Orencia

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*cm*

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

 MR Biosimilar Orencia SGM 2127-A – 10/2022.

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

Exception Criteria Questions:

A. Is the product being requested for the treatment of one of the following indications?
- Ankylosing spondylitis
- Crohn's disease
- Plaque psoriasis
- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Rheumatoid arthritis

❑ Yes ❑ No *If No, skip to Site of Service Questions*

B. These are the preferred products for which coverage is provided for treatment of the following indications:
- Ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis: **Simponi Aria**
- Plaque psoriasis: **Ilumya**
- Polyarticular juvenile idiopathic arthritis: **Simponi Aria**
- Crohn's disease: **Entyvio and Stelara IV**

Can the patient's treatment be switched to a preferred product?
❑ Yes, *Please obtain Form for preferred product and submit for corresponding PA*.
❑ No

If diagnosis is Plaque psoriasis, skip to Question K

C. Is this request for continuation of therapy with the requested product? ❑ Yes ❑ No, *If No, skip to Question E*

D. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If unknown, answer Yes. ❑ Yes ❑ No *If No, skip to Site of Service Questions*

E. What is the diagnosis?
❑ Ankylosing spondylitis, *skip to Question P*
❑ Crohn's disease, *skip to Question I*
❑ Psoriatic arthritis
❑ Polyarticular juvenile idiopathic arthritis, *skip to Question M*
❑ Rheumatoid arthritis
❑ Other, *skip to Site of Service Questions*

F. Is the request for an adult patient (18 years of age or older)? ❑ Yes ❑ No *If No, skip to Site of Service Questions*

G. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product (Simponi Aria)? ***.ACTION REQUIRED: If 'Yes', attach supporting chart note(s)***.
❑ Yes, *skip to Site of Service Questions* ❑ No

H. Does the patient have one of the following documented clinical reasons to avoid the preferred product that is a TNF inhibitors (Simponi Aria)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).***
❑ Not applicable – Requested medication is a TNF inhibitor *skip to Site of Service Questions*
❑ Yes – History of demyelinating disorder, *skip to Site of Service Questions*
❑ Yes – History of congestive heart failure *skip to Site of Service Questions*
❑ Yes – History of hepatitis B virus infection *skip to Site of Service Questions*
❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor) *skip to Site of Service Questions*
❑ Yes – History or risk of lymphoma or other malignancy *skip to Site of Service Questions*
❑ Yes – History of being a primary non-responder to a TNF inhibitor (i.e., no clinical response with initial treatment) *skip to Site of Service Questions*
❑ No – None of the above *skip to Site of Service Questions*

I. Is the request for an adult patient (18 years of age or older)? ❑ Yes ❑ No *If No, skip to Site of Service Questions*

J. Does the patient have a documented inadequate response or intolerable adverse event to both of the preferred products (Entyvio and Stelara IV)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).***
If Yes or No, skip to Site of Service Questions ❑ Yes ❑ No

K. Is the request for an adult patient (18 years of age or older) ❑ Yes ❑ No *If No, skip to Site of Service Questions*

L. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product indicated for plaque psoriasis (Ilumya)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** *If Yes or No, skip to Site of Service Questions* ❑ Yes ❑ No

M. Is the request for a patient 2 years of age or older? ❑ Yes ❑ No *If No, skip to Criteria Questions*

N. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product indicated for polyarticular juvenile idiopathic arthritis (Simponi Aria)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** *If Yes, skip to Site of Service Questions* ❑ Yes ❑ No

O. Does the patient have one of the following documented clinical reasons to avoid the preferred product that is a TNF inhibitor (Simponi Aria)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).***
- ❑ Yes – History of demyelinating disorder *skip to Site of Service Questions*
- ❑ Yes – History of congestive heart failure *skip to Site of Service Questions*
- ❑ Yes – History of hepatitis B virus infection *skip to Site of Service Questions*
- ❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor) *skip to Site of Service Questions*
- ❑ Yes – History or risk of lymphoma or other malignancy, *skip to Site of Service Questions*
- ❑ Yes – History of being a primary non-responder to a TNF inhibitor (i.e., no clinical response with initial treatment) *skip to Site of Service Questions*
- ❑ No – None of the above *skip to Site of Service Questions*

P. Is the request for an adult patient (18 years of age or older)? ❑ Yes ❑ No *If No, skip to Site of Service Questions*

Q. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product (Simponi Aria)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No

Site of Service Questions (SOS):

A. Where will this drug be administered?
- ❑ Ambulatory surgical, *skip to Clinical Questions*
- ❑ Home infusion, *skip to Clinical Questions*
- ❑ Off-campus Outpatient Hospital
- ❑ On-campus Outpatient Hospital
- ❑ Physician office, *skip to Clinical Questions*
- ❑ Pharmacy, *skip to Clinical Questions*

B. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes – This is a continuation of an existing treatment
- ❑ No – This is a new therapy request (patient has not received requested medication in the last 6 months) *skip to Clinical Criteria Questions*

C. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

D. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation.
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

E. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.*** *Indicate and continue to Clinical Criteria Questions*
❑ Yes ❑ No

Clinical Criteria Questions:

1. What is the prescribed quantity and frequency?
   a) Loading dose:
   - ❑ Orencia IV 250 mg Quantity and frequency: _____
   - ❑ Orencia SQ 125 mg Quantity and frequency: _____
   - ❑ Orencia SQ 87.5 mg Quantity and frequency: _____
   - ❑ Orencia SQ 50 mg Quantity and frequency: _____
   - ❑ Other _____

   b) Maintenance dose:
   - ❑ Orencia IV 250 mg Quantity and frequency: _____
   - ❑ Orencia SQ 125 mg Quantity and frequency: _____
   - ❑ Orencia SQ 87.5 mg Quantity and frequency: _____
   - ❑ Orencia SQ 50 mg Quantity and frequency: _____
   - ❑ Other _____

