

PATIENT SUPPORT PROGRAM ENROLLMENT FORM

Adalimumab-aaty



Monday - Friday, 8 AM - 8 PM ET / Phone: 1-877-81CONNC (1-877-812-6662) / Fax: 614-633-2259 / www.CelltrionConnect.com

Required fields are indicated in **bold**. | Complete online and print, then sign form. | Fax all pages to Celltrion CONNECT®: 614-633-2259

REQUESTED SERVICE(S): (check all that apply) Benefit Investigation Prior Authorization Support Appeals Support
Co-pay Support for Commercially Insured Patients Nurse Connector Support*

1. PATIENT INFORMATION

First Name: _____ **M.I.:** _____ **Last Name:** _____
Address: _____ **City:** _____ **State:** _____ **Zip:** _____
Date of Birth: MM / DD / YYYY **Sex:** Male Female Prefer Not to Answer **Email:** _____
Primary Phone: (____) ____ - ____ **Cell** **Home** **Secondary Phone:** (____) ____ - ____ **Cell** **Home** **Preferred Contact Method:** **Cell** **Home**
Alternate Contact: _____ **Relationship to Patient:** _____ **Preferred Contact:** **Patient** **Alternate Contact**
Primary Phone: (____) ____ - ____ **Cell** **Home** **Secondary Phone:** (____) ____ - ____ **Cell** **Home**

PLEASE ATTACH A COPY OF THE PATIENT'S INSURANCE CARD(S) (FRONT AND BACK). IF NOT AVAILABLE, PLEASE COMPLETE THE FOLLOWING:

2. PATIENT INSURANCE INFORMATION

Patient Does Not Have Insurance If patient is uninsured, please complete the Patient Assistance Program application available at www.CelltrionConnect.com.

Pharmacy Insurance Carrier: _____ **Policy/ID#:** _____
Group #: _____ **Rx BIN:** _____ **Rx PCN:** _____ **Phone:** (____) ____ - ____
Primary Medical Insurance Carrier: _____ **Insurance Type:** Commercial Medicare Medicaid Other: _____
Beneficiary/Cardholder Name: _____ **Policy/ID #:** _____ **Phone:** (____) ____ - ____

3. PATIENT AUTHORIZATION TO SHARE HEALTH INFORMATION

By signing this form, the patient gives their permission for their physicians, pharmacies, laboratories, and other healthcare providers ("Healthcare Providers") and their health insurers to share their individually identifiable health information with Celltrion USA, Inc., the Celltrion Patient Assistance Foundation, Celltrion affiliates and its vendors (collectively, "Celltrion").

The patient understands that their individually identifiable health information may include their full name, address, date of birth, demographic information, financial information, insurance information and information related to medical condition, treatment, care management, medication history, and prescriptions (collectively, "Health Information"), whether in written or verbal form, including portions of their medical record.

The patient's Health Information will be shared with Celltrion so that Celltrion may provide them with various support and information to help them access a Celltrion medicine, which may include the following, depending on the program (collectively, "Patient Support Activities"):

- Processing this Application;
- Verifying the information provided in this Application;
- Providing benefits investigations/verification and reimbursement support, including:
 - Assisting with identification of prior authorization requirements;
 - Assisting with identification of requirements of their insurer for appeal of a denied claim;
- Determining their eligibility for and helping them access co-pay support or free drug programs;
- Communicating with their Healthcare Providers about a Celltrion medicine and Patient Support Activities;
- Coordinating the dispensing and delivery of medication;
- Providing them with financial assistance resources and information if they are eligible;
- Providing them with disease management and other educational materials, as well as information about Celltrion's products, services, and programs, and may include sending them surveys about their experience with Celltrion products, services, and programs; and
- Providing them with access to Nurse Connectors who can assist in medication and adherence communications, medication dispensing support, and supplemental injection training.

