

JAKs - Where are we now and where might we be heading?



Janus Kinase Inhibitors (JAK inhibitors) are a hot topic within our community peer support spaces and are the number 1 repeated questions being asked to the AAAF team, so we wanted to provide an update about the current position regarding JAK inhibitor drugs as a potential treatment for alopecia areata.

Firstly, what is a JAK inhibitor and why are they being explored as a treatment option for alopecia areata?

JAK inhibitors are a type of drug that suppresses the activity or response of one or more of the Janus Kinase enzymes, also known as JAK1, JAK2, JAK3 and TYK2. JAK enzymes are known contributors to the autoimmune process. In a nutshell, JAK inhibitors could block the inflammatory pathways that occur in active alopecia areata, reducing the inflammation that occurs around the hair follicles and allowing hair to grow once again.

What is happening with clinical trials for JAK inhibitors for alopecia areata?

There are lots of stages of research, starting out with basic research and pilot studies before moving into clinical trials.

Clinical trials for JAK inhibitors as a treatment for alopecia areata are currently underway across the world with at least 4 pharmaceutical companies. Clinical trials can be a lengthy process as they need to rigorously test the drugs, first to check they are safe for use and then to see if they are effective, and monitor any side effects. These trials have been in operation since 2015.



Can I get JAK inhibitor drugs for my Alopecia Areata privately?

We are aware that some people are choosing to source JAK inhibitors themselves.

Because JAK inhibitors are licensed for treating rheumatoid arthritis and atopic dermatitis (eczema), some dermatologists are prepared to prescribe JAK inhibitors for patients with alopecia areata 'off-label'. This can be at a great cost for the drugs and the price will be determined by the supplier.



What is the position with any approval of JAK inhibitors for the treatment of alopecia areata?



The US Food and Drug Administration (FDA) approved a JAK inhibitor on 14 June 2022, history was made, marking the first FDA-approved treatment for the condition. The drug called Baricitinib (brand name Olumiant™) for the treatment of alopecia areata, In addition, in September 2022 the FDA accepted a New Drug Application for a JAK inhibitor called 'Ritlecitinib' for adults and adolescents 12 years and older with alopecia areata. The FDA decision is expected by mid-2023. AAAF will be representing the patient voice for the JAK inhibitor drugs - Baricitinib (Eli Lilly) and Ritlecitinib (Pfizer).

So the question then comes which drug will be best suited to my form of hair loss. Baricitinib is under consultation for the treatment of severe alopecia areata in adults and Ritlecitinib is under consultation for the treatment of moderate to severe alopecia areata in people aged 12 years and over. It is unlikely that it will be offered to patients with small patches of alopecia areata. We are unclear at this point what the criteria will be in terms of what is determined as 'severe' or 'moderate' hair loss.

What are the possible side effects of taking JAKs?

Many patients do not experience side effects and those who do, rarely experience serious side effects. Many side effects become less serious and frequent over time. Some less serious side effects include nausea, indigestion, diarrhea, headaches, upper respiratory tract infection, and increased cholesterol levels.

In rare cases, more serious side effects can occur, such as infection, abnormal blood counts, abnormal liver function tests, increased risk of bowel perforation, and decrease in kidney function.

Listing the JAK inhibitors for the treatment of Alopecia Areata onto the PBS

To understand the work involved to get a drug listed on the Pharmaceutical Benefits Scheme (PBS) you can familiarise yourself <u>here.</u>

AAAF is participating in conjunction with third parties, to obtain the vital inputs into the lodgements need by the pharmaceutical companies.

Managing Expectations?

It is important that anyone embarking on these treatments goes in with open eyes and realistic expectations. Whilst these JAK inhibitor drugs are a giant leap forward in the treatment of alopecia areata, they do not represent the cure that many are hoping

for.