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DUSC Secretary
Pharmaceutical Evaluation Branch
MDP 952
Department of Health
GPO Box 9848
CANBERRA ACT 2601

By email: dusc@health.gov.au

Dear Sir

Thank you for providing the Australasian College of Dermatologists with the opportunity to comment on the letter from the Drug Utilisation Sub-Committee (DUS) of the Pharmaceutical Benefits Advisory Committee (PBAC), seeking College's expert advice on the utilisation of biological medicines for severe chronic plaque psoriasis.

Psoriasis is a chronic systemic disease.

It is important to emphasize that psoriasis is now considered a chronic inflammatory systemic disease, manifest primarily in the skin. It has multiple associated co-morbidities. There is now solid evidence demonstrating that untreated moderate-to-severe chronic plaque psoriasis is associated with reduced life expectancy, lower quality of life, and associated disease states.

Psoriatic patients receiving biologic therapy.

It is our opinion that there are a significant number of individuals in the community with chronic plaque psoriasis that currently would (or should) be eligible for biological therapies, but are not receiving them. At the time of the initial PBAC positive recommendation for efalizumab (Raptiva), it was estimated that there would be 6,000 eligible patients, based on the current criteria. I say 'current criteria' as the criteria have not been changed, despite a number of new agents becoming available. As the members of the Drug Utilisation Sub-Committee would be aware, we have, 8 years after the initial listing of the first biologic, still not reached half the initial estimate.

Reasons for eligible patients not receiving biological therapies:

- relative lack of ready access to dermatologists prepared to prescribe these agents
- onerous administrative requirements associated with the application for and prescribing of these agents
- significant number of individuals with chronic plaque psoriasis with PASI scores between 10 and 15 fail to meet eligibility criteria, yet have moderate-to-severe disease with significantly impaired quality of life
- there are also those in both the general community with moderate-to-severe psoriasis and within the medical community that are unaware of the availability of biological agents for psoriasis
- the final group of individuals not accessing the biologics, despite having moderate-to-severe chronic plaque psoriasis, are those who are unwilling to subject themselves to the potential

toxicities associated with the currently available systemic therapies in order to meet the required eligibility criteria.

Natural history of psoriasis.

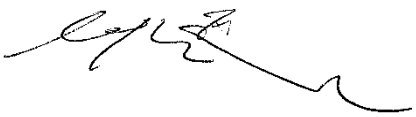
The text books of dermatology tend to suggest that psoriasis is a disease that waxes and wanes in severity. Whilst this is true, the disease tends to improve but not enter into remission. It certainly flares and/or has exacerbations regardless of whether or not patients are on therapy. However, none of our treatments are able to induce remission. Psoriasis, being a chronic systemic inflammation may have times in which the skin will appear to improve, but there is no evidence that the underlying systemic inflammation is modified. The known cardiovascular morbidities associated with chronic inflammation are more likely to be an issue with someone with uncontrolled (untreated) disease. We do not think we can say that psoriasis is a disease that goes into a remission allowing a break from therapy with reintroduction when the disease flares. We know that none of the currently available therapies work as well when withdrawn and then reintroduced. No agent has been shown to have a 100% recapture rate. We really need to be thinking of managing psoriasis in the same way our medical colleagues manage diabetes, hypertension and hyperlipidaemia.

Non-biologic therapies of psoriasis – efficacy and patient satisfaction.

The efficacy of currently available non-biological therapies, along with patient satisfaction, have been poorly documented in the medical literature. The best available efficacy data for methotrexate is what has come out from trials using methotrexate as the comparator agent for biological therapies. This medication is slow in its onset of action, peaks in efficacy around 6 months and tends to wane over time. Its efficacy (in terms of PASI 75 response) would appear to be less than 40%. There certainly are some patients who are satisfied with the level of disease control with non-biological therapies. However, this would not be the majority. You would be aware that a significant proportion of patients prescribed acitretin fail to tolerate the mucocutaneous side effects even if these do not meet the strict criteria for toxicity required for prescribing a biologic. It is important to note that the manufacturer of Neoral (cyclosporine) now recommends no more than 2 years cumulative therapy with cyclosporine for dermatological indications. They also recommend a reduction in dose if there is a **30% rise in baseline** creatinine, not the **150% upper limit of normal** toxicity criterion for biologic eligibility. Likewise the manufacturers suggest a reduction in dose if there is a 25% increase in blood pressure. Again, not an absolute value but a trend, indicating potentially irreversible damage.

In short, we know there are patients with moderate-to-severe chronic plaque psoriasis currently not receiving biological therapies. Some of these patients fail to meet the strict PBS criteria, others do not have access to prescribers, whilst there is also a group who are not aware that this treatment option is available. Whilst there is variation in severity of psoriasis, the disease does not go into remission and even in PASI 100 responders, a break in therapy may result in less effective responses when the agent is reintroduced. There is currently significant dissatisfaction with the available non-biological therapies, but unfortunately patients are required to be exposed to these agents, as a result of eligibility requirements rather than being standard of care or best practice.

Kind regards



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