Pharmacy Policy Bulletin

Title: Abatacept (Orencia) subcutaneous

Policy #: Rx.01.108

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

Abatacept (Orencia) subcutaneous is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.

The use of Abatacept (Orencia) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

Description:

Abatacept (Orencia), a selective costimulation modulator, 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 RA and are found in the synovium of patients with RA.

Policy:

Abatacept (Orencia SQ) is approved when there is a diagnosis of moderately to severely active Rheumatoid arthritis and one of the following inclusion criteria is met:

- Documentation of all of the following:
    - Age of 18 years or older
    - Medication is being recommended by a rheumatologist
    - No concurrent therapy with other biologic RA therapy, such as anakinra or tumor necrosis factor antagonists
    - Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
    - Patient had at least a 90 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) OR contraindication to ALL of the following DMARDs:
        - Methotrexate
        - Hydroxychloroquine
        - Leflunomide
        - Azathioprine
        - Sulfasalazine
        - A tumor necrosis factor inhibitor
- Documentation of abatacept (Orencia)- IV dose given within the last 30 days for members transitioning from abatacept (Orencia)- IV therapy

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Orencia [package insert]. Princeton NJ. Bristol-Meyers Squibb. 2011

Orencia website. Available at www.orencia.com. Accessed August 25, 2011.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Orencia	Abatacept

Cross References:

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