

Targeting much more than 'influenza of the skin'

ILUMYA: New biologic for chronic plaque psoriasis set to be PBS listed

A new targeted biologic for the estimated 19,000 Australian adults living with severe chronic plaque psoriasis¹ will be listed on the Pharmaceutical Benefits Scheme (PBS) on February 1, 2019 for those who meet the reimbursement criteria.²

ILUMYA™ (tildrakizumab) belongs to a new class of biologic medicines, known as interleukin (IL) inhibitors, that specifically block a protein called IL-23,³ an inflammatory substance known to play a key role in psoriasis.⁴ The treatment, which involves skin injections every 12 weeks, following an initial dose at day one and another dose at week four, can be stored outside a refrigerator for up to 30 days.³

ILUMYA's PBS listing announcement coincides with an article published in *MJA Insight* this week highlighting the substantially unrecognised burden of psoriasis and general lack of awareness among GPs and the broader patient community, of the availability of new biologic therapies, which may be delaying patient access to effective, long-lasting treatment.⁵

According to article author, clinical dermatologist and Director of Research, Skin & Cancer Foundation Inc., Associate Professor Peter Foley, Melbourne, although there is no cure for the debilitating disease, the introduction of targeted biologics represents a promising step forward in improving patient quality of life.

"While psoriasis was once thought of as little more than 'influenza of the skin', our improved understanding of this immune-driven disease has led to the development of much more targeted treatments.

"We now know that the protein, IL-23, plays a major role in the disease, and that blocking its action can disrupt the psoriasis pathway, relieving inflammation and reducing painful symptoms," A/Prof Foley said.

"These medications [IL-23 inhibitors] represent the latest development of targeted biologics for severe psoriasis. The availability of these new treatment options aimed at improving patient quality of life are welcomed by physicians."

Psoriasis affects between two to six per cent of Australians⁶ and the most common form of the disease, plaque psoriasis, accounts for up to 90 per cent of cases.⁷ It often appears as patches of thick, red, scaly skin, known as 'plaques',⁸ that can become itchy and painful, with the potential to crack and bleed.⁹

The immune-driven disease poses a significant physical, psychological and social burden, and can significantly compromise a person's quality of life.¹⁰ It is associated with several other health conditions, including heart disease and arthritis,¹¹ and disfigurement, disability and marked loss of productivity are the most commonly cited challenges faced by those afflicted.¹⁰

Heightened rates of clinical depression and anxiety have also been observed among those living with psoriasis,¹² and social exclusion, discrimination and stigma are some of the psychologically taxing hurdles endured by people living with psoriasis.¹⁰

Although it is unclear whether the psychosocial problems associated with psoriasis are a result of inflammation related to the disease itself, to stigmatisation or to treatment failure, research indicates an association between increased control of psoriasis symptoms and improvements in psychological wellbeing.⁵

Creative agency director, pizza shop owner and keen boxer, Matt, 36, Melbourne, was only 14 years of age when diagnosed with severe psoriasis in hospital. He understands the devastating effects of the skin disease and the importance of the availability of new treatment options for psoriasis.

"I wouldn't wish psoriasis on my worst enemy. It's crippling physically, but also mentally. I've developed a lot of resilience since living with psoriasis, but I've experienced a lot of discomfort to get to this point.

"[Over the years] my confidence plummeted. I became introverted and isolated, and constantly felt terrible," said Matt.

Despite being surrounded by a strong and supportive network of family and friends, Matt grew increasingly exasperated by the lack of treatments that were effective for him, and in 2013, entered a five-year-long clinical trial of a new class of biologic treatment.

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"I encourage other Australian adults living with uncontrolled severe psoriasis to be their own advocate and talk to their doctor or dermatologist about different treatments that might be suitable for them," Matt said.

Although recent years have seen the introduction of a range of effective treatment options for those living with plaque psoriasis, leading dermatologists cite lack of awareness may be hindering patient access to effective treatments.⁵

Clinical dermatologist and Principal, St George Dermatology, Associate Professor Stephen Shumack, OAM, Sydney, hopes enhanced education and awareness of the availability of new biologics for plaque psoriasis will improve patient access to treatment and subsequent outcomes.

"Many people were historically told their psoriasis was just a cosmetic problem and that there was nothing that could be done, or may have been unable to find a treatment that worked for them.

"Lack of patient awareness of the availability of these new treatments, PBS restrictions and poor information dissemination to GPs, may be discouraging patients from seeking medical attention, or delaying referrals to dermatologists, subsequently hindering patient access to these potentially life-changing treatments," A/Prof Shumack said.

"Australians living with severe plaque psoriasis should no longer despair, as we now have more options than ever available to effectively manage plaque psoriasis and maintain this in the long-term."

