NOTE: For requests for the IV dosage form of Orencia, please see the Orencia IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: for RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist
   - previous trial with at least one of the following DMARDs (disease-modifying antirheumatic drug) agents such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 18 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), or a TNF (tumor necrosis factor) inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria
   - previous trial with 2 preferred formulary TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

   If yes, approve for 4 months by GPID with a maximum quantity limit of #4 syringes per 28 days.

   APPROVAL TEXT: Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. If no, do not approve.

   DENIAL TEXT: Our guideline for ABATACEPT - SQ requires a diagnosis of moderate to severe rheumatoid arthritis. Additional guideline requirements apply.

   For patients with moderate to severe rheumatoid arthritis, our guideline requires:
   - therapy initiated by or in consultation with a rheumatologist
   - previous trial with at least one of the following DMARDs (disease-modifying antirheumatic drug) agents such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 18 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), or a TNF (tumor necrosis factor) inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria
   - previous trial with 2 preferred formulary TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

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ABATACEPT - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets all of the following criteria?
   • documentation that the patient experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy?

   If yes, approve for 12 months by GPIID with a quantity limit of #4 syringes per 28 days.
   If no, do not approve.

   DENIAL TEXT: Our guideline for ABATACEPT - SQ renewal requires a diagnosis of moderate to severe rheumatoid arthritis. Additional guideline requirements apply.

   Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:
   • Documentation that the patient experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy.

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for abatacept. Abatacept subcutaneous administration is only approved for the treatment of adult RA. Abatacept intravenous administration is approved for both treatment of adult RA and juvenile idiopathic arthritis.

FDA APPROVED INDICATIONS
Monotherapy or concomitant use with DMARDs other than TNF antagonists in patients with moderate to severe active rheumatoid arthritis or concomitantly with MTX for moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older.

Adult Rheumatoid Arthritis (RA)
Moderately to severely active RA in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older. ORENCIA may be used as monotherapy or concomitantly with MTX. The safety and efficacy of subcutaneous Orencia injection has not been studied in patients under 18 years of age.

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ABATACEPT - SQ

FDA APPROVED INDICATIONS (CONTINUED)
Important Limitations of Use
Should not be given concomitantly with TNF antagonists. Orencia is not recommended for use concomitantly with other biologic rheumatoid arthritis therapy such as anakinra.

REFERENCES

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<tr>
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<th>Commercial</th>
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