# ORENCIA® SC Assist

1-800-ORENCIA (1-800-673-6242) 1-817-767-4614

ORENCIA® (abatacept)

## PATIENT INFORMATION (REQUIRED to be completed)

### Patient Contact Information

Patient name: *(first and last name)* ☐ Male ☐ Female Birth date: / /

Address: City: State: Zip:

Home phone: Mobile:

### Insurance Information

**Do you have insurance through:**

☐ Private/Employer-based insurance ☐ VA or military ☐ State assistance program for medication ☐ Medicaid

Medicare: ☐ Part D ☐ Medicare Advantage ☐ None

Primary Prescription Drug Insurance carrier: Policy ID Number:

Phone: Group #: Rx BIN Number: Rx PCN Number:

Secondary Prescription Drug Insurance carrier: Policy ID Number:

Phone: Group #: Rx BIN Number: Rx PCN Number:

## PHYSICIAN (REQUIRED to be completed by Physician)

### Assistance Requested

☐ Benefits Review, Prior Authorization ☐ Appeals Assistance ☐ ORENCIA Commence Rx (If checked, please complete ORENCIA Commence Rx Program Section)

### Administration Form/Diagnosis

**Please indicate one or both administration forms desired:** ☐ Prefilled Syringe ☐ ClickJect™ Autoinjector

**Clinical Information** Patient Diagnosis: ICD 10 Code of FDA approved use _____

### Physician Information

Physician Name (first and last name): State License #: Physician NPI #: State Medicaid #:

Facility Name: Phone: Fax:

Facility Address: City: State: Zip:

Primary Contact Name: Title: Primary Contact Email Address:

Phone: Fax: Preferred Method of Communication ☐ Phone ☐ Fax ☐ Both Note: If no option is selected, form will default to Both.

### Physician Certification

**If third party information is not received in order for BMS to provide verification, supporting information from the patient's EMRs will need to be provided.**
I certify to the following: (1) to the best of my knowledge, the information that I provide to BMS in this form is complete and accurate; (2) I have the authority to disclose this patient's information to BMS and its respective agents and assignees, and I have obtained this patient's authorization for the disclosure, if required by HIPAA or other applicable privacy laws; and (3) treatment with the above medication is medically necessary and for an FDA-approved use. I understand that BMS (1) may verify all information provided, and not allow or suspend participation if inadequate information is received; (2) may modify, limit, or terminate these programs, or recall or discontinue medications, at any time without notice; and (3) is relying on these certifications.

**SIGNATURE** **Prescriber's signature** **Date**

Physician or Licensed Prescriber signature (required—no stamps)

## ORENCIA (abatacept) Commence Rx Program (REQUIRED to be completed by Physician if applicable)

**Available for commercially insured patients only.** For eligible commercially insured new subcutaneous (SC) ORENCIA patients, if a coverage determination is delayed for more than ten (10) business days, the patient will be provided subcutaneous (SC) ORENCIA at no cost until coverage is received, a prior authorization is denied and not appealed, or for one year, whichever is earlier. Please see the complete Terms and Conditions on page 2 and complete this section if you would like your patient to be considered for this program.

### Dispensing Instructions for ORENCIA SC

☐ 125-mg ClickJect™ Autoinjector SC once-weekly, Quantity #4, 12 refills

☐ 50-mg pre-filled syringe SC once-weekly, Quantity #4, 12 refills

☐ 87.5-mg pre-filled syringe SC once-weekly, Quantity #4, 12 refills

☐ 125-mg pre-filled syringe SC once-weekly, Quantity #4, 12 refills

### Delivery Instructions:

Patient Name: _____

Patient Phone Number: _____

Patient Street Address: _____

City, State, Zip: _____

Medication is dispensed directly to the patient's home address (shipments cannot be sent to PO Boxes). Medication will not be sent to the patient's healthcare provider. Prescribers must comply with the prescription requirements of their state. For prescribers in a state with official prescription form requirements, such as New York, please submit prescriptions on an official state prescription form, in addition to this form.