About ILUMYA

ILUMYA is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy.³

ILUMYA contains the active substance, tildrakizumab, a monoclonal antibody belonging to a group of medicines called interleukin (IL) inhibitors. ILUMYA works by neutralising a specific protein called IL-23 which is involved in normal inflammatory and immune responses. In plaque psoriasis, the body produces too much IL-23 and this can lead to symptoms of itching, pain and scaling.¹³

ILUMYA is administered directly into the skin by injection every 12 weeks, after initial doses on day one and then 4 weeks later. It may be given by a doctor or nurse or, following training from a healthcare professional, may be self-administered by a patient, or administered by a carer.³

ILUMYA will be listed on the PBS on February 1, 2019 for adults with chronic severe plaque psoriasis who meet the reimbursement criteria. A prescribing authority is required from the PBS for each patient and the prescription must be written by a dermatologist. See the *Schedule of Pharmaceutical Benefits* for more details.²

ILUMYA should not be used in people who have had a severe allergic reaction to the active ingredient, tildrakizumab, or any other ingredients in ILUMYA, or in those with an active infection considered important by a doctor, such as tuberculosis.³

Precautions should be taken in patients with: a history of ongoing or recurrent infections; active or latent tuberculosis (TB); hypersensitivity to the ingredients; a history of malignancy, or development of malignancy, and in patients under 18 years of age. Patients who have used ILUMYA should not receive live vaccines during treatment or for at least 17 weeks after treatment. The most common side effects of ILUMYA are upper respiratory tract infections with symptoms such as sore throat and stuffy nose (nasopharyngitis), headache and injection site pain.³

General storage is between 2° – 8°C. For purposes of travel or transporting between refrigerated storage, ILUMYA can be stored for up to 30 days at, or below 25°C. After 30 days outside the refrigerator, ILUMYA should be used immediately or discarded.¹³

About psoriasis

Psoriasis is an inflammatory, immune-driven skin disease⁶ in which the immune system reacts abnormally to certain environmental conditions.¹⁴ An over-active immune system causes skin cells to rapidly multiply, too quickly for the skin to shed, resulting in raised, red, scaly patches¹⁵ which can often become itchy and painful.⁹

Psoriasis affects men and women equally.¹⁶ Most people develop psoriasis before 45 years of age, although some people may develop the disease later in life.¹⁴

Although the exact cause of the disease is unknown,¹⁴ the development of psoriasis is thought to be influenced by the relationship between the immune system, genes, and environmental and lifestyle factors.⁴

Psoriasis plaques are the result of a complex interaction between skin cells, immune cells, and pro-inflammatory proteins, called cytokines.¹⁷ In skin affected by psoriasis, levels of the protein IL-23 are elevated, which leads to the over-production of other substances, such as IL-17A, that cause inflammation and rapid skin growth.^{3,4,18}

The new class of IL-23 inhibitors work to counteract the effects caused by the increased levels of IL-23, by turning off the excessive production of IL-17A and other substances. This can help to relieve the inflammation and reduce the symptoms of psoriasis.^{3,17}

Contact Sun Pharma Medical Information on 1800 726 229 for more information.

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AVAILABLE FOR INTERVIEW:

- **A/Prof Peter Foley, MJA Insight article author, Clinical Dermatologist & Director of Research, Skin & Cancer Foundation Inc., MELBOURNE**
- **A/Prof Stephen Shumack, OAM, Dermatologist, Clinical Associate Professor, University of Sydney and principal, St George Dermatology, SYDNEY**
Matt, 36, Creative Agency Director, pizza shop owner & keen boxer who has lived with psoriasis for 22 years, MELBOURNE
- **Tim, 42, Father-to-two & avid outdoorsman who has lived with severe psoriasis for ten years, MELBOURNE**
- **Grant, 56, Sales Manager, keen traveller & father-to-two who lived with uncontrolled psoriasis for 2 decades before enrolling in a clinical trial, MELBOURNE**

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To access the full digital media kit, head to www.psoriasismediakit.com.au.

See Consumer Medicine Information for further information:

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-CMI-02293-1&d=201901151016933>

About Sun Pharma

Sun Pharma is a global pharmaceutical company providing high quality, affordable medicine trusted by customers and patients in over 150 countries across the world, and supported by 42 manufacturing facilities across five continents. Sun Pharma ANZ market an expanding portfolio of branded dermatology products and a range of oral and specialty generics. In Australia, the company also manufactures poppy-derived opiate raw materials primarily used in the manufacture of analgesics.

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Sun Pharma ANZ supports disclosure and transparency on interactions between the healthcare industry and healthcare professionals to ensure public trust and confidence. Compensation has been provided to A/Prof Foley, and A/Prof Shumack for involvement in the clinical trial programme for ILUMYA and A/Prof Foley for participation on the ILUMYA advisory board. All expert spokespeople have been offered compensation for time spent on activities pertaining to this media campaign and have been briefed on the approved use of this product and their obligations with regard to promotion to the general public. All opinions expressed are their own.

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