Celltrion also may use their Health Information for auditing for compliance with Program requirements, quality assurance purposes, and to evaluate and improve our operations and services.

The patient understands that they do not have to sign this form, and choosing not to sign will not affect their ability to receive treatment from their Healthcare Providers or payment from their health insurer. However, if they do not sign this form, Celltrion may not be able to provide them with assistance.

The patient understands that once their Health Information is shared, it may no longer be protected by federal privacy law. However, Celltrion agrees to protect their Health Information and to use it for the purposes described in this form or as required or permitted by law. Select pharmacies may receive remuneration from Celltrion in exchange for their Health Information and/or for any Patient Support Activities provided to them. The patient understands that this form will remain in effect for [4] years from the date of their signature or shall otherwise expire at a shorter duration as required under applicable State law, unless they provide written notice that they would like to withdraw their approval to share their Health Information sooner. MARYLAND HEALTHCARE PROVIDERS, under Md. Code, Health - Gen. § 4-303(b)(4), this authorization expires ONE YEAR from the date of signature. If the patient would like to withdraw their approval, they may contact Celltrion at PO BOX 610 Columbus, OH 43216. This withdrawal will not affect the use or sharing of their Health Information that took place before they withdraw their approval. The patient understands that they may receive a copy of this form.

Sign & Date **Patient or Patient Authorized Representative Signature:** _____ **Date:** MM / ____ / ____
Patient Representative First Name: _____ **Patient Representative Last Name:** _____
Relationship to Patient: _____

*Note: Nurse Connectors assist patients in medication and adherence communications, medication dispensing support, and supplemental injection training. Nurse Connectors are provided by Celltrion and do not work under direction of the patient's healthcare provider. Nurse Connectors will direct patients to their healthcare provider for treatment-related inquiries and medical decision making.

Please see Important Safety Information including Boxed Warning on last page. Please see full Prescribing Information [here](#).

4. PATIENT AUTHORIZATION TO TELEPHONE CONSUMER PROTECTION ACT (TCPA) INFORMATION

By signing up for text messages from Celltrion, the patient agrees that they are the primary owner of the phone number provided and consent to receiving promotional communications in the form of phone calls or text messages relating to Celltrion products and services and/or their condition or treatment. Messages may be sent from an automated system. Consent is not required for the purchase of any goods or services. Message and Data Rates May Apply. Unsubscribe at any time by replying STOP or clicking the unsubscribe link (where available). Text HELP for help. Message frequency varies. To the maximum extent permitted by law: (i) all information contained in SMS text messages is provided "as is" without warranty of any kind, either express or implied, including, but not limited to, the implied warranties of merchantability, fitness for a particular purpose, or non-infringement; and (ii) Celltrion expressly excludes any liability for any direct, indirect, or consequential loss or damage incurred by any user in connection with the receipt, use, failure of, or inability to use, SMS text messages.

The patient also gives their permission to receive communications from Celltrion and parties acting on its behalf, including calls made with an autodialer or prerecorded voice at the phone number(s) provided to determine their eligibility and provide benefits verification, prior authorization/appeals assistance, and financial assistance resources and information, such as co-pay support or free drug programs, Nurse Connectors, supplemental injection training, and/or other non-marketing purposes. The patient understands that they can opt-out of these telephonic communications concerning Patient Support Activities at any time by contacting Celltrion at 1-877-81CONN (1-877-812-6662), Monday - Friday, 8 AM - 8 PM ET, or in writing at PO BOX 610 Columbus, OH 43216.

Celltrion CONNECT®: View our privacy policy: <https://www.celltrionconnect.com/patient-privacy-policy> | View our terms of use: <https://www.celltrionconnect.com/terms-of-use/>

By signing below, the patient expressly consents to the terms of this section.



