizumab	Raptiva®, 125mg	Serono	powder for injection
Etanercept	Enbrel® 25mg/ml, and 50mg/ml	Pfizer (1954W; 1963H; 1964J; 9037P; 9091L; 9429G; 9431J; 9461Y; 9462B; 11223Q; 11224R; 11225T)	Subcutaneous injection weekly
	Brenzys® 50mg/ml	Merck, Sharp and Dohme (11221N; 11222P; 9461Y; 9462B; 9091L; 9431J)	
Infliximab	Remicade®, 100 mg/vial	Janssen-Cilag (5758C; 9617E)	Intravenous infusion over a 2- hour period followed by additional doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.
	Inflectra® 100 mg/vial	Pfizer (5758C; 9617E)	
	Renflexis® 100 mg/vial	Merck, Sharp and Dohme (5758C; 9617E)	
Adalimumab	Humira® 40mg/0.8mL	AbbVie (9425C; 9426D; 9427E; 9428F)	Subcutaneous injection (Weeks 0 and 1 and then every 2 weeks)
Ustekinumab	Stelara® 45mg/0.5mL	Janssen-Cilag (9304Q; 9305R)	Subcutaneous injection (Weeks 0 and 4 and then every 12 weeks)
Secukinumab	Cosentyx® 150mg/mL	Novartis Pharmaceuticals (10425Q; 10494H; 10910F)	Subcutaneous injection every week to Week 4, then every four weeks thereafter.
Ixekizumab	Taltz® 80mg/mL	Eli Lilly (11032P; 11033Q)	Subcutaneous injection every two weeks to Week 12, then every four weeks thereafter.

Adalimumab is a recombinant human immunoglobulin (IgG1) monoclonal antibody, which binds to human tumour necrosis factor (TNF antagonist) in psoriasis plaques, reducing the inflammatory response.

Efalizumab is a monoclonal antibody, which binds to the CD11a subunit of lymphocyte function-associated antigen 1 and acts as an immunosuppressant by inhibiting lymphocyte activation and cell migration out of blood vessels into tissues. Efalizumab was associated with fatal brain infections and was withdrawn from the market in 2009.

Etanercept is a human tumour necrosis factor receptor p75 Fc fusion protein (TNF antagonist).

Infliximab is a chimeric human-murine monoclonal antibody that binds to human tumour necrosis factor-alpha (TNF antagonist).

Ixekizumab targets the interleukin cytokine 17 (IL-17) pathway which is a pro-inflammatory cytokine with an affinity to the homodimer IL-17A and the heterodimer IL-17A/F.

Ustekinumab is a human IgG1 monoclonal antibody that blocks interleukin 12 (IL-12) and interleukin 23 (IL-23) by binding to the p-40 subunit of both interleukins.

Secukinumab is a fully human IgG1 antibody that selectively binds to and neutralises the pro-inflammatory cytokine protein interleukin 17A.

B.4.3 How the intervention might work

In psoriasis it is thought that an abnormally large number of T cells trigger the release of cytokines, resulting in inflammation, redness, itching and flaky skin patches.(2) Biologic agents interfere with specific components of the autoimmune response.(2) They are selective agents which are designed to target only the chemicals (molecules) involved in causing psoriasis. For example, etanercept, infliximab and adalimumab are tumour necrosis factor-alpha (TNF α) blockers, which is the primary cytokine involved in psoriasis. Ustekinumab targets IL-12 and IL-23; secukinumab and ixekizumab target IL-17.(2)

B.4.4 PBS listing history

The first requests for listing of a biologic in severe CPP were initially alefacept and efalizumab in 2004. Both were rejected but triggered a stakeholder meeting between the PBAC, clinicians and pharmaceutical companies which was held in December of 2004. Subsequent requests for listing of alefacept, efalizumab and etanercept were based on the findings from this meeting (PSDs for; Alefacept March 2005, Etanercept March 2005 and Efalizumab July 2005). Efalizumab and etanercept were the first biologics listed for CPP in November 2005 and March 2006 respectively. The PBS restrictions around prior therapies and PASI thresholds are therefore based on those proposed for efalizumab and etanercept (which integrated the December 2004 stakeholder meeting). Subsequently listed biologics for CPP were recommended on the basis that the restrictions were consistent with those already listed (dosing and the initiation periods were amended where appropriate). Infliximab, adalimumab and ustekinumab were listed in the following four years, with another four years before secukinumab and ixekizumab were listed in 2015 and 2017, respectively (Figure B.1).

