KEVZARAconnect®

Enrollment Form

Prescription Information and KevzaraConnect® Patient Enrollment Form

Complete and fax pages 1-4 to KevzaraConnect® at 1-844-538-8960.

For additional assistance, call us at 1-844-KEVZARA (1-844-538-9272), Option 1, M-F 8 AM-8 PM ET

KEVZARA® (sarilumab) injection 200 mg | 150 mg

Please see Indication and Important Safety Information on pages 5-7. Click here to see the full Prescribing Information including Boxed WARNING.

PATIENT TO FILL OUT

SECTION 1 – Patient Information

Patient Name (First, MI, Last) _____ DOB (mm/dd/yyyy) _____ Gender ☐ M ☐ F

Street Address _____ Mobile Phone _____ ☐ Preferred # ☐ Voicemail

City _____ State _____ ZIP Code _____ ☐ I have read the Text Messaging Consent in Section 7 and expressly consent to receive text messages by or on behalf of the Program.

Preferred Patient Language (if not English) _____

Email _____ Alternate Phone _____ ☐ Preferred # ☐ Voicemail

PATIENT AUTHORIZATION

I have read and agree to the Patient Certifications included in Section 7.

Sign _____ Date (mm/dd/yyyy) _____

Patient Signature/Legal Representative

If signed by a legal representative

Printed Name _____ Relationship to patient _____

I have read and agree to the Patient Authorization to Use and Disclose Health Information included in Section 8.

Sign _____ Date (mm/dd/yyyy) _____

Patient Signature/Legal Representative

If signed by a legal representative

Printed Name _____ Relationship to patient _____

SECTION 2 – Insurance Information (Please attach copies of front and back of medical and prescription cards.)

☐ **CHECK IF PATIENT DOES NOT HAVE INSURANCE (Please see Section 6 for Patient Assistance Program eligibility.)**

Primary Medical Insurance _____ Insurance Phone _____

Policy ID Number _____ Group Number _____

Policy Holder Name (First, Last) _____ DOB (mm/dd/yyyy) _____

Relationship to Patient _____

Primary Prescription Drug Insurance ☐ **Secondary Insurance card attached**

Primary Prescription Drug Insurance Name _____

Insurance Phone _____

Policy ID Number _____ Group Number _____

Rx BIN Number _____ Rx PCN Number _____

PRESCRIBER TO FILL OUT

SECTION 3 – Prescriber Information

Prescriber Name (First, MI, Last) _____ Practice Name _____ Group Tax ID # _____

Specialty _____ Title _____ Street Address _____

NPI# _____ State License # _____ City _____ State _____ ZIP Code _____

Office Contact Name _____ Phone _____ Fax _____

Office Contact Email _____

SECTION 4 – Clinical and Diagnosis Information (Please attach any clinical or office notes relevant to therapy.)

Primary ICD-10 Diagnosis Code _____ **Other ICD-10 Diagnosis Code (please specify)** _____ TB/PPD Test Date _____ ☐ POS ☐ NEG

Allergies _____ Current Medications _____

Current/Prior Failed RA Medication(s) Treatment		Length (mm/yyyy) – (mm/yyyy)	Reason for Discontinuation (if applicable)	Current/Prior Failed RA Medication(s) Treatment		Length (mm/yyyy) – (mm/yyyy)	Reason for Discontinuation (if applicable)
☐ ACTEMRA® (tocilizumab)	☐ Current ☐ Prior ☐ Failed	–		☐ REMICADE® (infliximab)	☐ Current ☐ Prior ☐ Failed	–	
☐ CIMZIA® (certolizumab)	☐ Current ☐ Prior ☐ Failed	–		☐ RITUXAN® (rituximab)	☐ Current ☐ Prior ☐ Failed	–	
☐ ENBREL® (etanercept)	☐ Current ☐ Prior ☐ Failed	–		☐ SIMPONI®/SIMPONI ARIA® (golimumab)	☐ Current ☐ Prior ☐ Failed	–	
☐ HUMIRA® (adalimumab)	☐ Current ☐ Prior ☐ Failed	–					
☐ methotrexate	☐ Current ☐ Prior ☐ Failed	–		☐ XELJANZ® (tofacitinib)	☐ Current ☐ Prior ☐ Failed	–	
☐ ORENCIA® (abatacept)	☐ Current ☐ Prior ☐ Failed	–		☐ Other	☐ Current ☐ Prior ☐ Failed	–	

SECTION 5 – Prescription Information

My Preferred Specialty Pharmacy Name _____ Phone _____ Fax _____

☐ I have already sent this prescription to the specialty pharmacy above. By checking this box, I acknowledge that KevzaraConnect will NOT conduct a benefits verification. The specialty pharmacy is responsible for securing coverage on my patient's behalf.