SIGN & DATE

Patient or Patient Authorized Representative Signature: _____ **Date:** MM / DD / YYYY

Cell Phone: (_____) _____ - _____

5. CELLTRION CARES™ CO-PAY ASSISTANCE PROGRAM INFORMATION

The patient authorizes the Celltrion CARES™ Co-pay Assistance Program ("Program") to provide payment directly to the patient's pharmacy, and not to them, for their out-of-pocket drug costs when their pharmacy submits the co-pay claim. The patient authorizes their pharmacy to contact the Program on their behalf to initiate payment for services after they have been rendered. The patient understands that they will be responsible for any out-of-pocket expenses for their Celltrion medicine if (1) their pharmacy does not request payment within 180 days of the issue date on their Explanation of Benefits (EOB), or (2) if the patient is deemed ineligible for reimbursement from the Program.

Celltrion CARES™ Co-pay Assistance Program Terms and Conditions:

- Patient must have private/commercial health insurance that provides coverage for the cost of the drug. Patients do not qualify if they are covered, in whole or in part, under Medicaid, Medicare, a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered), TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan ("Healthcare Reform"), or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program (collectively, "Government Programs"), or where otherwise prohibited by law or the patient's health insurance provider. If at any time a patient begins receiving prescription drug coverage under any such federal, state, or government-funded healthcare program, the patient will no longer be able to use the Celltrion's Co-pay Assistance Program and the patient must call Celltrion CARES™ at 1-877-81CONN (1-877-812-6662) to stop participation
- Patient must be a resident of the United States or the Commonwealth of Puerto Rico. Product must originate and be shipped to locations in the United States or the Commonwealth of Puerto Rico
- Patient must be prescribed the Celltrion product for an on-label diagnosis

Celltrion CARES™: View our privacy policy: www.celltrionconnect.com/patient-privacy-policy | View our terms and conditions: <https://www.celltrioncares.com/adalimumab-aaty/terms-and-conditions>

By checking this box, the patient is eligible to participate in this program and agrees to the Terms and Conditions specified here.

6. PRESCRIBER INFORMATION

Prescriber First Name: _____ M.I.: _____ **Last Name:** _____ **Prescriber NPI:** _____
Prescriber PTAN: _____ **Prescriber Address:** _____ **City:** _____
State: _____ **Zip:** _____ **Phone:** (____) _____ - _____ **Fax:** (____) _____ - _____
Practice Name: _____ **Practice Contact First Name:** _____ **Practice Contact Last Name:** _____
Title: _____ **Phone:** (____) _____ - _____

7. PHARMACY PRESCRIPTION INFORMATION

Patient First Name: _____ **Patient Last Name:** _____ **Patient Date of Birth:** MM / DD / YYYY
 Patient's Preferred Pharmacy/Specialty Pharmacy: _____
Patient Weight (kg) (if under 18): _____ **Patient's Concurrent Medications:** _____ **Treatment Start Date:** MM / DD / YYYY
Diagnosis ICD-10 Code: _____ **Drug Allergies:** No Yes (If yes, please list medication(s) and reaction(s)): _____

Adalimumab-aaty	7a. Select Supply	Adalimumab-aaty Prefilled Auto-Injector	Adalimumab-aaty Prefilled Syringe with Safety Guard
	7b. Select Indication and Instructions		

Crohn's Disease Adults and Pediatric Patients 6 years of age or older: ≥ 40 kg (88 lbs) Please select a starting/loading dose and maintenance dose.

Starting Dose:	Maintenance Dose:
Adalimumab-aaty 80 mg/0.8 mL: Administer 2 injections (160 mg) SQ on Day 1 (given in 1 day or split over 2 consecutive days). Then administer 1 injection (80 mg) SQ on Day 15. Then start Maintenance prescription. Quantity (1 month): 3 injections, Refills: 0	Adalimumab-aaty 40 mg/0.4 mL: Starting on Day 29: Administer 1 injection (40 mg) SQ every other week. Quantity (1 month): 2 injections

Crohn's Disease Pediatric Patients 6 years of age or older: 17 kg (37 lbs) to <40 kg (88 lbs) Please select a starting/loading dose and maintenance dose.