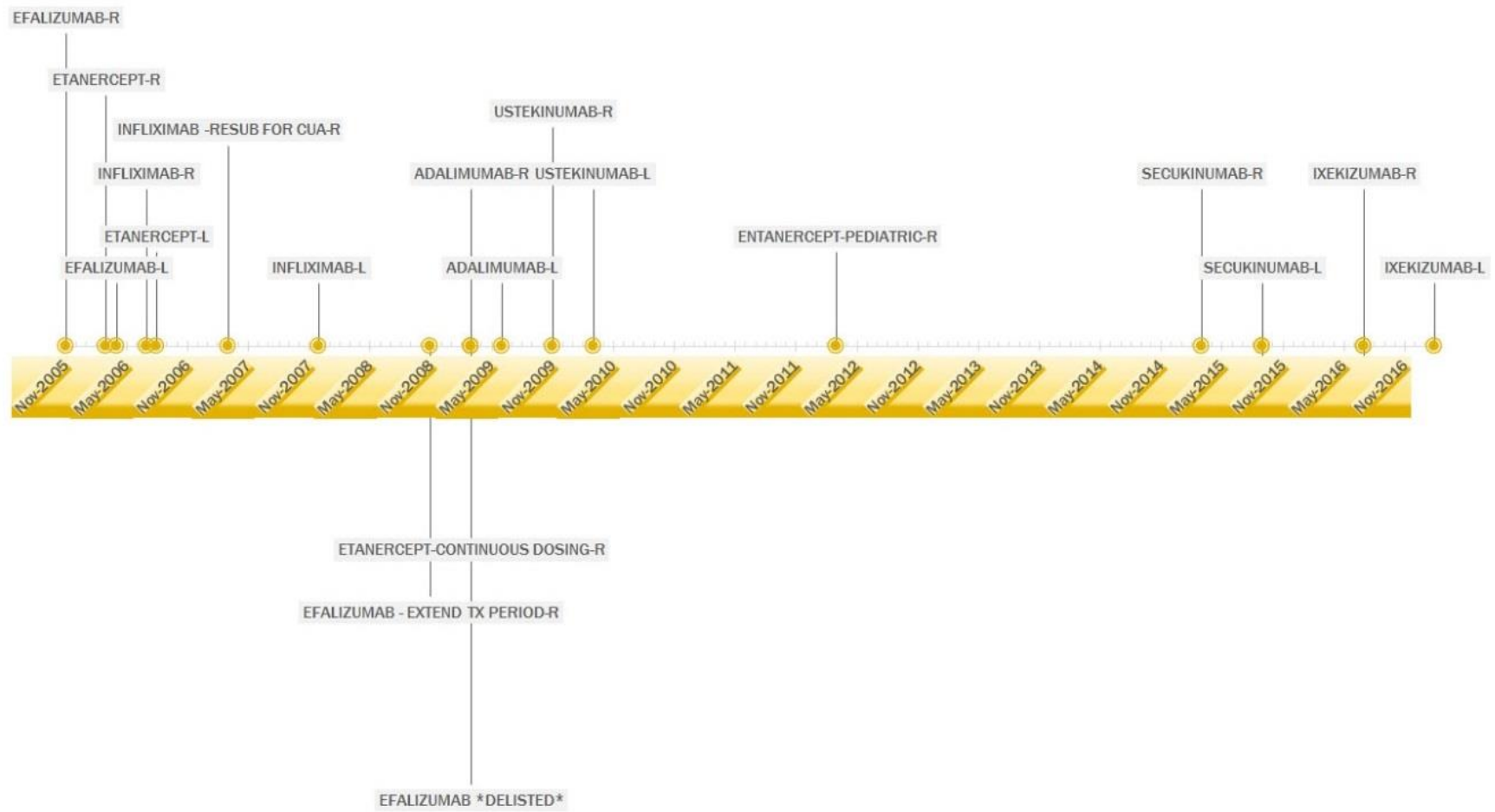


Figure B.1: Timeline for PBAC recommendations and listings of medicines on the PBS
 R = recommended; L = Listed. Those below the date line are changes to existing recommended listings.

Table B.2 presents a summary of the dates of recommendation and the basis of recommendation for each biologic.