KEVZARA Injection: single dose pre-filled pen, Package of 2

☐ 200 mg/1.14 mL ☐ 150 mg/1.14 mL

Quantity____ (package of 2) Refills_____ Days' supply ☐ 30 ☐ 90

SIG ☐ 1 injection subcutaneously every 2 weeks ☐ Other_____

KEVZARA Injection: single dose pre-filled syringe, Package of 2

☐ 200 mg/1.14 mL ☐ 150 mg/1.14 mL

Quantity____ (package of 2) Refills_____ Days' supply ☐ 30 ☐ 90

SIG ☐ 1 injection subcutaneously every 2 weeks ☐ Other_____

My signature certifies that the person named on this form is my patient, the information provided on this application, to the best of my knowledge, is complete and accurate, and that therapy with KEVZARA is medically necessary. I understand that my patient's information provided to Regeneron Pharmaceuticals, Inc., Sanofi US, and their affiliates and agents (the "Alliance"), is for the use of KevzaraConnect solely to verify my patient's insurance coverage, to assess, if applicable, my patient's eligibility for patient assistance and other support programs, and to otherwise administer KEVZARA for the patient. I request that KevzaraConnect conduct a benefit investigation for my patient and authorize KevzaraConnect to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan; provided that if this prescription is not so designated, KevzaraConnect is authorized to transmit this prescription to a network pharmacy it selects, or to the pharmacy otherwise indicated. I understand that free product is not contingent on any purchase obligations. I also understand that no free product may be submitted for reimbursement to any payer, including Medicare, and Medicaid; and no free product may be sold, traded, or distributed for sale. I consent to KevzaraConnect contacting me by fax, mail, or email to provide additional information about KEVZARA injection or KevzaraConnect, and that KevzaraConnect may revise, change, or terminate any program services at any time without notice to me.

If you are a New York prescriber, please use an original New York State prescription form. The prescriber is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance with state specific requirements could result in outreach to the prescriber.

Sign _____ **Collaborating MD Name** _____ **NPI#** _____

Prescriber Signature (No Stamps) ☐ Dispense as Written Date (mm/dd/yyyy)

Quick Start Prescription Information

KEVZARA Injection: single dose pre-filled pen, Package of 2

☐ 200 mg/1.14 mL ☐ 150 mg/1.14 mL

Quantity____ (package of 2) Refills_____ Days' supply ☐ 30 ☐ 90

SIG ☐ 1 injection subcutaneously every 2 weeks ☐ Other_____

KEVZARA Injection: single dose pre-filled syringe, Package of 2

☐ 200 mg/1.14 mL ☐ 150 mg/1.14 mL

Quantity____ (package of 2) Refills_____ Days' supply ☐ 30 ☐ 90

SIG ☐ 1 injection subcutaneously every 2 weeks ☐ Other_____

I authorize for **my commercially insured patient** one or more months of temporary shipments of KEVZARA during a benefits determination delay or during the appeals process after an initial coverage denial for KEVZARA by the patient's insurer. I authorize KevzaraConnect to forward this prescription to the pharmacy dispensing the KEVZARA Quick Start Program product to the patient named herein.

If you are a New York prescriber, please use an original New York State prescription form. The prescriber is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance with state specific requirements could result in outreach to the prescriber.

Sign _____ **Collaborating MD Name** _____ **NPI#** _____

Prescriber Signature (No Stamps) ☐ Dispense as Written Date (mm/dd/yyyy)

Patient Name _____ **Prescriber Name** _____ **NPI #** _____

SECTION 6 – Household Income
(Only required if applying for the KevzaraConnect Patient Assistance Program)

How many people live in your household? _____

What is your total annual household income? _____

Total annual household income includes annual gross salary/wages, Social Security income, unemployment insurance benefits, disability income, worker's compensation, and any other income for your household.