**SIGNATURE** **Prescriber's signature** **Date**

Physician or Licensed Prescriber Signature (required—no stamps)

# ORENCIA® SC Assist

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ORENCIA® (abatacept)

## ORENCIA Commence Rx Terms & Conditions

1. This offer is available to eligible commercially insured, new subcutaneous ORENCIA® patients only.
2. Patients who have prescription insurance coverage through Medicare, Medicaid, or any other federal or state healthcare program, or who are residents of Massachusetts and Michigan, are not eligible. Offer is available for no more than 6 months to residents of Minnesota and Rhode Island.
3. Available only for patients being treated with subcutaneous ORENCIA for an FDA-approved indication.
4. If a coverage determination is delayed for more than ten (10) business days, the patient will be provided subcutaneous ORENCIA at no cost until coverage is received, a prior authorization is denied and not appealed, or for one year, whichever is earlier.
5. Patients continuing into the following year will be re-verified for eligibility in January. For patients whose insurance coverage changes during the course of program participation and otherwise remain eligible, a new prior authorization needs to be submitted.
6. Program reserves the right to re-verify patient's insurance coverage at any point during the patient's participation in the program.
7. No claim for reimbursement for product dispensed pursuant to this offer may be made to any third-party payer.
8. This offer is not conditioned on any past, present, or future purchase, including refills.
9. Valid only in the US.
10. This offer is not health insurance.
11. Other restrictions may apply.
12. Bristol Myers Squibb reserves the right to rescind, revoke, or amend this offer at any time without notice.

## IMPORTANT SAFETY INFORMATION FOR ORENCIA® (abatacept)

### Indications and Usage

**Adult Rheumatoid Arthritis:** ORENCIA® (abatacept) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).

**Polyarticular Juvenile Idiopathic Arthritis:** ORENCIA is indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA).

**Adult Psoriatic Arthritis:** ORENCIA is indicated for the treatment of adult patients with active psoriatic arthritis (PsA).

**Limitations of Use:** The concomitant use of ORENCIA with other potent immunosuppressants [e.g., biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended.

### Important Safety Information for ORENCIA

**Concomitant Use with TNF Antagonists, Other Biologic RA/PsA Therapy, or JAK Inhibitors:** Concurrent therapy with ORENCIA and a TNF antagonist is not recommended. In controlled clinical trials, adult RA patients receiving concomitant intravenous ORENCIA and TNF antagonist therapy experienced more infections (63% vs 43%) and serious infections (4.4% vs 0.8%) compared to patients treated with only TNF antagonists, without an important enhancement of efficacy. Additionally, concomitant use of ORENCIA with other biologic RA/PsA therapy or JAK inhibitors is not recommended.

**Hypersensitivity:** There were 2 cases (<0.1%; n=2688) of anaphylaxis reactions in clinical trials with adult RA patients treated with intravenous ORENCIA. Other reactions potentially associated with drug hypersensitivity, such as hypotension, urticaria, and dyspnea, each occurred in <0.9% of patients. There was one case of a hypersensitivity reaction with ORENCIA in pJIA clinical trials (0.5%; n=190). In postmarketing experience, fatal anaphylaxis following the first infusion of ORENCIA and life-threatening cases of angioedema have been reported. Angioedema has occurred as early as after the first dose of ORENCIA, but also has occurred with subsequent doses. Angioedema reactions have occurred within hours of administration and in some instances had a delayed onset (i.e., days). Appropriate medical support measures for treating hypersensitivity reactions should be available for immediate use. If an anaphylactic or other serious allergic reaction occurs, administration of intravenous or subcutaneous ORENCIA should be stopped immediately and permanently discontinued, with appropriate therapy instituted.

**Infections:** Serious infections, including sepsis and pneumonia, were reported in 3% and 1.9% of RA patients treated with intravenous ORENCIA and placebo, respectively. Some of these infections have been fatal. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy which, in addition to their underlying disease, could further predispose them to infection. Caution should be exercised in patients with a history of infection or underlying conditions which may predispose them to infections. Treatment with ORENCIA should be discontinued if a patient develops a serious infection. Patients should be screened for tuberculosis and viral hepatitis in accordance with published guidelines, and if positive, treated according to standard medical practice prior to therapy with ORENCIA.

**Immunizations:** Prior to initiating ORENCIA in pediatric and adult patients, update vaccinations in accordance with current vaccination guidelines. Live vaccines should not be given concurrently with ORENCIA or within 3 months after discontinuation. ORENCIA may blunt the effectiveness of some immunizations.