Table B.2: Biological medicines listed on the PBS for chronic plaque psoriasis

Active ingredient	First Date of PBAC recommendation	PBS listing date	Basis of listing	PBS listing type
Efalizumab	Nov-05	delisted	CUA to standard medical management	Authority required
Etanercept	Mar-06	Aug-06	Cost-minimisation to Efalizumab Prior submission was CUA compared to standard medical management	Authority required
Infliximab	Jul-06	Dec-07	Cost-minimisation basis with efalizumab The submission presented a CUA compared to efalizumab but PBAC suggested cost minimisation was more appropriate.	Authority required
Adalimumab	Mar-09	Jun-09	Cost-minimisation to efalizumab or etanercept	Authority required
Ustekinumab	Nov-09	Mar-10	CUA to etanercept	Authority required
Secukinumab	Mar-15	Sep-15	Cost-minimisation to adalimumab	Authority required
Ixekizumab	Jul-16	Feb-17	Cost-minimisation to ustekinumab secukinumab and adalimumab	Authority required

A number of cost-effectiveness based submissions were presented to the PBAC, but were rejected and a basis of cost minimisation was used for listing instead (Etanercept and Infliximab). Adalimumab also requested an expansion of the restriction in March 2013 to include moderate CPP (PASI >10 or DLQI >10), using a cost-effectiveness model. The PBAC

considered that a PASI >10 was not appropriate and the PBAC rejected the submission on the basis of highly uncertain cost-effectiveness.

B.4.5 PBS prescribing restrictions

The PBS restriction was based on the Stakeholder meeting that was carried out in December 2004. The summary of the December 2004 Stakeholder meeting concerning the restriction is outlined below. *The following text is directly from the 2004 Stakeholder meeting report, and the issues highlighted in the text have been resolved with various iterations of PBS submissions.*

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Current restrictions

All biologics for CPP are Authority Required listings. To be eligible for treatment with a biologic, a patient must be treated by a dermatologist and must meet strict clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment,

AND

- The treatment must be as systemic monotherapy (other than methotrexate),

AND

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Continuation of the same biologic under the PBS requires patients to experience a reduction in PASI of 75% or more compared with their baseline level (PASI75).

References

1. Australian College of Dermatologists. A-Z of skin: psoriasis 2017 2017 [Available from: <http://www.dermcoll.edu.au/atoz/psoriasis/>].
2. DermNet New Zealand. Topics: plaque psoriasis [Available from: <http://www.dermnetnz.org/topics/plaque-psoriasis>]

Appendix A – Reference Group Members

Member	Type of Membership	Area of Expertise/organisation
Professor Geoff McColl	Chair	Pharmaceutical Benefits Policy
Dr Debra Rowett	Technical Expert	Drug Utilisation (PBAC Sub-committee)
Dr Jane Woods	Organisational Representative	Australasian College of Dermatologists
Professor Nigel Stocks	Organisational Representative	Royal Australian College of General Practice
Ms Jing Jing Li	Technical Expert	Health Economics
Dr Sasha Bennett	Organisational Representative	Society of Hospital Pharmacists of Australia
Ms Elizabeth de Somer	Organisational Representative	Medicines Australia
Ms Eileen Jerga	Consumer Advocate	Consumers Health Forum of Australia
Dr Andrew Miller	Organisational Representative	Australian Medical Association
Dr Anita Wluka	Clinical Expert	Rheumatology /Epidemiology
Dr Jane Cook	Organisational Representative	Therapeutic Goods Administration

