BlueCross BlueShield
Federal Employee Program

ORENCIA
(abatacept)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Orencia (abatacept) is a selective costimulation modulator that inhibits T cell (T lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28. This interaction provides a costimulatory signal necessary for full activation of T lymphocytes. Activated T lymphocytes are implicated in the pathogenesis of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, and psoriatic arthritis (1).

Regulatory Status

FDA-approved indications: Orencia is a selective T cell costimulation modulator indicated for: (1)

1. Adult Rheumatoid Arthritis (RA)
    a. Orencia is indicated for the treatment of adult patients with moderately to severely active RA. Orencia may be used as monotherapy or concomitantly with DMARDs other than JAK inhibitors or biologic DMARDs.
2. Polyarticular Juvenile Idiopathic Arthritis (pJIA)
    a. Orencia is indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Orencia may be used as monotherapy or concomitantly with methotrexate.
3. Psoriatic Arthritis (PsA)
    a. Orencia is indicated for the treatment of patients 2 years of age and older with active PsA.
4. Prophylaxis for Acute Graft versus Host Disease (aGVHD)
    a. Orencia is indicated for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

<u>Limitations of Use:</u>

The concomitant use of Orencia with other potent immunosuppressants [e.g., biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended (1).

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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 less than 2 years of age with pJIA, PsA, or prophylaxis of acute graft versus host disease (aGVHD) have not been established. The safety and effectiveness of Orencia in pediatric patients less than 18 years of age with RA have not been established (1).

Summary

Orencia (abatacept) is indicated for the treatment of rheumatoid arthritis (RA) in adults; and for polyarticular juvenile idiopathic arthritis (pJIA), psoriatic arthritis (PsA), and prophylaxis of acute graft versus host disease (aGVHD) in pediatric patients 2 years of age and older. 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.

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References

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; May 2024.