**Use in Patients with Chronic Obstructive Pulmonary Disease (COPD):** In Study V, adult COPD patients treated with ORENCIA for RA developed adverse events more frequently than those treated with placebo, including COPD exacerbations, cough, rhonchi, and dyspnea. In the study, 97% of COPD patients treated with ORENCIA developed adverse events versus 88% treated with placebo. Respiratory disorders occurred more frequently in patients treated with ORENCIA compared to those on placebo (43% vs 24%, respectively), including COPD exacerbation, cough, rhonchi, and dyspnea. A greater percentage of patients treated with ORENCIA developed a serious adverse event compared to those on placebo (27% vs 6%), including COPD exacerbation [3 of 37 patients (8%)] and pneumonia [1 of 37 patients (3%)]. Use of ORENCIA in patients with COPD should be undertaken with caution, and such patients monitored for worsening of their respiratory status.

**Immunosuppression:** In clinical trials in adult RA patients, a higher rate of infections was seen in ORENCIA-treated patients compared to placebo-treated patients. The impact of treatment with ORENCIA on the development and course of malignancies is not fully understood. There have been reports of malignancies, including skin cancer in patients receiving ORENCIA. Periodic skin examinations are recommended for all ORENCIA-treated patients, particularly those with risk factors for skin cancer.

**Blood Glucose Testing:** ORENCIA for intravenous administration contains maltose, which may result in falsely elevated blood glucose readings on the day of infusion when using blood glucose monitors with test strips utilizing glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ). Consider using monitors and advising patients to use monitors that do not react with maltose, such as those based on glucose dehydrogenase nicotine adenine dinucleotide (GDH-NAD), glucose oxidase or glucose hexokinase test methods. ORENCIA for subcutaneous (SC) administration does not contain maltose; therefore, patients do not need to alter their glucose monitoring.

**Pregnancy:** There are no adequate and well-controlled studies of ORENCIA use in pregnant women and the data with ORENCIA use in pregnant women are insufficient to inform on drug-associated risk. A pregnancy registry has been established to monitor pregnancy outcomes in women exposed to ORENCIA during pregnancy. Healthcare professionals are encouraged to register patients by calling 1-877-311-8972.

**Lactation:** There is no information regarding the presence of abatacept in human milk, the effects on the breastfed infant, or the effects on milk production. However, abatacept was present in the milk of lactating rats dosed with abatacept.

**Most Serious Adverse Reactions:** Serious infections (3% ORENCIA vs 1.9% placebo) and malignancies (1.3% ORENCIA vs 1.1% placebo).

**Malignancies:** The overall frequency of malignancies was similar between adult RA patients treated with ORENCIA or placebo. However, more cases of lung cancer were observed in patients treated with ORENCIA (0.2%) than those on placebo (0%). A higher rate of lymphoma was seen compared to the general population; however, patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. The potential role of ORENCIA in the development of malignancies in humans is unknown..

**Most Frequent Adverse Events (≥10%):** Headache, upper respiratory tract infection, nasopharyngitis, and nausea were the most commonly reported adverse events in the adult RA clinical studies. Other events reported in ≥5% of pJIA patients were diarrhea, cough, pyrexia, and abdominal pain. In general, the adverse events in pediatric pJIA and adult PsA patients were similar in frequency and type to those seen in adult RA patients.

**Note concerning ORENCIA administration options:** ORENCIA may be administered as an intravenous infusion only for patients 6 years of age and older. PJIA patients may self-inject with ORENCIA or the patient's caregiver may administer ORENCIA if both the healthcare practitioner and the parent/legal guardian determines it is appropriate. The ability of pediatric patients to self-inject with the autoinjector has not been tested.

## PATIENT

### Patient Authorization & Agreement

The ORENCIA® SC Assist and Commence Rx programs are support programs by Bristol-Myers Squibb Company (BMS) that help patients understand their insurance coverage for subcutaneous ORENCIA, as well as provide free medication assistance to those who qualify. To participate in these programs, we will need to receive, use, and disclose your personal information. Please read this authorization carefully, and contact BMS at 1-800-ORENCIA if you have any questions. Once you have read and agreed to this form, fax your signed copy to 1-817-767-4614.

