BlueCross BlueShield
Federal Employee Program

OPZELURA
(ruxolitinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Opzelura (ruxolitinib) is indicated for the topical treatment of mild to moderate atopic dermatitis and nonsegmental vitiligo. Atopic dermatitis, a chronic inflammatory skin disease, is often referred to as "eczema," which is a general term for the several types of inflammation of the skin. Atopic dermatitis is the most common of the many types of eczema and onset typically begins in childhood and can last through adulthood. The cause of atopic dermatitis is a combination of genetic, immune and environmental factors. Opzelura is a topical Janus kinase (JAK) inhibitor. Janus kinases (JAK1 and JAK2) are involved in a signaling cascade that recruits signal transducers and activators of transcription (STATs) to the nucleus leading to modulation of gene expression for many pathways including immune function (1).

Regulatory Status

FDA-approved indications: Opzelura is a Janus kinase (JAK) inhibitor indicated for (1):

- the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

Limitations of Use:

Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended (1).

Opzelura has a boxed warning regarding serious infections. Serious infections have occurred in patients receiving oral JAK inhibitors and serious lower respiratory tract infections were reported by patients using topical ruxolitinib. Use in active, serious infection should be avoided. Risks and benefits should be carefully considered before using in patients with a history of or at an increased risk for: chronic or recurrent infection, opportunistic infection, or tuberculosis. All patients should be closely monitored for development of infection and treatment interrupted and permanently

discontinued as appropriate (1).

Opzelura also carries boxed warnings for mortality and major adverse cardiovascular events (MACE). A higher risk of all-cause mortality, including sudden cardiovascular death was observed in clinical trials of oral JAK inhibitors. Additionally, these clinical trials recorded MACE, which includes fatal cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke. The risks and benefits of treatment with Opzelura should be carefully considered before prior to initiating or continuing treatment (1).

The last boxed warnings are regarding malignancies and thrombosis. Lymphoma and other malignancies have been observed in patients treated with oral Janus kinase inhibitors. Non-melanoma skin cancers, including basal cell and squamous cell have occurred in patients treated with Opzelura. Thrombosis, including pulmonary embolism, deep venous thrombosis, and arterial thrombosis have occurred in patients treated with oral JAK inhibitors used to treat inflammatory conditions (1).

Opzelura has a maximum dose of 60 grams (one tube) per week. The manufacturer notes that it expects typical use to be 3-4 tubes of medication per year (1-2).

The safety and effectiveness of Opzelura in patients less than 12 years of age have not been established (1).

Summary

Opzelura (ruxolitinib) is a topical JAK inhibitor indicated for the treatment of mild to moderate atopic dermatitis and nonsegmental vitiligo in patients 12 years of age and older. Opzelura carries boxed warnings regarding infection, mortality, malignancy, MACE, and thrombosis. Patients should be carefully evaluated for risks of benefits of treatment before initiating or continuing therapy. The safety and effectiveness of Opzelura in patients less than 12 years of age have not been established (1).

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

OPZELURA
(ruxolitinib)

References

1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation.; August 2024.
2. Opzelura (ruxolitinib) cream FDA Approval Call; Incyte Manufacturer Website; https://s21.q4cdn.com/114423841/files/doc_presentations/2021/Rux-Cream-approval-call_v31_no-notes.pdf; September 22, 2021.