To qualify for the KevzaraConnect Patient Assistance Program, I understand that either (a) I do not have insurance coverage for the product prescribed or (b) I have coverage through my Medicare Part D plan. KevzaraConnect may ask for proof of income at any time for the purpose of audit/verification. If requested, I agree to provide proof of income within thirty (30) days of the request. Enrollment and continuation in the program is conditioned upon timely verification of income. In addition, I agree to notify KevzaraConnect if my insurance situation changes.

I also agree that Regeneron Pharmaceuticals, Inc., Sanofi US, and their affiliates and agents (together, the "Alliance") may verify my eligibility for the KevzaraConnect Patient Assistance Program, and I understand that such verification may include contacting me or my healthcare provider for additional information and/or reviewing additional financial, insurance, and/or medical information. I authorize the Alliance to use my Social Security number and/or additional demographic information to access reports on my individual credit history from consumer reporting agencies. I understand that, upon request, the Alliance will tell me whether an individual consumer report was requested and the name and address of the agency that furnished it. I further understand and authorize the Alliance to use any consumer reports about me and information collected from me, along with other information they obtain from public and other sources, to estimate my income in conjunction with the Patient Assistance Program eligibility determination process, if applicable. I further understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid; and no free product may be sold, traded, or distributed for sale.

Complete and fax pages 1-4 to KevzaraConnect at 1-844-538-8960.

SECTION 7 – Patient Certifications

(Please read the following carefully, then date and sign where indicated in Section 1 of page 1)

I am enrolling in KevzaraConnect (the "Program") and authorize Regeneron Pharmaceuticals, Inc., Sanofi US, and their affiliates and agents (together the "Alliance") to provide me services under the Program, as described in this Program Enrollment Form and as may be added in the future. Such services include medication and adherence communications and support, medication dispensing support, coverage and financial assistance support, disease and medication education, injection training and other support services (the "Services").

I agree to my enrollment in the KevzaraConnect Copay Card Program if confirmed as eligible, understand that Copay Card information will be sent to the designated specialty pharmacy along with my prescription, and any assistance with my applicable cost-sharing or co-payment for KEVZARA® (sarilumab) injection will be made in accordance with the Program terms and conditions.

If I am completing Section 6, I confirm my agreement with the conditions set forth in Section 6, and certify that my household income is true and accurate to the best of my knowledge. I authorize the Alliance to contact me by mail, telephone, or email, with information about the Program, rheumatoid arthritis (RA) and products, promotions, services and research studies, and to ask my opinion about such information and topics, including market research and disease-related surveys. I further authorize the Alliance to de-identify my health information and use it in performing research including linkage with other de-identified information the Alliance receives from other sources, education, business analytics, marketing studies or for other commercial purposes. I understand that members of the Alliance may share identifiable health information with one another in order to de-identify it for these purposes and as needed to perform the Services or to send the communications listed above (the "Communications"). I understand and agree that the Alliance may use my health information for these purposes and may share my health information with my doctors, specialty pharmacies, and insurers. I understand that I may be contacted by the Alliance in the event that I report an adverse event.

I understand that I do not have to enroll in the Program or receive the Communications, and that I can still receive KEVZARA (sarilumab) injection, as prescribed by my physician. I may opt out of receiving Communications, individual support services offered by the Program, including the KEVZARA Patient Support Copay Card, or opt out of the Program entirely at any time by notifying a Program representative by telephone at 1-844-KEVZARA (844-538-9272), Option 1, or by sending a letter to KevzaraConnect, 1800 Innovation Point Fort Mill, SC 29715. I also understand that the Services may be revised, changed, or terminated at any time.

Text Messaging Consent:

I acknowledge that by checking the Text Messaging Consent box on page 1, I expressly consent to receive text messages from or on behalf of the Program at the mobile telephone number(s) that I provide.

I confirm that I am the subscriber for the mobile telephone number(s) provided, and I agree to notify the Alliance promptly if any of my number(s) change in the future. I understand that my wireless service provider's message and data rates may apply. I understand that I can opt out of future text messages at any time by texting KEVSTOP to 39771 from my mobile phone, and that I can get help for text messages by texting KEVHELP to 39771. I also understand that additional text messaging terms and conditions may be provided to me in the future as part of an opt-in confirmation text message. I understand that my consent is not required as a condition of purchasing any goods or services from Regeneron Pharmaceuticals, Inc., Sanofi US, or their affiliates. Message and data rates may apply.

Complete and fax pages 1-4 to KevzaraConnect at 1-844-538-8960.