Starting Dose:	Maintenance Dose:
Adalimumab-aaty 40 mg/0.4 mL: Administer 2 injections (80 mg) SQ on Day 1. Then administer 1 injection (40 mg) SQ on Day 15. Then start Maintenance prescription. Quantity (1 month): 3 injections, Refills: 0	Adalimumab-aaty 20 mg/0.2 mL: Starting on Day 29: Administer 1 injection (20 mg) SQ every other week. Quantity (1 month): 2 injections

Hidradenitis Suppurativa Please select a starting/loading dose and maintenance dose.

Starting Dose:	Maintenance Dose:
Adalimumab-aaty 80 mg/0.8 mL: Administer 2 injections (160 mg) SQ on Day 1 (given in 1 day or split over 2 consecutive days). Then administer 1 injection (80 mg) SQ on Day 15. Then start Maintenance prescription. Quantity (1 month): 3 injections, Refills: 0	Adalimumab-aaty 40 mg/0.4 mL: Starting on Day 29: Administer 1 injection (40 mg) SQ every week. Quantity (1 month): 4 injections Adalimumab-aaty 80 mg/0.8 mL: Starting on Day 29: Administer 1 injection (80 mg) SQ every other week. Quantity (1 month): 2 injections

Plaque Psoriasis or

Adult Uveitis Please select a starting/loading dose and maintenance dose.

Starting Dose:	Maintenance Dose:
Adalimumab-aaty 40 mg/0.4 mL: Administer 2 injections (80 mg) SQ on Day 1. Then administer 1 injection (40 mg) SQ on Day 8 and Day 22. Then start Maintenance prescription. Quantity (1 month): 4 injections, Refills: 0	Adalimumab-aaty 40 mg/0.4 mL: Starting on Day 36: Administer 1 injection (40 mg) SQ every other week. Quantity (1 month): 2 injections*

Ulcerative Colitis (Adult) Please select a starting/loading dose and maintenance dose.

Starting Dose:	Maintenance Dose:
Adalimumab-aaty 80 mg/0.8 mL: Administer 2 injections (160 mg) SQ on Day 1 (given in 1 day or split over 2 consecutive days). Then administer 1 injection (80 mg) SQ on Day 15. Then start Maintenance prescription. Quantity (1 month): 3 injections, Refills: 0	Adalimumab-aaty 40 mg/0.4 mL: Starting on Day 29: Administer 1 injection (40 mg) SQ every other week. Quantity (1 month): 2 injections*

Juvenile Idiopathic Arthritis ≥ 2 years of age and 15 kg (33 lbs) to <30 kg (66 lbs)

Juvenile Idiopathic Arthritis ≥ 2 years of age and >30 kg (66 lbs)

Adalimumab-aaty 20 mg/0.2 mL: Administer 1 injection (20 mg) SQ every other week. Quantity (1 month): 2 injections	Adalimumab-aaty 40 mg/0.4 mL: Administer 1 injection (40 mg) SQ every other week. Quantity (1 month): 2 injections
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Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis (Adults)

Adalimumab-aaty 40 mg/0.4 mL: Administer 1 injection (40 mg) SQ every other week. Quantity (1 month): 2 injections	*Discontinue in patients without evidence of clinical remission by 8 weeks (Day 57). †Some patients with rheumatoid arthritis not receiving methotrexate may benefit from increasing the dosage to 40 mg every week or 80 mg every other week.
Adalimumab-aaty 40 mg/0.4 mL: Administer 1 injection (40 mg) SQ every week.† Quantity (1 month): 4 injections	
Adalimumab-aaty 80 mg/0.8 mL: Administer 1 injection (80 mg) SQ every other week.† Quantity (1 month): 2 injections	


7c. Select Refills Maintenance Refills: _____

8. PRESCRIBER ATTESTATION/AUTHORIZATION

By signing this document the prescriber attests that they have obtained any and all authorizations and consents from the patient or the patient's authorized personal representative necessary under HIPAA and state law to release protected health information, including that contained on this form, to Celltrion and its employees or agents for the purposes relating to Celltrion's patient support program, including, assisting the patient with benefits verification, prior authorization/appeals assistance, dispensing and delivery of the medication, financial assistance resources and information, such as co-pay support or free drug programs, for which the patient may be eligible, and other support for Celltrion's medication.

