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1.0 Description of the Procedure, Product, or Service

Orencia (abatacept) is a biologic drug used to reduce the signs and symptoms of rheumatoid arthritis. It is a fusion protein that blocks T-cell activation. This inhibits the progression of structural damage, which occurs over time with rheumatoid arthritis. Orencia (abatacept) is a selective co-stimulatory signal required for full T-cell activation. T-cell activation is key in rheumatoid arthritis immunopathology.

Rheumatoid arthritis is a chronic condition where the recipient's own immune system causes inflammation of the joints and the tissue around the joints. The body is equipped with a defense mechanism called the immune system which protects you from disease and infection. When a recipient has an autoimmune condition, the immune system creates antibodies that attack its own tissues by mistake. Rheumatoid arthritis usually starts between the age of 25 and 55 and the cause is unknown. Symptoms of rheumatoid arthritis (RA) are described as painful inflammation of the synovial tissue lining the joints. These recipients have elevated levels of tumor necrosis factor-alpha (TNF-a) in their joints. Chronic joint inflammation leads to tissue break down, cell damage to the bone, edema, warmth, redness, joint stiffness, and pain. These recipients are also fatigued, weak, have a low-grade fever, and loss of appetite.

Arthritis occurring in children is referred to as juvenile idiopathic arthritis (JIA) (juvenile rheumatoid arthritis (JRA).) Children with JIA have similar symptoms to those which adults with RA exhibit.

1.1 Medical Term Definitions

- a. Antibody: a protein that is produced by the immune system against a specific antigen.
- b. Rheumatoid arthritis: a chronic disease considered to be autoimmune and characterized by pain, stiffness, inflammation, swelling, and sometimes destruction of joints.
- c. T-cells: a type of white blood cell (lymphocyte). It is called T-cell because it is derived from the thymus gland. Its function is to control cell mediated immune reactions.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Orencia (abatacept) may be medically necessary for the treatment of rheumatoid arthritis when the medical criteria and guidelines shown below are met:

- a. The recipient has moderate to severe rheumatoid arthritis.
- b. Orencia (abatacept) may be used alone or in combination with methotrexate.
- c. Orencia (abatacept) may be covered when used for the treatment of moderate to severe juvenile idiopathic arthritis (JIA) in recipients six years and older.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Orencia (abatacept) may not be a covered benefit in the following situations:

- a. When the criteria in **SubSection 3.2** are not met.
- b. Orencia (abatacept) should not be used in combination with Tumor Necrosis Factor (TNF) inhibiting drugs or other rheumatoid arthritis biologics including Rituxan (rituximab) or Kineret (anakinra), an interleukin-1 receptor antagonist.
- c. Orencia (abatacept) is not covered when used for the treatment of multiple sclerosis, systemic lupus erythematosus, graft versus host disease (GVHD) and other non FDA-approved indications. These indications are considered investigational.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for Abatacept.

5.2 Renewal of Authorization

Orencia (abatacept) is administered as a 30 minute IV infusion based on weight. It should be given at two (2) and four (4) weeks after the first infusion, then every four (4) weeks. Authorization may be renewed if the biologic has improved the recipient's condition as determined by clinical assessment or various Rheumatoid Arthritis disease assessment tools.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
	Throughout	Policy Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Abatacept is covered with diagnosis codes 714.0, 714.2, 714.30-714.33.

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

All physician-administered drugs must be billed with appropriate HCPCS code (J0129), National Drug Code (NDC), and NDC units. Claims for Orencia (abatacept) will deny unless prior approval has been obtained.

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Office

G. Co-payments

Co-payment(s) may apply to covered prescriptions and services.

H. Reimbursement

Providers must bill their usual and customary charges.