



Louisiana

abatacept (Orencia[®])

Policy # 00214

Original Effective Date: 09/20/2006

Current Effective Date: 01/01/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Rheumatoid Arthritis

Based on review of available data, the Company may consider abatacept (Orencia[®])[†] for the treatment of adult rheumatoid arthritis (RA) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of abatacept (Orencia) for the treatment of rheumatoid arthritis (RA) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has moderately to severely active rheumatoid arthritis (RA); AND
- Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs); AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- For Orencia SubQ requests or for Orencia intravenous loading dose requests prior to initiating Orencia SubQ therapy: Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: tocilizumab (Actemra^{®†}), etanercept (Enbrel^{®†}), adalimumab (Humira^{®†}), or tofacitinib (Xeljanz^{®†}/XR) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Orencia may be used alone or in combination with disease-modifying anti-rheumatic drugs (DMARDs); AND
- Orencia is NOT given concomitantly with biologic DMARDs, such as adalimumab (Humira) or etanercept (Enbrel), or other drugs such as apremilast (Otezla^{®†}) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g. purified protein derivative [PPD], blood test) prior to treatment.

Juvenile Idiopathic Arthritis

Based on review of available data, the Company may consider the use of abatacept (Orencia) for the treatment of moderately to severely active juvenile idiopathic arthritis (JIA) to be **eligible for coverage**.

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Patient Selection Criteria

Coverage eligibility for the use of abatacept (Orencia) for the treatment of juvenile idiopathic arthritis (JIA) will be considered when all of the following criteria met:

- Patient is 6 years of age or older for Orencia intravenous requests OR 2 years of age or older for Orencia SubQ requests; AND
- Patient has moderately to severely active juvenile idiopathic arthritis (JIA); AND
- Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs); and
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- For Orencia SubQ requests or for Orencia intravenous dose requests with the intent of switching to Orencia SubQ therapy: Patient has failed treatment with adalimumab (Humira) OR etanercept (Enbrel) after at least two months of therapy (unless there is clinical evidence or patient history that suggests that these products will be ineffective or cause an adverse reaction to the patient); AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Orencia may be used as monotherapy or concomitantly with methotrexate (MTX) ; AND
- Orencia is NOT given concomitantly with biologic DMARDs, such as adalimumab (Humira) or etanercept (Enbrel), or other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g. purified protein derivative [PPD], blood test) prior to treatment.

Psoriatic Arthritis

Based on review of available data, the Company may consider abatacept (Orencia) for the treatment of adult psoriatic arthritis (PsA) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of abatacept (Orencia) for the treatment of psoriatic arthritis (PsA) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has psoriatic arthritis (PsA); AND
- Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs); AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- For Orencia SubQ requests or for Orencia intravenous loading dose requests prior to initiating Orencia SubQ therapy: Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), ustekinumab (Stelara®†), or secukinumab (Cosentyx®†) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

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*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- Orencia is NOT given concomitantly with biologic DMARDs, such as adalimumab (Humira) or etanercept (Enbrel), or other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g. purified protein derivative [PPD], blood test) prior to treatment.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of abatacept (Orencia) when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as not **medically necessary****).

Based on review of available data, the Company considers the use of abatacept (Orencia) for indications other than those listed above to be **investigational.***

When Services Are Considered Not Medically Necessary

Based on review on available data, the Company considers the use of abatacept (Orencia) when any of the following criteria for their respective disease state listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary****:

- For adult rheumatoid arthritis:
 - o Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs)
 - o Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: tocilizumab (Actemra), etanercept (Enbrel), adalimumab (Humira), or tofacitinib (Xeljanz/XR). This criterion only applies to Orencia SubQ requests or Orencia intravenous loading dose requests prior to initiating Orencia SubQ therapy
- For juvenile idiopathic arthritis:
 - o Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDS)
 - o Patient has failed treatment with adalimumab (Humira) OR etanercept (Enbrel) after at least two months of therapy. This criterion only applies to Orencia SubQ requests or for Orencia intravenous dose requests with the intent of switching to Orencia SubQ therapy
- For adult psoriatic arthritis:
 - o Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs)
 - o Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), ustekinumab (Stelara), or secukinumab (Cosentyx). This criterion only applies to Orencia SubQ requests or for Orencia intravenous dose requests with the intent of switching to Orencia SubQ therapy

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Background/Overview

Orencia is an injectable synthetic protein produced by recombinant deoxyribonucleic acid (DNA) technology that is used for the treatment of rheumatoid arthritis as well as juvenile idiopathic arthritis. Orencia is a selective costimulation modulator that binds to CD80 and CD86 to block the interaction with CD28 required for full T lymphocyte (T cell) activation. Activated T cells have been found in the synovium of patients with rheumatoid arthritis. These activated T cells multiply and release chemicals that cause destruction of tissues around the joints, and cause symptoms of rheumatoid arthritis.

