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SILIQ (brodalumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Siliq is subcutaneous injectable treatment that helps regulate inflammation in people with moderate to severe plaque psoriasis (PsO). Brodalumab is an antibody that binds to a protein (interleukin IL-17A) which is involved in inflammation. Brodalumab binds to IL-17A and prevents it from binding to its receptor, and it inhibits its ability to trigger the inflammatory response that plays a role in the development of plaque psoriasis (1).

Regulatory Status

FDA-approved indication: Siliq is a human interleukin-17 receptor A (IL-17RA) antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies (1).

Siliq has a boxed warning for suicidal ideation and behavior which occurred in patients treated with Siliq. A causal association between treatment with Siliq and increased risk of suicidal ideation and behavior has not been established. Prescribers should weigh the potential risks and benefits before using Siliq in patients with a history of depression or suicidality. Patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate. Prescribers should also reevaluate the risks and benefits of continuing treatment with Siliq if such events occur. Siliq is available only through a restricted program under the SILIQ REMS Program because of the observed suicidal ideation and behavior in subjects treated with Siliq (1).

Siliq is contraindicated in patients with Crohn's disease because it may cause worsening of the disease (1).

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Siliq. Do not administer to patients with active TB infection. Initiate treatment for latent TB prior to administering Siliq. Consider anti-TB therapy prior to initiation of Siliq in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients receiving Siliq for signs and symptoms of active TB during and after treatment (1).



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Siliq affects the immune system, thus patients may be at greater risk for infection. If a patient develops a serious infection or is not responding to standard therapy for the infection, monitor the patient closely and discontinue Siliq therapy until the infection resolves (1).

Avoid use of live vaccines in patients treated with Siliq. There is no data available on the ability of live or inactive vaccines to elicit an immune response in patients being treated with Siliq (1).

The safety and effectiveness of Siliq have not been evaluated in pediatric patients (1).

Summary

Siliq is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies. It is administered as an injection under the skin. Because of the observed suicidal behavior in subjects treated with Siliq, Siliq is available only through a restricted Risk Evaluation and Mitigation Strategy (REMS) program called the SILIQ REMS Program (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Siliq while maintaining optimal therapeutic outcomes.

References

1. Siliq [package insert]. Bridgewater, NJ: Bausch Health US, LLC; August 2024.