RX.PA.052.CCH ORENCIA (ABATACEPT) INTRAVENOUS

The purpose of this policy is to define the prior authorization process for Orencia® (abatacept) Intravenous.

Orencia® (abatacept) intravenous is indicated for:

- Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adults with moderately to severely active rheumatoid arthritis (RA)
- Reducing signs and symptoms in pediatric patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA).
- Treatment of active psoriatic arthritis in adults
- 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

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity and approval by the Medical Policy Committee.

The drug, Orencia® (abatacept) intravenous, is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed under the respective diagnosis:

For All Diagnoses:

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.*TB* test (T-Spot)]
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))

- Must have no evidence of active infection
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

1. Rheumatoid Arthritis:

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active rheumatoid arthritis
- Must have an adequate trial (of at least 3 months) of methotrexate to a therapeutic dose of 15mg per week with an inadequate response
    - Members with significant side effects/toxicity or have a contraindication to methotrexate, must have an adequate trial (of at least 3 months) of a different conventional DMARD (such as leflunomide, hydroxychloroquine, or sulfasalazine) with an inadequate response, or significant side effects/toxicity, or have a contraindication to these therapies (see Appendix 1)
- Must have an adequate trial (of at least 3 months) of at least 2 preferred biologic or targeted synthetic DMARDs (such as TNF-alpha inhibitors or JAK inhibitors) with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies
    - Preferred alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

2. Juvenile Idiopathic Arthritis without systemic symptoms, includes polyarticular juvenile arthritis (PJIA):

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 2 or older
- Must have a diagnosis of moderately to severely active juvenile idiopathic arthritis
- Must have an adequate trial (of at least 3 months) of methotrexate or a different conventional DMARD (such as leflunomide or sulfasalazine) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies (see Appendix 1)
    - If no response is observed after at least 6 weeks of therapy on a conventional DMARD, member does not need to complete the 3-month trial before either changing to monotherapy or adding on therapy with a biologic
- Must have an adequate trial (of at least 3 months) of at least 2 preferred biologic or targeted synthetic DMARDs (such as TNF-alpha inhibitors or JAK inhibitors) with an inadequate response, or significant side effects/toxicity, or have a contraindication to these therapies

- Preferred alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

3. Psoriatic Arthritis

- Must be prescribed by or in consultation with a rheumatologist or dermatologist
- Must be age 18 years or older
- Must have a diagnosis of active psoriatic arthritis
- Must meet ONE of the following:
  - *For predominantly axial disease or enthesitis:* Must have an adequate trial (of at least 4 weeks each) with TWO NSAIDs at anti-inflammatory doses with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
  - *For all other types of psoriatic arthritis:* Must have an adequate trial of at least 3 months increased to a therapeutically effective dose on methotrexate or other conventional disease modifying anti-rheumatic drug (DMARD), such as sulfasalazine or leflunomide with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies (See Appendix 1)
- Must have an adequate trial (of at least 3 months) and failure of at least 2 preferred biologic or targeted synthetic DMARDs (such as TNF-alpha inhibitors or JAK inhibitors) with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies
  - Preferred alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

4. Acute Graft versus Host Disease (aGVHD)

- Must be prescribed by or in consultation with a transplant specialist or an oncologist
- Must be age 2 years or older
- Must be undergoing hematopoietic stem cell transplantation (HSCT)
- Must have an adequate trial of methotrexate or mycophenolate mofetil (MMF) AND a calcineurin inhibitor (e.g., cyclosporine, tacrolimus, etc.) with an inadequate response, or significant side effects/toxicity or have a contraindication to these therapies
- Must be used in combination with a calcineurin inhibitor and methotrexate, unless not tolerated or contraindicated

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at one-year intervals based upon:

- Chart documentations from the provider that the member's condition had improved

based upon the prescriber's assessment while on therapy

- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, ifrequired for the plan and level of request.

APPENDIX 1

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin
• Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease • Breastfeeding • Drug interaction • Cannot be used due to risk of treatment-related toxicity (e.g., true allergy, severe side effects that cannot be resolved with dosage or administration modification) • Pregnancy or currently planning pregnancy • Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, renal impairment)

HCPCS Codes:

HPCPS Code	Brand	Description
J0129	**ORENCIA**	INJECTION ABATACEPT 10 mg

REFERENCES

1. Orencia (abatacept) [package insert] Princeton, NJ: Bristol-Myers Squibb Company; December 2021.
2. Genovese MC, Becker JC, Schiff M, Luggen M, Sherrer Y, Kremer J, Birbara C, Jane Box J, Natarajan K, Nuamah I , Li T, Aranda R, Hagerty DT, Dougados M. Abatacept for Rheumatoid Arthritis Refactory to Tumor Necrosis Inhibition. N Engl J Med 2005;353(21): 1114-23
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123

4. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis infection – United States 2010. Department of Health and Human Services Centers for Disease Control and Prevention [U.S.]. vol 59, RR-5. 2010 June 25.
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8. Hamilton BK. Current approaches to prevent and treat GVHD after allogeneic stem cell transplantation. *Hematology Am Soc Hematol Educ Program*. 2018;2018(1):228-235.
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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial Review	3/22