2. Has the patient been diagnosed with any of the following?
   - ❑ Moderately to severely active rheumatoid arthritis (RA)
   - ❑ Moderately to severely active **polyarticular** juvenile idiopathic arthritis (pJIA)
   - ❑ Moderately to severely active **oligoarticular** juvenile idiopathic arthritis
   - ❑ Active psoriatic arthritis (PsA)
   - ❑ Chronic graft versus host disease
   - ❑ Immune checkpoint inhibitor-related toxicity
   - ❑ Prophylaxis of acute graft versus host disease
   - ❑ Systemic juvenile idiopathic arthritis (sJIA)
   - ❑ Other _____

3. What is the ICD-10 code? _____

4. What is the patient's weight? __Kg

Section A: All Requests

5. Will the requested drug be used in combination with any other biologic (e.g. Humira) or targeted synthetic disease-modifying antirheumatic drug (DMARD) (e.g., Olumiant, Otezla, Xeljanz)? ❑ Yes ❑ No

6. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic DMARD (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis? *If Yes, skip to #10* ❑ Yes ❑ No

7. Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [PPD], interferon-release assay [IGRA], chest x-ray) within 6 months of initiating therapy? ❑ Yes ❑ No

8. What were the results of the tuberculosis (TB) test?
   ❑ Positive for TB ❑ Negative for TB, *skip to #10* ❑ Unknown

9. Which of the following applies to the patient?
   - ❑ Patient has latent TB and treatment for latent TB has been initiated
   - ❑ Patient has latent TB and treatment for latent TB has been completed
   - ❑ Patient has latent TB and treatment for latent TB has not been initiated
   - ❑ Patient has active TB

10. Is the patient currently receiving Orencia? ❑ Yes ❑ No
    If diagnosis is chronic graft versus host disease, Immune checkpoint inhibitor-related toxicity, or Prophylaxis of acute graft versus host disease, skip to diagnosis section.

11. Is this request for continuation of therapy with the requested drug?
    ❑ Yes ❑ No *If No, skip to diagnosis section.*

12. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to diagnosis section.* ❑ Yes ❑ No ❑ Unknown

13. Has the patient achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms since starting treatment with the requested drug? ❑ Yes ❑ No

Complete the following section based on the patient's diagnosis, if applicable.

Section B: Rheumatoid Arthritis
Continuation

14. What is the percent of disease activity improvement from baseline in tender joint count, swollen joint count, pain, or disability? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.*** _____% *No further questions*

Initiation

15. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) that is indicated for moderately to severely active rheumatoid arthritis? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No

16. Does the patient meet either of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker and the RF biomarker test was positive, or b) the patient was tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker and the anti-CCP biomarker test was positive? ***ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing and skip to #18***. ❑ Yes ❑ No

17. Has the patient been tested for all of the following biomarkers: a) rheumatoid factor (RF), b) anti-cyclic citrullinated peptide (anti-CCP), and c) C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)? ***ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing.*** ❑ Yes ❑ No

18. Has the patient experienced an inadequate response after at least 3 months of treatment with methotrexate at a dose greater than or equal to 15 mg per week? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions***. ❑ Yes ❑ No

19. Has the patient experienced an intolerance to methotrexate? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.*** ❑ Yes ❑ No

20. Does the patient have a contraindication to methotrexate? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy and indicate the contraindication.*** ❑ Yes ❑ No ***If Yes, please indicate the contraindication:*** _____

Section C: Articular Juvenile Idiopathic Arthritis
Continuation

21. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.*** *No further questions after answering.*
    - ❑ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
    - ❑ Functional ability
    - ❑ Number of joints with limitation of movement
    - ❑ None of the above

Initiation

22. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic disease-modifying antirheumatic drug (DMARD) indicated for moderately to severely active articular juvenile idiopathic arthritis? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No

23. Has the patient had an inadequate response to methotrexate or another non-biologic DMARD administered at an adequate dose and duration? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record***

documentation, or claims history supporting previous medications tried, including response to therapy and no further questions. ❑ Yes ❑ No

24. Does the patient have any of the following risk factors?
    ❑ Positive rheumatoid factor ❑ Pre-existing joint damage
    ❑ Positive anti-cyclic citrullinated peptide antibodies ❑ None of the above

25. Does the patient meet any of the following?
    ❑ High-risk joints are involved (e.g., cervical spine, wrist, or hip) ❑ High disease activity
    ❑ High risk for disabling joint disease ❑ None of the above

Section D: Psoriatic Arthritis

Continuation

26. Which of the following has the patient experienced an improvement in from baseline?
    ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response. *No further questions after answering.*
    ❑ Number of swollen joints ❑ Enthesitis ❑ Number of tender joints
    ❑ Skin and/or nail involvement ❑ Dactylitis ❑ None of the above

Section E: Chronic Graft Versus Host Disease

27. Has the patient experienced an inadequate response to systemic corticosteroids? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #29.*** ❑ Yes ❑ No

28. Does the patient have an intolerance or contraindication to corticosteroids? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

29. Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? ❑ Yes ❑ No

Section F: Immune Checkpoint Inhibitor-Related Toxicity

30. Does the patient have cardiac toxicity? ❑ Yes ❑ No

31. Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? ❑ Yes ❑ No

Section G: Prophylaxis of Acute Graft Versus Host Disease

32. Is the patient undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor? ❑ Yes ❑ No

33. Will the requested medication be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate? ❑ Yes ❑ No

Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	Yes	No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720