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BRIEF REPORT

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Paediatric indications and dosing guidance for advanced targeted treatments in Australia

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Abstract

As with adults, paediatric patients may benefit from a number of advanced targeted therapies for inflammatory skin disease. This brief report aims to be an accessible reference tool with respect to regulatory approval and reimbursement of these treatments within Australia.

KEYWORDS

advanced targeted treatments, atopic dermatitis, alopecia areata, Australia, chronic spontaneous urticaria, hidradenitis suppurativa, paediatric, psoriasis

While there are a number of agents available for the treatment of inflammatory skin diseases in adults that are both indicated by the Therapeutic Goods Administration (TGA)[1] and subsidised by the Pharmaceutical Benefits Scheme (PBS),[2] there are much fewer in the paediatric population. Although individual prescription rates are not known to the public, the reasons for the discrepancy between adults and patients are likely multifactorial and include:

(i) A lack of clinical trial data for many agents in the paediatric population;
(ii) The cost of entry for pharmaceutical sponsors to apply for indication recognition and government reimbursement where population and therefore market sizes vary;
(iii) Possible perceived safety concerns, both short and long term, in paediatric patients;

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TABLE 1 Recognised advanced targeted treatments in dermatology.

Advanced targeted treatment	Trade name	Biosimilars	Indication	Other paediatric indications	Pharmaceutical sponsor	TGA approval age (dermatological indication)	PBS approval age
aTNF inhibitors							
Etanercept	Enbrel	Brenzys, Nepexto	Psoriasis	Juvenile idiopathic arthritis (>2 years), enthesitis-related arthritis (>12 years)	Pfizer, Samsung Bioepis, Maxx Pharma	4 years	Under 18 years
Adalimumab	Humira	Adalicip, Amgevita, Hadlima, Hyrimoz, Isacio, Yuflyma	Psoriasis	Juvenile idiopathic arthritis, juvenile psoriatic arthritis (>2 years), Crohn's disease (>6 years)	Abbvie, Cipla, Amgen, Samsung Bioepis, Sandoz, Celltrion	4 years	No PBS approval (<18 years)
Adalimumab	Humira	Adalicip, Amgevita, Hadlima, Hyrimoz, Isacio, Yuflyma	Hidradenitis suppuritiva	Juvenile idiopathic arthritis, juvenile psoriatic arthritis (>2 years), Crohn's disease (>6 years)	Abbvie, Cipla, Amgen, Samsung Bioepis, Sandoz, Celltrion	12 years	Under 18 years
Infliximab	Remicaide	Inflectra, Renflexis, Remsima	Psoriasis	Chron's disease, ulcerative colitis (>6 years)	Janssen, Pfizer, Celltrion Healthcare	Over 18 only	No PBS approval (<18 years)
Certolizumab Pegol	Cimzia		Psoriasis	Over 18 only	UCB Pharma	Over 18 only	No PBS Approval (<18 years)
IL-12/23 inhibitors							
Ustekinumab	Stelara		Psoriasis	Over 18 only	Janssen	6 years	Under 18 years
IL-17 inhibitors							
Secukinumab	Cosentyx		Psoriasis	Enthesitis-related arthritis (>6 years), psoriatic arthritis (>2 years)	Novartis	6 years	No PBS Approval (<18 years)
Ixekizumab	Taltz		Psoriasis	Over 18 only	Eli-Lilly	Over 18 only	No PBS Approval (<18 years)
Bimekizumab	Bimzelx		Psoriasis	Over 18 only	UCB Pharma	Over 18 only	No PBS Approval (<18 years)
IL-23 inhibitors							
Tildrakizumab	Ilumya		Psoriasis	None	Sun Pharma	Over 18 only	No PBS Approval (<18 years)

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TABLE 1 (Continued)

