BlueCross BlueShield
Federal Employee Program

CIBINQO
(abrocitinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Cibinqo (abrocitinib) is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Cibinqo modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs (1).

Regulatory status

FDA-approved indication: Cibinqo is a Janus kinase (JAK) inhibitor indicated for the treatment of adults and pediatric 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 (1).

Limitations of Use: (1)
Cibinqo is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Cibinqo carries several boxed warnings: (1)

1. Serious infections
    a. Serious infections, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infection leading to hospitalization or death. If a serious infection develops, discontinue Cibinqo until the infection is controlled. Prior to starting Cibinqo, perform a test for latent tuberculosis; if it is positive, start treatment for tuberculosis prior to starting Cibinqo. Monitor all patients for active tuberculosis during treatment, even if the initial latent tuberculosis test is negative.
2. Mortality
    a. RA patients 50 years of age and older with at least one cardiovascular risk factor showed a higher rate of all-cause mortality, including sudden cardiovascular death, in patients treated with JAK inhibitors compared to TNF blockers.

   b. Cibinqo is not approved for use in RA patients.

3. Malignancies
   a. Lymphoma and other malignancies have been observed in patients treated with Cibinqo.
   b. In RA patients treated with a JAK inhibitor, a higher rate of malignancies was observed when compared with TNF blockers.
4. Major adverse cardiovascular events (MACE)
   a. RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor showed a higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) when compared to TNF blockers. Patients who are current or past smokers are at increased risk. Cibinqo should be discontinued in patients that have experienced a myocardial infarction or stroke.
5. Thrombosis
   a. Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death.
   b. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers.

Cibinqo is contraindicated in patients taking antiplatelet therapies, except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment (1).

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

Summary

Cibinqo (abrocitinib) is a Janus kinase (JAK) inhibitor indicated for patients with atopic dermatitis. Cibinqo has several boxed warnings including risk of serious infections, mortality, malignancies, MACE, and thrombosis. The safety and effectiveness of Cibinqo in pediatric patients less than 12

years of age have not been established (1).

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

References

1. Cibinqo [package insert]. New York, NY: Pfizer Inc.; December 2023.