Orencia comes as a lyophilized powder for intravenous infusion that provides 250mg of Orencia in a 15mL vial. Orencia also comes in a 125mg/mL single dose prefilled ClickJect autoinjector for subcutaneous use in patients with rheumatoid arthritis and psoriatic arthritis. More recently, 50 mg/0.4mL, 87.5 mg/0.7mL, and 125 mg/mL in a single dose prefilled syringe have been approved for use in juvenile idiopathic arthritis.

Rheumatoid Arthritis

Rheumatoid Arthritis is a chronic (long-term) disease that causes inflammation of the joints and surrounding tissues. It can also affect other organs. It is considered an autoimmune disease. In an autoimmune disease, the immune system confuses healthy tissue for foreign substances. Typically first line treatments such as DMARDs (disease modifying anti-rheumatic drugs) are used to treat this condition. An example of a DMARD would include methotrexate.

Juvenile Idiopathic Arthritis

Juvenile idiopathic arthritis includes the inflammation of joints and presence of arthritis in children. Juvenile idiopathic arthritis typically occurs in a symmetrical manner with knees, wrists, and ankles most frequently affected. However certain subgroups of children do have predominantly asymmetrical involvement. Typically first line treatments such as DMARDs are used to treat this condition. An example of a DMARD would include methotrexate.

Psoriatic Arthritis

Psoriatic arthritis is an arthritis that is often associated with psoriasis of the skin. Typically first line treatments such as DMARDs are used to treat this condition. An example of a DMARD would include methotrexate.

Disease-Modifying Anti-Rheumatic Drugs

Disease-modifying anti-rheumatic drugs are typically used for the treatment of rheumatoid arthritis and juvenile idiopathic arthritis. These drugs slow the disease process by modifying the immune system.

- Methotrexate
- Cyclosporine
- Sulfasalazine
- Mercaptopurine
- Gold Compounds

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Orencia is approved for the treatment of moderately to severely active rheumatoid arthritis in adults. Orencia is also approved to treat juvenile idiopathic arthritis in patients 2 years of age and older. It should be noted that the intravenous form of Orencia for use in juvenile idiopathic arthritis is only approved for those 6 years of age or older. In 2017, Orencia also gained an indication for use in adults with psoriatic arthritis.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The approval of Orencia for adult rheumatoid arthritis is based on outcome data from three double blind, randomized, placebo-controlled trials that evaluated the biologic agent in adults with rheumatoid arthritis who had an unsuccessful response to other rheumatoid arthritis drugs. These trials include the Abatacept Trial in Treatment of Anti-TNF Inadequate responders (ATTAIN), Abatacept in Inadequate responders to Methotrexate (AIM), and Abatacept Study of Safety in Use with other RA therapies (ASSURE).

In the AIM study, which was a one year placebo controlled Phase III trial using a fixed dose of Orencia in patients with active rheumatoid arthritis despite methotrexate treatment. This study showed that Orencia plus methotrexate inhibits radiographic progression of joint damage significantly better than placebo plus methotrexate.

The purpose of the ASSURE trial was to assess the safety of combination therapy with Orencia and approved biologic and non-biologic DMARDs in patients with active rheumatoid arthritis. This study showed that Orencia and placebo have a similar safety profile when added to DMARD therapy in patients with active rheumatoid arthritis and co-morbidities. However, Orencia added with biologic therapy showed the least favorable profile with increased incidences of adverse events and infections.

The ATTAIN study is a randomized, double blind, phase III trial that evaluated the efficacy of Orencia in patients with active rheumatoid arthritis and an inadequate response to anti-TNF-alpha therapy. In both phase III studies (AIM and ATTAIN), Orencia demonstrated significant improvement in the signs and symptoms of RA as measured by the American College of Rheumatology (ACR). Significant improvements in physical function were noted as compared to placebo. These improvements were maintained up to three years in a Phase II trial of patients with inadequate response to methotrexate.

The approval of intravenous Orencia for juvenile idiopathic arthritis was assessed in a three part study (JIA-1) in patients 6-17 years of age. The ACR scores were assessed in these patients at the end of the first part of the study and the pediatric ACR 30/50/70 responses were 65%, 50%, and 28%, respectively. Period B

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included a withdrawal phase and patients on abatacept had fewer disease flares than those patients treated with placebo. The last part of the trial was an open label extension.