Appendix B – Glossary of terms

Term	Explanation
Adverse event	A side effect or an unintended and sometimes harmful occurrence caused by a medicine or medical treatment. A serious adverse event is one that requires hospitalisation, causes disability or permanent damage, requires intervention to prevent disability or permanent damage, is life-threatening, causes death, results in a birth defect, or causes another serious medical event.
AGREE	The Appraisal of Guidelines for Research and Evaluation instrument is a tool used to assess the quality of clinical guidances. Only guidances assessed as having an overall quality of four or above (on a scale of one to seven) were included.
Ankylosing spondylitis	A type of arthritis that causes long term inflammation of the joints in the spine. Ankylosing spondylitis can be treated with some biologic medicines.
Biologic medicine or biopharmaceutical	Medicines produced from biological sources. Most of the biologic medicines used to treat psoriasis are monoclonal antibodies, which are identical proteins usually made in special cell cultures.
Biosimilar	A biosimilar medicine is a biologic medicine that is highly similar to a 'reference biological medicine'. They are checked for safety and to confirm they provide the same health outcomes as the reference biological medicine. Some biosimilars are 'substitutable', which means pharmacists can substitute between brands in consultation with the patient but without needing to refer back to the doctor.
Blinded study / trial	Is where the information about the medicine or placebo given in a medical study is not given to the study participant (or patient), treating clinicians or the data analyst who reports the results. This reduces the chance that one treatment is more favourably considered than the other (see risk of bias).
CASPAR criteria	The Classification Criteria for Psoriatic Arthritis are the current standard diagnostic criteria for psoriatic arthritis.
Chronic plaque psoriasis	Plaque psoriasis is the most common type of psoriasis. It causes raised red patches (plaques) with silver or white scales. It is usually an ongoing (chronic) condition.
DLQI	The Dermatology Life Quality Index is a validated questionnaire used to measure quality of life of people with skin conditions. The Children's Dermatology Life Quality Index (CDLQI) is a version of the DLQI developed for children.
Epidemiological studies / estimates	Epidemiological studies are studies that look at the patterns and causes of conditions. Epidemiological estimates in this report are estimates of the number of patients with psoriasis and patterns of psoriasis from epidemiological studies.
GRADE	Grading of Recommendations Assessment, Development, and Evaluation is a systematic way of judging scientific studies and recommendations.
Incidence	The incidence of a medical condition is the number of people who developed that condition over a particular point in time.
Minimal clinically important difference	The minimal clinically important difference is the smallest difference in a score that patients consider meaningful.

Term	Explanation
Network meta-analysis	A statistical method of bringing together the results of many studies of different treatments for a particular condition. This technique gives results that allows each treatment to be compared to each of the other treatments included in the analysis.
Psoriasis Area and Severity Index	The Psoriasis Area and Severity Index is a way of measuring how severe a patient's psoriasis is based on the area of the body affected by psoriasis, the level of redness, the thickness and level of scaling.
PASI 75	A 75% or greater reduction in PASI score
Persistence	In this report, treatment persistence is how long patients continue treatment without a break.
Physician's Global Assessment	An assessment of all psoriatic lesions based on redness, scale and thickness. There are many variations on how this assessment is done.
Prevalence	The prevalence of a medical condition is the total number of patients with that condition
Psoriatic arthritis	A type of inflammatory arthritis that occurs in people affected by psoriasis. It usually occurs after patients develop psoriasis of the skin. Psoriatic arthritis is more likely to affect the joints at the ends of the fingers and the lower back than other types of arthritis.
PUVA	Psoralen and ultraviolet A phototherapy. This involves using psoralens, which make the skin more sensitive to ultraviolet light, then applying ultraviolet light to treat psoriasis and other conditions.
Quality of life	An evaluation of positive and negative aspects of life. In this report, quality of life refers mostly to health-related quality of life which is related to physical, mental, emotional, and social functioning. It can be measured in many ways. For example, the Dermatology Life Quality Index is a questionnaire that is specific to measure quality of life in patients with skin conditions.
Randomised controlled trial	A type of scientific study where participants are randomly allocated to the experiment group or a placebo or standard treatment group. Randomised controlled trials are considered to be the best type of clinical trial to compare the effectiveness of medical treatments because random allocation reduces bias (see risk of bias) and there is a very similar group (placebo or standard care group) to compare the results.
Rheumatoid arthritis	A type of inflammatory arthritis that mostly affects the joints in the wrist and fingers.
Risk of bias	The risk of bias in a scientific study is the chance that an interference has happened that might make the study results differ substantially from the truth. This may be due to factors like sicker patients leaving the trial early, a newer medicine being assessed more favourably or patients with more severe psoriasis being more involved in studies of psoriasis. The risk of bias of the clinical trials was assessed using the Cochrane Collaboration's 'Risk of bias tool'. A risk of bias tool for prevalence studies was used to assess studies that estimated the number of people with psoriasis, the severity and location of psoriasis, and the number of people with psoriatic arthritis.
Standard coverage days	The number of days of treatment provided by a prescription. In this report, the time taken for half of PBS patients to have a repeat prescription dispensed (median) was the standard coverage days for the biologic.
Systematic review	A structured way to gather and analyse research papers.

Term	Explanation
Treatment holiday or drug holiday	A break from medical treatment for a period of time. In this report, treatment holidays were where patients stopped using biologic prescriptions and restarted treatment.
Utilisation or drug utilisation	The pattern of medicine use. In this report, patterns of biologic medicine use for CPP was examined using prescription dispensing data.