YUSIMRY® (adalimumab-aqvh)

YUSIMRY Solutions™ Enrollment Form

Call 1-800-YUSIMRY (1-800-987-4679)
Monday to Friday | 8 AM to 8 PM CT
FAX 1-800-987-9888
www.YUSIMRY.com

*Denotes **REQUIRED** Information

Patient Name:* _____

Check for services requested (check all that apply):*

☐ Benefits Verification ☐ Prior Authorization & Appeals Information ☐ Co-pay Savings Program

1 PATIENT INFORMATION

Patient's First Name:* Patient's Last Name:*

DOB:* (MM/DD/YYYY) / / Gender:* ☐ Male ☐ Female ☐ Other

Patient's Address:*

City:* State:* ZIP:*

Patient's Phone #: ☐ Home ☐ Mobile ☐ Work

OK to Leave a Message: ☐ Yes ☐ No Best Time to Contact: ☐ Morning ☐ Afternoon ☐ Evening

Email Address:

Preferred Method of Contact: ☐ Phone ☐ Email ☐ Text Preferred Language:

Patient's Guardian/Caregiver Name:* *(If patient is a minor)*

Relationship to Patient:

Patient's Guardian/Caregiver Phone #: ☐ Home ☐ Mobile ☐ Work

2 PRIMARY PHARMACY BENEFITS

Plan Type:* Plan Name:*

Pharmacy Benefit Manager (PBM):*

Rx Member ID:* BIN:*

Rx Group ID:* Rx PCN:*

Rx Phone Number:* Rx Fax Number:*

SECONDARY PHARMACY BENEFITS (if applicable)

Plan Type:* Plan Name:*

Pharmacy Benefit Manager (PBM):*

Rx Member ID:* BIN:*

Rx Group ID:* Rx PCN:*

Rx Phone Number:* Rx Fax Number:*

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3 PRIMARY MEDICAL BENEFITS Insurance (if applicable)

	PRIMARY MEDICAL INSURANCE*	SECONDARY MEDICAL INSURANCE* (if applicable)
Insurance Type*		
Insurance Name*		
Group ID*		
Member ID*		
Group Number*		
Card Holder First Name*		
Card Holder Last Name*		
Card Holder Date-of-birth*	/ /	/ /
Insurance Phone Number*		
Insurance Fax Number*		

4 MEITHEAL PATIENT CONSENT*

Uses and Disclosure of Personal Information

I authorize Meitheal Pharmaceuticals, Inc. and its contractors and business partners ("Meitheal") to use and/or disclose my personal information, including my personal health information, only for the following purposes:

To operate, administer, enroll me in, and/or continue my participation in YUSIMRY Solutions™ program or any other Meitheal-affiliated services and activities related to my condition or treatment (for example, co-pay card programs, reimbursement assistance programs, drug coverage verification, nurse educator services, adherence program and disease management support); To contact, with my permission, my doctor and the rest of my healthcare team and share with them my health information that may be useful for my care; To provide me with informational and promotional materials relating to Meitheal products and services, and/or my condition or treatment; and/or To improve, develop, and evaluate products, services, materials and programs related to my condition or treatment. In order for Meitheal to provide me with the services and/or programs described above, Meitheal needs to collect and use my personal information, including my personal health information. I understand that my personal health information may include any information, in electronic or physical form, in the possession of or derived from a healthcare provider, healthcare plan, pharmacy, pharmaceutical company, laboratory and/or their contractor ("Healthcare Provider"). This may include select information from or about my medical history and general health, my healthcare plan benefits, payment limits or restrictions covered by my healthcare plan policy, and/or my adherence to my treatment. I authorize my Healthcare Providers to disclose my personal health information to Meitheal, and between themselves, as necessary, but only for the purposes stated above in this Consent. I understand that certain of my Healthcare Providers (such as pharmacies and specialty pharmacies) may receive remuneration from Meitheal in exchange for disclosing my personal health information and/or for using my information to contact me with communications about Meitheal products which have been prescribed to me (for example medication reminder programs) and other services.