**1. What information will be used and disclosed?**

My personal information will be disclosed, including:

- Information on the ORENCIA SC Assist enrollment form
- My contact information and date of birth
- Social Security number (which is voluntary)
- Insurance benefit information
- Health records and information, including medications
- Biometric & Genetic information, including tests that identify the kind of illness that I have and/or medication indicated for my treatment

**2. Who will disclose, receive, and use the information?**

This authorization permits my caretakers, which includes my healthcare providers, pharmacists, health plans, and health insurers who provide services to me, as well as other people that I say can help me apply, to disclose my personal information to BMS and its authorized agents and assignees (its "Administrators"). BMS and its Administrators may also share my information with my caretakers and with other healthcare providers, pharmacists, health insurers, and charitable organizations to determine if I am eligible for, or enrolled in, another plan or program.

**3. What is the purpose for the use and disclosure?**

My personal information will be used by and shared with the persons and organizations described in this authorization to:

- Process my application for the ORENCIA SC Assist program and provide the program services to me, including verifying my insurance benefits, researching insurance coverage options, and referring me and my caretakers to other plans, support, or assistance programs that may be able to help me
- Contact my caretakers and me about the BMS support programs and services that are available to me, including Copay Assistance and, if I choose, sharing my personal information, including benefits information, with these programs in order to help me enroll
- Provide me with free medication through the Commence Rx program, if I qualify
- Administer BMS support programs, including analyzing the use and effectiveness of BMS support programs, business and communication planning, and improving or developing program services and materials

**4. When will this authorization expire?**

This authorization will be effective for 5 years unless it expires earlier by law or I cancel it in writing. I may cancel this authorization for either or both programs by writing to:

**ORENCIA SC Assist**
**P.O. Box 221509**
**Charlotte, NC 28222-1509**

If I cancel this authorization for a program, I will no longer be able to participate in that program. That program will stop using or disclosing my information for the purposes listed in this authorization, except as necessary to end my participation or as required or allowed by law. Canceling your authorization for these programs will not cancel your participation in any other BMS program.

**(continued on next page)**

**PATIENT OR PERSONAL REPRESENTATIVE INITIALS** _____

## PATIENT

Patient Authorization & Agreement

**5. Notices:**

I understand that once my health information has been disclosed, privacy laws may no longer restrict its use or disclosure. If I cancel this authorization, the Program will stop using or disclosing my information for the purposes listed here, except as allowed or required by law or as necessary to end my participation in the program. I also have a right to receive a copy of this form after I have signed it. The Program agrees use and disclose my information only for the purposes described in this authorization or as allowed or required by law. BMS and its Administrators does not sell or rent personal information collected about you from this program. I further understand that I may refuse to sign this authorization and that if I refuse, my eligibility for health plan benefits and treatment by my healthcare providers will not change, but I will not have access to receive ORENCIA SC Assist program assistance or free drug, if eligible through the Commence Rx program. I understand that certain state laws may allow for the right to request access to, or deletion of, my information. I understand that these state rights are not absolute and only apply in certain circumstances. Therefore, I acknowledge that BMS may not respond or address my requests to the extent required or permitted under relevant laws. I agree that I may need to provide additional information in order to verify my identity, such as a government-issued ID, before BMS will honor a request to provide access to, or deletion of, my information. BMS will not discriminate against me for exercising my rights, but I understand that it may not be able to provide me with program services if it is not able to use my information. To submit an access or deletion request, I may call 855-961-0474 or complete the online form at www.bms.com/dpo/us/request.

**6. Patient certifications:**

I certify that the personal information that I provide to BMS is true and complete. I agree that, at any time during my participation in ORENCIA SC Assist and Commence Rx programs, BMS may request additional documentation to verify my personal information.If there is missing information or I do not respond to requests for additional documents, my participation may be delayed or I may no longer be able to participate.

If I qualify for, and receive, free medication assistance from BMS, I agree to comply with the Commence Rx program Terms and Conditions and I will not get reimbursed for the assistance I receive from anyone else, including from an insurance program, another charity, or from a health savings, flexible spending, or other health reimbursement account. I understand that assistance with free medication is temporary. I will contact ORENCIA SC Assist at 1-800-673-6242 if my insurance or treatment changes in any way.

**I HAVE READ THIS AUTHORIZATION AND AGREE TO ITS TERMS:**

Print Name of Patient or Personal Representative:

Description of Personal Representative's Authority:

Preferred E-mail Address:

Patient Date of Birth: Zip: Initials:

Date:

**SIGNATURE OF PATIENT OR PERSONAL REPRESENTATIVE**

**The patient or his/her personal representative must be provided with a copy of pages 3 and 4 of this form after it has been signed.**