The provider certifies that they have obtained consent from the patient or the patient's caregiver to be contacted by Celltrion, Celltrion CONNECT®, and parties acting on their behalf at the phone number(s) provided regarding the purposes described above and for other non-marketing purposes.

The provider certifies that they are the prescriber of Adalimumab-aaty to the patient and that the therapy is medically necessary. The provider authorizes Celltrion to act on their behalf to transmit this prescription by any means necessary to the pharmacy chosen by the patient.

 **SIGN & DATE** **Prescriber Signature:** _____ **Date:** MM / DD / YYYY

Please see Important Safety Information including Boxed Warning on last page. Please see full Prescribing Information [here](#).

Celltrion CONNECT® does not guarantee coverage or reimbursement. Coverage and reimbursement decisions are made by insurance companies following the receipt of claims.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about Adalimumab-aaty?

You should discuss treatment characteristics of Adalimumab-aaty with your doctor, including potential benefits and risks. Adalimumab-aaty is a TNF blocker medicine that can lower the ability of your immune system to fight infections. Notify your doctor if you have any kind of infection before you start taking Adalimumab-aaty.

Serious infections have happened in people taking adalimumab products, including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some of these infections have been fatal.

Your doctor should test you for TB prior to treatment with Adalimumab-aaty, and monitor closely for signs and symptoms of TB throughout treatment with Adalimumab-aaty, regardless of your TB test results. Your doctor may choose to treat you with a medicine for TB if they feel you are at risk.

Cancer. The chance of getting cancer may increase for children and adults taking TNF blockers, including adalimumab, including cases of unusual cancers. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma, which is often fatal. Your chance of getting two types of skin cancer (basal cell and squamous cell) may increase while using TNF blockers, including adalimumab. Basal cell and squamous cell skin cancer are typically not life-threatening if treated. You should tell your doctor if you notice a bump or open sore that doesn't heal.

What should I tell my doctor BEFORE starting Adalimumab-aaty?

Give your doctor a complete description of your health, including the following:

- Current infection, treatment for infection, or symptoms of an infection
- Frequent infections or infections that don't resolve with treatment
- Diabetes
- Confirmed TB or close contact with someone who has TB, or were born in, lived in, or traveled where there is more risk for getting TB
- Current or prior residence in major river valleys where risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis) is increased. These infections may happen or become more severe if you use Adalimumab-aaty. Ask your doctor about these infections to check if they are common in your area.
- Current or prior hepatitis B infection
- Scheduled for major surgery
- Current or prior cancer
- Disease that affects your nervous system that results in numbness or tingling in your extremities (multiple sclerosis, Guillain-Barré syndrome, etc.)
- Heart failure
- Recent or scheduled vaccines. While taking Adalimumab-aaty, patients may continue to receive vaccines except for live vaccines. Children should receive all recommended vaccines before starting Adalimumab-aaty.
- Known allergy to Adalimumab-aaty or any of its ingredients
- Current or planned pregnancy, or if you are currently breastfeeding or plan to
- If you have a baby while taking Adalimumab-aaty during your pregnancy. Tell your baby's doctor before your baby receives any vaccines

Also, tell your doctor about all the medicines you take. You should not take Adalimumab-aaty with ORENCIA® (abatacept), KINERET® (anakinra), REMICADE® (infliximab), ENBREL® (etanercept), CIMZIA® (certolizumab pegol), or SIMPONI® (golimumab). Tell your doctor if you have ever used RITUXAN® (rituximab), IMURAN® (azathioprine), or PURINETHOL® (mercaptopurine, 6-MP).