Expiration, Right to Obtain a Copy and Right to Cancel

I understand that by signing this form, I authorize my Healthcare Providers or others who might hold my health information to only release it to Meitheal employees, as well as to its contractors and business partners, who are performing the services set forth in this Authorization. I also understand I am authorizing my personal information, including my personal health information, to be used for the purposes described above. I understand and agree that by signing below, I am authorizing those who rely on this Consent to release my personal health information for the earlier of five (5) years or until my participation in the program ends through my cancellation, unless a shorter time period is required by state law. I understand that I can obtain a copy of this Authorization or cancel this Authorization at any time by calling YUSIMRY Solutions™ at 1-800-YUSIMRY (1-800-987-4679) or by writing to PO Box 7613, Overland Park, Kansas, 66207. If I cancel my consent, I will no longer qualify for the services described. I also understand that if a Healthcare Provider is disclosing my personal health information to Meitheal on an authorized on-going basis, my cancellation with Meitheal will be effective with respect to any such Healthcare Providers as soon as they receive notice of my cancellation.

Please see Indications and Important Safety Information on pages 6-8 and accompanying Prescribing information including Boxed Warning.

*Denotes **REQUIRED** Information

Patient Name:* _____

4 MEITHEAL PATIENT CONSENT* (CONT'D)

No Effect on Treatment

I understand I do not have to sign this Consent and that my enrollment in any of the services and/or programs described above is entirely voluntary. I understand that Meitheal, as well as Healthcare Providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment or other care, to sign this Consent. Federal Law (including HIPAA) requires a signed consent in order for Meitheal to collect this information from my Healthcare Providers. I understand I cannot participate in the listed services and/or programs without signing this Consent or an equivalent consent with my Healthcare Providers.

Information Received from Healthcare Providers

I understand that once my personal health information has been disclosed to Meitheal, federal privacy laws may no longer apply and protect it from further disclosure. Meitheal agrees, however, to protect my personal health information by only using and disclosing it as stated in the Consent or as otherwise allowed or required by law.

Consent to Contact

I understand and consent to Meitheal or a Meitheal contractor, contacting me using the contact information provided in this form to enroll me in, operate, and administer YUSIMRY and/or programs as described above other than promotional communications by telephone or SMS/text (which I can separately opt in below). I understand that the operation and administration of certain of these services and/or programs may require that Meitheal contact me by telephone or SMS/text.

By signing below, I am indicating that I have read and understood Meitheal's Patient Consent (above in its full text), that I am legally authorized to consent and that I am providing my consent as the patient or the patient's legal representative for Meitheal and its contractors and business partners to use and share the personal information I provide for the purposes described within the Patient Consent.

Applicable if healthcare provider is assisting: By checking the box below, I represent and am indicating that the patient read and understood Meitheal's Patient Consent (above in its full text) and that I am acknowledging the patient's consent on their behalf. I further represent that I received consent from the patient to disclose their personal health information to Meitheal and its contractors and business partners for them to use and share the personal information the patient provided for the purposes described within the Patient Consent. A copy of the Patient Consent will be provided to the patient via email.

MEITHEAL PATIENT CONSENT & PRIVACY NOTICE (Required)*

☐ **I consent to the collection, use, and disclosure of my personal health data by Meitheal as described in the MEITHEAL PATIENT CONSENT section above. My consent is required to process personal data under certain privacy laws, and I have the right to withdraw my consent by calling YUSIMRY Solutions™ at 1-800-YUSIMRY (1-800-987-4679) or by writing to PO Box 7613, Overland Park, Kansas, 66207.**

PATIENT TEXT MESSAGE (OPTIONAL CONSENT)

☐ Meitheal may use automatic dialing machines or artificial or prerecorded messages to contact me and may leave a voicemail or SMS/text message. Meitheal may send automated and recurring text messages from YUSIMRY Solutions™ or Meitheal including service updates, marketing messages, refill reminders, and other notifications (standard text messaging rates may apply). SMS/text messages from YUSIMRY Solutions™ will be sent to the mobile phone number provided. Reply HELP for help or STOP to cancel. I understand that I am not required to provide this consent as a condition of purchasing any goods or services.

MARKETING (OPTIONAL CONSENT)

☐ I consent to the collection, use, and disclosure of my health-related personal data to receive communications from YUSIMRY Solutions™ or Meitheal, regarding its products, programs, services, scientific research and other research opportunities. My consent is required to process personal data under certain privacy laws, and I have the right to withdraw my consent by calling YUSIMRY Solutions™ at 1-800-YUSIMRY (1-800-987-4679) or by writing to PO Box 7613, Overland Park, Kansas, 66207.

