RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Orencia is a prescription medication that reduces signs and symptoms in adults with moderate to severe rheumatoid arthritis (RA), including those who have experienced an inadequate response to other medications for RA. Orencia may prevent further damage to bones and joints and may help the patient’s ability to perform daily activities. In adults, Orencia may be used alone or with other RA treatments other than tumor necrosis factor (TNF) antagonists (1).

Orencia is indicated to reduce the signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in pediatric patients 2 years of age and older. Patients may receive Orencia alone (monotherapy) or in combination with methotrexate (1).

Regulatory Status
FDA-approved indication: Orencia is a selective T cell co-stimulation modulator indicated for: (1)

1. Adult Rheumatoid Arthritis (RA) – Moderately to severely active RA in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists
2. Juvenile Idiopathic Arthritis – Moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 2 years of age and older. Orencia may be used as monotherapy or concomitantly with methotrexate
3. Adult Psoriatic Arthritis (PsA) – active PsA in adults

Limitations of Use:
Orencia should not be given concomitantly with TNF antagonists as it can increase the risk of infections and serious infections (1).

Physicians should exercise caution when considering the use of Orencia in patients with a history of recurrent infections, underlying conditions which may predispose them to infections, or chronic, latent, or localized infections. Patients who develop a new infection while undergoing treatment with Orencia should be monitored closely. Administration of Orencia should be discontinued if a patient develops a serious infection. A higher rate of serious infections has been observed in adult RA patients treated with concurrent TNF antagonists and Orencia (1).
Prior to initiating immunomodulatory therapies, including Orencia, patients should be screened for latent tuberculosis infection with a tuberculin skin test. Orencia has not been studied in patients with a positive tuberculosis screen, and the safety of Orencia in individuals with latent tuberculosis infection is unknown. Patients testing positive in tuberculosis screening should be treated by standard medical practice prior to therapy with Orencia (1).

Antirheumatic therapies have been associated with hepatitis B reactivation. Therefore, screening for viral hepatitis should be performed in accordance with published guidelines before starting therapy with Orencia. In clinical studies with Orencia, patients who screened positive for hepatitis were excluded from study (1).

The safety and effectiveness of Orencia in pediatric patients below 2 years of age have not been established (1).

Summary
Orencia is indicated for the treatment of moderately to severely active RA and PsA in adults, may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists. Orencia is also indicated for pediatric patients 2 years of age or older with moderately to severely active polyarticular juvenile idiopathic arthritis, may be used as monotherapy or concomitantly with methotrexate. Prior to initiating immunomodulatory therapies, including Orencia, patients should be screened for latent tuberculosis infection with a tuberculin skin test. Antirheumatic therapies have been associated with hepatitis B reactivation (1).

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

References