What should I watch for AFTER starting Adalimumab-aaty?

Adalimumab products, including Adalimumab-aaty, can cause serious side effects, including the following:

- **Serious infections.** Any infection caused by viruses, fungi, or bacteria, including TB. Common TB symptoms include cough, low-grade fever, weight loss, or loss of body fat and muscle.
- **Hepatitis B infection in carriers of the virus.** Common hepatitis B symptoms include muscle aches, feeling very tired, dark urine, skin or eyes that look yellow, little or no appetite, vomiting, clay-colored bowel movements, fever, chills, stomach discomfort, and skin rash.
- **Allergic reactions.** Common symptoms of a serious allergic reaction include hives, trouble breathing, and swelling of the face, eyes, lips, or mouth.

- **Nervous system problems.** Common signs and symptoms include numbness or tingling, problems with vision, weakness in your arms or legs, and dizziness.
- **Blood problems** (decreased blood cells that help fight infections or stop bleeding). Common symptoms include a fever that does not go away, bruising or bleeding very easily, or very pale skin tone.
- **Heart failure** (new or worsening). Common symptoms include shortness of breath, swelling in the ankles or feet, and sudden weight gain.
- **Immune reactions including a lupus-like syndrome.** Common symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or a rash on cheeks or arms that gets worse in the sun.
- **Liver problems.** Common symptoms include feeling very tired, skin or eyes that look yellow, poor appetite or vomiting, and pain on the right side of the stomach (abdomen). These problems can lead to liver failure and death.
- **Psoriasis** (new or worsening). Common symptoms include red scaly patches or raised, pus-filled bumps.

Call your doctor or get medical care right away if you develop any of the above symptoms.

Common side effects of adalimumab products include injection site reactions (redness, rash, swelling, itching, or bruising), upper respiratory infections (sinus infections), **headaches, and rash.** These are not all the possible side effects with adalimumab products, including Adalimumab-aaty. Tell your doctor if you have any side effect that bothers you or that does not go away.

Remember, tell your doctor right away if you have an infection or symptoms of an infection, including:

- Fever, sweats, or chills
- Muscle aches
- Cough
- Shortness of breath
- Blood in phlegm
- Weight loss
- Warm, red, or painful skin or sores on your body
- Diarrhea or stomach pain
- Burning when you urinate
- Urinating more often than normal
- Feeling very tired

Adalimumab-aaty is given by injection under the skin.

This is the most important information to know about Adalimumab-aaty. For more information, talk to your healthcare provider.

Indications

Adalimumab-aaty is a prescription medicine used:

- **To reduce the signs and symptoms of:**
 - **Moderate to severe rheumatoid arthritis (RA) in adults.** Adalimumab-aaty can be used alone, with methotrexate, or with certain other medicines.
 - **Moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in children** 2 years of age and older. Adalimumab-aaty can be used alone or with methotrexate.
 - **Psoriatic arthritis (PsA) in adults.** Adalimumab-aaty can be used alone or with certain other medicines.
 - **Ankylosing spondylitis (AS) in adults.**
 - **Moderate to severe hidradenitis suppurativa (HS) in adults.**
- **To treat moderate to severe Crohn's disease (CD) in adults and children 6 years of age and older.**
- **To treat moderate to severe ulcerative colitis (UC) in adults.** It is not known if Adalimumab-aaty is effective in people who stopped responding to or could not tolerate anti-TNF medicines.
- **To treat moderate to severe chronic plaque psoriasis (Ps) in adults** who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
- **To treat non-infectious intermediate, posterior, and panuveitis in adults.**

Please see full Prescribing Information including Boxed Warning [here](#).