Patient Signature:* _____ **Date:*** ___/___/___

Patient's Guardian/Caregiver Signature: _____ **Date:** ___/___/___
(If signing on patient's behalf)

Relationship to Patient: _____

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Patient Name:* _____

5 PRESCRIBER INFORMATION

Prescriber's Name:*

NPI Number:*

Office Contact Name:*

Facility Name:*

Address:*

City:* State:* ZIP:*

Phone Number:* Fax Number:*

6 HEALTHCARE PROFESSIONAL AUTHORIZATION

IMPORTANT INFORMATION: By submitting this form you are referring the above patient to YUSIMRY Solutions™ to determine eligibility and receive support related to a Meitheal product. Meitheal, its affiliates, collaborators and agents will use the information collected about you and your patient to provide the patient support and perform research and analytics, on a de-identified basis, for management of the program. For more information about the categories of personal information collected by Meitheal and the purposes for which Meitheal uses personal information, visit https://www.meithealpharma.com/privacy-policy. Please share this information with your patient.

I certify that I have received the appropriate written consent from the patient, in accordance with the Health Insurance Portability and Accountability Act of 1996, applicable state health information privacy law(s), and any other applicable requirements, in order to release the patient's personal and medical information to Meitheal and its agents and contractors for the purposes of assessing the patient's insurance coverage and eligibility for participation in YUSIMRY Solutions™, conducting random audits to verify the information provided on this enrollment form, and for other purposes as outlined in the Patient Consent. Meitheal is authorized to contact me about the information provided on this form and as needed to facilitate my patient's enrollment and participation in YUSIMRY Solutions™. I understand that Meitheal may, if authorized by the patient, contact the patient directly to verify YUSIMRY Solutions™ eligibility and updates to insurance coverage, as well as to confirm the receipt of Meitheal medication.

Healthcare Professional's Signature:* _____ **Date:*** / /

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Patient Name:* _____

7 PRESCRIPTION* (MUST BE COMPLETED BY A LICENSED PRESCRIBER)

Medication Name: **YUSIMRY**

Strength: **Single-dose prefilled pen: 40 mg/0.8 mL**

Quantity: Refills: ☐ Dispense as Written **OR** ☐ Substitutions Allowed

DIAGNOSIS ICD-10 Code:

INDICATION	DOSAGE /DIRECTIONS FOR USE
Rheumatology Indications: ☐ Rheumatoid Arthritis (RA) ☐ Psoriatic Arthritis (PsA) ☐ Ankylosing Spondylitis (AS)	☐ 40 mg every other week ☐ 40 mg every week ☐ 80 mg every other week
☐ Pediatric Polyarticular Juvenile Idiopathic Arthritis (JIA)	☐ 40 mg every other week
Dermatology Indications: ☐ Chronic Plaque Psoriasis (Ps) ☐ Adult Uveitis (UV)	☐ Initial Dose: 80 mg followed by 40 mg every other week starting one week from the initial dose.
☐ Hidradenitis Suppurativa (HS)	☐ Initial Dose: 160 mg (Day 1) followed by 80 mg 2 weeks later (Day 15) followed by 40 mg given every week or 80 mg every other week two weeks later (Day 29).
Gastroenterology Indications: ☐ Crohn's Disease (CD) ☐ Ulcerative Colitis (UC)	☐ Initial Dose: 160 mg (Day 1) followed by 80 mg 2 weeks later (Day 15) followed by 40 mg given every other week beginning two weeks later (Day 29).
☐ Pediatric Crohn's Disease (CD)	☐ Initial Dose: 160 mg (Day 1) followed by 80 mg 2 weeks later (Day 15) followed by 40 mg given every other week beginning two weeks later (Day 29).

PRESCRIBER PLEASE SIGN AND DATE

Prescriber's Signature:* _____ **Date:*** / /

SIGNATURE BY OTHER OFFICE PERSONNEL AND STAMP OR GRAPHIC/IMAGES ARE NOT ALLOWED.