Advanced targeted treatment	Trade name	Biosimilars	Indication	Other paediatric indications	Pharmaceutical sponsor	TGA approval age (dermatological indication)	PBS approval age
Guselkumab	Tremfya		Psoriasis	Over 18 only	Janssen	Over 18 only	No PBS Approval (<18 years)
Risankizumab	Skyrizi		Psoriasis	Over 18 only	Abbvie	Over 18 only	No PBS Approval (<18 years)
IL-4/13 inhibitors							
Dupilumab	Dupixent		Atopic dermatitis	Severe asthma (>6 years)	Sanofi	6 months	12 years and over
JAK/Tyk inhibitors							
Tofacitinib	Xeljanz		No dermatological indication	Juvenile idiopathic arthritis, juvenile psoriatic arthritis (>2 years)	Pfizer	No derm indication	No PBS Approval (<18 years)
Upadacitinib	Rinvoq		Atopic dermatitis	Over 18 only	Abbvie	12 years	12 years and over
Baricitinib	Olumiant		Alopecia areata	Over 18 only	Eli Lilly	Over 18 only	No PBS Approval (<18 years)
Deucravacitinib	Sotyktu		Psoriasis	Over 18 only	Bristol-Myers Squibb	Over 18 only	No PBS Approval (<18 years)
IgE inhibitors							
Omalizumab	Xolair		Chronic spontaneous urticaria	Allergic asthma (>6 years)	Novartis	12 years	Under 18 years
PDE4 inhibitor							
Apremilast	Otezla		Psoriasis	Over 18 only	Amgen	Over 18 only	No PBS Approval (<18 years)

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TABLE 2 Dosing recommendations for dermatologically indicated medications from the Therapeutic Goods Administration.

Advanced targeted treatment	Therapeutic indication	Body weight	Dosing schedule
aTNF inhibitors			
Etanercept	The treatment of patients 4 years or older with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.	<63 kg	0.8 mg/kg weekly
		≥63 kg	50 mg weekly
Adalimumab	The treatment of severe chronic plaque psoriasis in children and adolescent patients from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy.	<40 kg	20 mg fortnightly
		≥40 kg	40 mg fortnightly
Adalimumab	The treatment is indicated for the treatment of active moderate-to-severe hidradenitis suppurativa (acne inversa) in patients with an inadequate response to conventional systemic hidradenitis suppurativa therapy.	>30 kg	40 mg fortnightly, increasing to 40 mg weekly or 80 mg fortnightly may be considered (if 40 mg is not adequate for disease control)
IL-12/23 inhibitors			
Ustekinumab	The treatment of moderate-to-severe plaque psoriasis in children and adolescent patients from 6 years of age who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.	<60 kg	0.75 mg/kg q12w
		≥60 to ≤100 kg	45 mg q12w
		>100 kg	90 mg q12w
IL-17 inhibitors			
Secukinumab	The treatment of moderate-to-severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy.	<50 kg	75 mg monthly
		≥50 kg	150 mg monthly
IL-4/13 inhibitors			
Dupilumab	The treatment of adult and paediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.	5–15 kg	200 mg q4w
		15–30 kg	300 mg q4w
		30 kg to less than 60 kg	200 mg fortnightly
		60 kg or more	300 mg fortnightly
JAK/Tyk Inhibitors			
Upadacitinib	Adults and paediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.	>40 kg	15 mg daily. If an adequate response is not achieved, consider increasing the dosage to 30 mg daily.
IgE inhibitor			
Omalizumab	Chronic spontaneous urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.	Dosing not dependent on body weight.	300 mg q4w

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(iv) Local availability of treatments in appropriate dose delivery systems and/or
(v) A lack of familiarity by clinicians of which drugs are therapeutically indicated and/or reimbursed, at what age and/or weight limit(s) and the relevant dosing thereof.

This clinical letter aims to provide clarity with respect to the latter point regarding unfamiliarity in the context of advanced targeted treatments in paediatric patients with inflammatory skin diseases. The aim is to serve as a quick point of reference for dermatologists who treat these patients.

For the purposes of this manuscript, advanced targeted treatments include any agents that are listed by the TGA for the specific treatment of inflammatory skin diseases in adults or children, including psoriasis, atopic dermatitis, alopecia areata, hidradenitis suppuritiva and chronic spontaneous urticaria. Table 1 provides a list of these agents (both generic and trade names) as well as other paediatric indications and at what age the treatment is indicated and/or reimbursed for by the TGA and PBS respectively. For those agents that are TGA indicated in paediatric patients, the recommended dosing quantitites are found in Table 2. For the sake of simplicity, unless clearly indicated by the TGA, loading doses have been omitted.

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