The approval of subcutaneous Orencia for juvenile idiopathic arthritis without an intravenous loading dose was assessed in study JIA-2, which was a 2 period, open label study that included children 2 to 17 years of age. At study entry, 80% of subjects were taking methotrexate and remained stable on their dose of methotrexate. The ACR 30/50/70 responses assessed at 4 months in the 2 to 17 year old patients were consistent with the results from the intravenous study, JIA-1.

Orencia was assessed in 594 patients with psoriatic arthritis in two trials. The primary endpoint for both trials was the proportion of patients achieving an ACR20 response at week 24. A higher proportion of patients achieved an ACR20 response after treatment with Orencia as compared to placebo at week 24.

References

1. http://www.orencia.com/orencia/home/index.jsp?BV_UseBVCookie=Yes .
2. U.S. Food and Drug Administration. (2009 August) Center for Drug Evaluation and Research. FDA Labeling Information. Orencia (Abatacept). <http://www.fda.gov>.
3. Orencia (abatacept) Package insert. 6/2017.

Policy History

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09/06/2006	Medical Director review
09/20/2006	Medical Policy Committee review
09/05/2007	Medical Director review
09/19/2007	Medical Policy Committee review. Rheumatology criterion removed for patient selection criteria. Policy statements added for not medically necessary, not covered and investigational.
05/07/2008	Medical Director review
05/21/2008	Medical Policy Committee approval. Added new FDA indication for juvenile idiopathic arthritis.
04/02/2009	Medical Director review.
04/15/2009	Medical Policy Committee approval. "Must not be on a live vaccine concurrently with abatacept or within three months of its discontinuation" added as a criteria bullet for adult rheumatoid arthritis.
07/02/2009	Medical Director review.
07/22/2009	Medical Policy Committee approval. Added the criteria bullet: <ul style="list-style-type: none">• May be used alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs) other than TNF antagonists. The When Services Are Not Covered section was deleted from the policy. Added that when patient selection criteria are not met, or if abatacept is used for non-FDA approved indications, to deny investigational.
07/01/2010	Medical Policy Committee approval.
07/21/2010	Medical Policy Implementation Committee approval. No change to coverage.
07/07/2011	Medical Policy Committee approval.
07/20/2011	Medical Policy Implementation Committee approval. No change to coverage.
06/28/2012	Medical Policy Committee approval.

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07/27/2012	Medical Policy Implementation Committee approval. Added a not medically necessary denial section to deny step therapy in absence of inadequate clinical response to one or more therapies specific to the condition such as Disease Modifying Antirheumatic Drugs (DMARDs) or tumor necrosis factor (TNF) antagonists. Juvenile rheumatoid arthritis was removed from list of investigational conditions.
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. Removed requirement regarding vaccines. Clarified that PPD is required. Changed wording of criteria to match policy wording for similar drugs. Moved notes into the patient selection criteria section. Reworded and simplified the investigational and not medically necessary sections.
10/10/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. Added criteria that requires Humira AND Enbrel be tried prior to use of Orencia for Rheumatoid Arthritis. Modified the not medically necessary section to reflect changes.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. No change to coverage.
11/21/2014	Medical Policy Implementation Committee approval. "For Orencia SubQ requests or for Orencia intravenous loading dose requests prior to initiating Orencia SubQ therapy" was added to eligibility criteria, and "This criterion only applies to Orencia SubQ requests or Orencia intravenous loading dose requests prior to initiating Orencia SubQ therapy" was added under the not medically necessary section for adult rheumatoid arthritis section.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Changed age to 2 for juvenile idiopathic arthritis based on changes in the package insert. Delineated between the new subcutaneous injects for juvenile idiopathic arthritis. Changed the nomenclature to drop the term "polyarticular" from juvenile idiopathic arthritis. Updated background information. Updated rationale/source with updated information.
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. For RA, changed to use two of the following: Actemra, Enbrel, Humira, Xeljanz/XR. For JIA, changed to use Humira or Enbrel. For PsA, changed to use two of the following: Enbrel, Humira, Stelara, Cosentyx.
Next Scheduled Review Date:	11/2018

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J0129
ICD-10 Diagnosis	D89.810-D89.813, G35, L40.0-L40.9, M05.00-M05.9, M06.00-M06.9, M08.00-M08.9, M32.0-M32.9, T86.00-T86.99

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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