SHIP TO:

☐ Patient Address ☐ Prescriber Address

☐ Other

PREFERRED PHARMACY (if applicable)

Pharmacy:*

Phone Number:* Fax Number:*

Address:*

City:* State:* ZIP:*

Please see Indications and Important Safety Information on pages 6-8 and accompanying Prescribing information including Boxed Warning.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

YUSIMRY® (adalimumab-aqvh) is biosimilar to Humira® (adalimumab)**

See full prescribing information for complete boxed warning.

INDICATIONS

- **Rheumatoid Arthritis:** YUSIMRY is indicated, alone or in combination with methotrexate or other non-biologic DMARDs, for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.
- **Juvenile Idiopathic Arthritis:** YUSIMRY is indicated, alone or in combination with methotrexate, for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
- **Psoriatic Arthritis:** YUSIMRY is indicated, alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis.
- **Ankylosing Spondylitis:** YUSIMRY is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.
- **Crohn's Disease:** YUSIMRY is indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- **Ulcerative Colitis**: YUSIMRY is indicated for the treatment of moderately to severely active ulcerative colitis in adult patients.

  Limitations of Use:

  The effectiveness of YUSIMRY has not been established in patients who have lost response to or were intolerant to TNF blockers.
- **Plaque Psoriasis:** YUSIMRY is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. YUSIMRY should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- **Hidradenitis Suppurativa:** YUSIMRY is indicated for the treatment of moderate to severe hidradenitis suppurativa in adult patients.
- **Uveitis:** YUSIMRY is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with YUSIMRY are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue YUSIMRY if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before YUSIMRY use and during therapy. Initiate treatment for latent TB prior to YUSIMRY use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with YUSIMRY prior to initiating therapy in patients: 1. with chronic or recurrent infection; 2. who have been exposed to TB; 3. with a history of opportunistic infection; 4. who resided in or traveled in regions where mycoses are endemic; 5. with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with YUSIMRY, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

INDICATIONS AND IMPORTANT SAFETY INFORMATION CONT'D

SERIOUS INFECTIONS, CONT'D

- Do not start YUSIMRY during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in rheumatoid arthritis (RA) patients treated with rituximab who received subsequent treatment with a tumor necrosis factor (TNF) blocker. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of YUSIMRY with other biologic disease-modifying antirheumatic drugs (DMARDs) (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions as well as the lack of demonstrated benefit of such combinations.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including adalimumab. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including adalimumab. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

- Consider the risks and benefits of YUSIMRY treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among adalimumab-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for adalimumab-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or psoralen plus ultraviolet A light (PUVA) therapy, for the presence of NMSC prior to and during treatment with YUSIMRY.
- In adalimumab clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk of lymphoma than the general population, even in the absence of TNF blockers.
- Postmarketing cases of acute and chronic leukemia were reported with TNF blocker use. Approximately half of the postmarketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents.

HYPERSENSITIVITY

- Anaphylaxis and angioneurotic edema have been reported following adalimumab administration. If a serious allergic reaction occurs, stop YUSIMRY and institute appropriate therapy.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including adalimumab, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy.
- Exercise caution in patients who are carriers of HBV and monitor them during and after YUSIMRY treatment.
- Discontinue YUSIMRY and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming YUSIMRY after HBV treatment.

INDICATIONS AND IMPORTANT SAFETY INFORMATION CONT'D

NEUROLOGIC REACTIONS

- TNF blockers, including adalimumab, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome.
- Exercise caution when considering YUSIMRY for patients with these disorders; discontinuation of YUSIMRY should be considered if any of these disorders develop.
- There is a known association between intermediate uveitis and central demyelinating disorders.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with adalimumab.
- Consider stopping YUSIMRY if significant hematologic abnormalities occur.

CONGESTIVE HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers. Cases of worsening CHF have been observed with adalimumab; exercise caution and monitor carefully.

AUTOIMMUNITY

- Treatment with YUSIMRY may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Patients on YUSIMRY should not receive live vaccines.
- Pediatric patients, if possible, should be brought up to date with all immunizations before initiating YUSIMRY therapy.
- Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the *in utero* exposed infant. The safety of administering live or live-attenuated vaccines in infants exposed to YUSIMRY *in utero* is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants.

ADVERSE REACTIONS

- The most common adverse reactions in adalimumab clinical trials (>10%) were: infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

**Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of YUSIMRY has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

Please see accompanying Prescribing Information, including Boxed Warnings.

meitheal
Generics | Brands | Biologics