North Carolina State Health Plan for Teachers and State Employees
www.shpnc.org

medco®

abatacept (*Orencia*®)

To Initiate a Coverage Review, call 1 800 753-2851

Covered Medication
abatacept (*Orencia*®)

What it does and how it is used

- Abatacept is the first in a new class of drugs that inhibit T-cell activation. *Orencia* is used in the treatment of moderate to severely active adult rheumatoid arthritis (RA) and juvenile idiopathic arthritis (JIA).
- T-cells are important cells in the immune system and when activated in autoimmune diseases such as RA, trigger a cascade of events which increase levels of inflammatory mediators such as TNF-α (tumor necrosis factor).
- Patients with RA are found to have increased TNF-α in their joints leading to inflammation and damage in surrounding joints and tissues.
- RA is a chronic condition causing painful inflammation of synovial tissue and surrounding joints. Chronic joint inflammation eventually leads to tissue destruction, cellular damage to the bone along with edema (swelling), warmth, redness, joint stiffness, and pain.
- Patients with RA may also experience fatigue, weakness, low-grade fever, and loss of appetite.
- When arthritis occurs in children, it is referred to as juvenile idiopathic arthritis (JIA), or juvenile rheumatoid arthritis (JRA). Some children will "outgrow" their condition, while others may continue to have arthritis symptoms into adulthood.
- In addition to the symptoms adults with RA experience, JIA is associated with medical conditions such as inflammation of the inner parts of the eye (known as uveitis) that may persist independent of arthritis symptoms. If untreated, uveitis can lead to glaucoma, cataracts, and permanent vision damage so patients must see ophthalmologists regularly.
- RA treatment is aggressive soon after diagnosis with the goal of treatment being to eliminate synovitis (joint swelling) and joint destruction. Joint erosion is due to the presence of inflammatory mediators which cause joint and cartilage destruction. These damaging substances include; prostaglandins, cytokines, and tumor necrosis factor.
- All patients should be started on a disease modifying antirheumatic drug (DMARD) as part of initial therapy, generally within 3 months of diagnosis. DMARDs decrease pain, slow disease progression, and retard joint erosions.
- Methotrexate is the most commonly used DMARD. It may be used alone or with a biologic agent (e.g., *Enbrel*®, *Remicade*®, *Orencia*®, *Kineret*® or *Humira*®).
- Abatacept can be used as monotherapy or in combination with certain other DMARDs (e.g., methotrexate). Abatacept should not be used in combination with TNF antagonists or *Kineret*® due to increased risk of infections.
- Abatacept is administered over a 30-minute infusion at a weight-based dose: for the average adult (60 – 100 kg) a 750-mg dose (using three 250-mg vials) is administered. It should then be given at 2 and 4 weeks after the first infusion, followed by every 4 weeks thereafter. Children ages 6 and up follow the same dosing regimen, with doses of 10 mg/kg.

Rationale for coverage authorization

To provide coverage for abatacept for juvenile idiopathic arthritis and adult rheumatoid arthritis.

Benefit design

- Coverage for abatacept is determined through prior authorization for every claim.

Coverage authorization criteria

- Coverage is provided for the treatment of moderate to severe juvenile idiopathic arthritis.
- Coverage is provided for the treatment of moderate to severe rheumatoid arthritis.
- Coverage is <u>not</u> provided for use in combination with TNF inhibitors or other RA biologics (i.e., *Enbrel*®, *Kineret*®, *Humira*®, *Remicade*®, Rituxan® or Cimzia®.)

Coverage duration: 5 years. Coverage may be renewed.

References

- *Orencia*® (Abatacept). Prescribing information. Princeton, NJ: Bristol-Myers Squibb. April 2008.
- Schiff M, Keiserman M, Codding C, et al. Efficacy and safety of abatacept or infliximab vs placebo in ATTEST: a phase III, multi-centre, randomised, double-blind, placebo-controlled study in patients with rheumatoid arthritis and an inadequate response to methotrexate. *Ann Rheum Dis*. 2008 Aug;67(8):1096-103. Epub 2007, Nov 29.