SECTION 8 – Patient Authorization To Use And Disclose Health Information

(Please read the following carefully, then date and sign where indicated in Section 1 of page 1)

I authorize my healthcare providers and staff, my health insurer, health plan or programs that provide me healthcare benefits (together, "Health Insurers"), and any specialty pharmacies that dispense my medication to disclose to Regeneron Pharmaceuticals, Inc., Sanofi US, and their affiliates and agents (together, the "Alliance") health information about me, including information related to my medical condition and treatment, health insurance coverage and claims, prescription (including fill/refill information) related to my prescription for KEVZARA (sarilumab) injection therapy ("My Information"). I understand the disclosure to the Alliance will be for the purposes of enrolling me in and providing certain services, (collectively referred to as the "KevzaraConnect Program)," including

- to determine if I am eligible to participate in KevzaraConnect coverage assistance programs, patient assistance programs or other support programs (the "Program")
- to investigate my health insurance coverage for KEVZARA injection
- to obtain prior authorization for coverage
- to assist with appeals of denied claims for coverage
- for the operation and administration of the KevzaraConnect Program
- to refer me to, or to determine my eligibility for other programs, foundations or alternative sources of funding or coverage that may be available to provide assistance to me with the costs of my medication

I authorize and agree that the Alliance's field level employees may have access to My Information in order to assist the Alliance in providing support services in connection with the KevzaraConnect Program.

I understand and agree that my healthcare providers, Health Insurers, and specialty pharmacy(ies) may receive remuneration from the Alliance in exchange for disclosing My Information to the Alliance and/or for providing me with support services in connection with the KevzaraConnect Program.

Once My Information has been disclosed to the Alliance, I understand that federal privacy laws may no longer protect it from further disclosure. However, I also understand that the Alliance will protect My Information by using and disclosing it only for the purposes allowed by me in this Authorization or as otherwise allowed by law.

I understand that I do not have to sign this Authorization. A decision by me not to sign this Authorization will not affect my ability to obtain medical treatment, insurance coverage, access to health benefits or Alliance medications. However, if I do not sign this Authorization, I understand that I will not be able to participate in the KevzaraConnect Program.

I understand that this Authorization expires 18 months from the date support is last provided under the Program, subject to applicable law, unless and until I withdraw (take back) this Authorization before then, or as otherwise required by law. Further, I understand that I may withdraw this Authorization at any time by mailing or faxing a written request to KevzaraConnect at 1800 Innovation Point, Fort Mill, SC 29715; Fax: 1-844-538-8960. Withdrawal of this Authorization will end my participation in the KevzaraConnect Program and will not affect any disclosure of My Information based on this Authorization made before my request is received and processed by my healthcare providers and staff, my Health Insurers and specialty pharmacy(ies).

I understand that I may request a copy of this Authorization.

Complete and fax pages 1-4 to KevzaraConnect at 1-844-538-8960.

INDICATION

KEVZARA® (sarilumab) is indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs).

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS INFECTIONS

Patients treated with KEVZARA are at increased risk for developing serious infections that may lead to hospitalization or death. Opportunistic infections have also been reported in patients receiving KEVZARA. Most patients who developed infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of KEVZARA in patients with an active infection.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before KEVZARA use and during therapy. Treatment for latent infection should be initiated prior to KEVZARA use.**
- **Invasive fungal infections, such as candidiasis, and pneumocystis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral and other infections due to opportunistic pathogens.**

Closely monitor patients for signs and symptoms of infection during treatment with KEVZARA. If a serious infection develops, interrupt KEVZARA until the infection is controlled.

Consider the risks and benefits of treatment with KEVZARA prior to initiating therapy in patients with chronic or recurrent infection.

CONTRAINDICATION

Do not use KEVZARA in patients with known hypersensitivity to sarilumab or any of the inactive ingredients.

WARNINGS AND PRECAUTIONS

- ***Infections.*** Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients receiving immunosuppressive agents for rheumatoid arthritis (RA). The most frequently observed serious infections with KEVZARA included pneumonia and cellulitis. Among opportunistic infections, TB, candidiasis, and pneumocystis were reported with KEVZARA.

Please see additional Important Safety Information on next page and click here to see the full Prescribing Information including Boxed WARNING.

IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

- Hold treatment with KEVZARA if a patient develops a serious infection or an opportunistic infection.
- Patients with latent TB should be treated with standard antimycobacterial therapy before initiating KEVZARA. Consider anti-TB therapy prior to initiation of KEVZARA in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but having risk factors for TB infection.
- Consider the risks and benefits of treatment prior to initiating KEVZARA in patients who have: chronic or recurrent infection, a history of serious or opportunistic infections, underlying conditions in addition to RA that may predispose them to infection, been exposed to TB, or lived in or traveled to areas of endemic TB or endemic mycoses.
- Viral reactivation has been reported with immunosuppressive biologic therapies. Cases of herpes zoster were observed in clinical studies with KEVZARA.

- ***Laboratory Abnormalities.*** Treatment with KEVZARA was associated with decreases in absolute neutrophil counts (including neutropenia), and platelet counts; and increases in transaminase levels and lipid parameters (LDL, HDL cholesterol, and/or triglycerides). Increased frequency and magnitude of these elevations were observed when potentially hepatotoxic drugs (e.g., MTX) were used in combination with KEVZARA. Assess neutrophil count, platelet count, and ALT/AST levels prior to initiation with KEVZARA. Monitor these parameters 4 to 8 weeks after start of therapy and every 3 months thereafter. Assess lipid parameters 4 to 8 weeks after start of therapy, then at 6 month intervals.
- ***Gastrointestinal Perforation.*** GI perforation risk may be increased with concurrent diverticulitis or concomitant use of NSAIDs or corticosteroids. Gastrointestinal perforations have been reported in clinical studies, primarily as complications of diverticulitis. Promptly evaluate patients presenting with new onset abdominal symptoms.
- ***Immunosuppression.*** Treatment with immunosuppressants may result in an increased risk of malignancies. The impact of treatment with KEVZARA on the development of malignancies is not known but malignancies have been reported in clinical studies.
- ***Hypersensitivity Reactions.*** Hypersensitivity reactions have been reported in association with KEVZARA. Hypersensitivity reactions that required treatment discontinuation were reported in 0.3% of patients in controlled RA trials. Injection site rash, rash, and urticaria were the most frequent hypersensitivity reactions. Advise patients to seek immediate medical attention if they experience any symptoms of a hypersensitivity reaction. If anaphylaxis or other hypersensitivity reaction occurs, stop administration of KEVZARA immediately. Do not administer KEVZARA to patients with known hypersensitivity to sarilumab.
- ***Active Hepatic Disease and Hepatic Impairment.*** Treatment with KEVZARA is not recommended in patients with active hepatic disease or hepatic impairment, as treatment with KEVZARA was associated with transaminase elevations.

Please see additional Important Safety Information on next page and click here to see the full Prescribing Information including Boxed WARNING.

IMPORTANT SAFETY INFORMATION (cont'd)

- ***Live Vaccines.*** Avoid concurrent use of live vaccines during treatment with KEVZARA due to potentially increased risk of infections. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving KEVZARA.

ADVERSE REACTIONS

- The most common serious adverse reactions were infections. The most frequently observed serious infections included pneumonia and cellulitis. The most common adverse reactions (occurred in at least 3% of patients treated with Kevzara + DMARDS) are neutropenia, increased ALT, injection site erythema, upper respiratory infections, and urinary tract infections.

DRUG INTERACTIONS

- Exercise caution when KEVZARA is co-administered with CYP substrates with a narrow therapeutic index (e.g. warfarin or theophylline), or with CYP3A4 substrates (e.g. oral contraceptives or statins) as there may be a reduction in exposure which may reduce the activity of the CYP3A4 substrate.
- Elevated interleukin-6 (IL-6) concentration may down-regulate CYP activity such as in patients with RA and hence increase drug levels compared to subjects without RA. Blockade of IL-6 signaling by IL-6Rα antagonists such as KEVZARA might reverse the inhibitory effect of IL-6 and restore CYP activity, leading to altered drug concentrations.

USE IN SPECIFIC POPULATIONS

- KEVZARA should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. Because monoclonal antibodies could be excreted in small amounts in human milk, the benefits of breastfeeding and the potential adverse effects on the breastfed child should be considered along with the mother's clinical need for KEVZARA.
- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to KEVZARA during pregnancy. Physicians are encouraged to register patients and pregnant women are encouraged to register themselves by calling 1-877-311-8972.
- Use caution when treating the elderly.

Advise patients to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

Please click here to see the full Prescribing Information including Boxed WARNING.