

# PATIENT ASSISTANCE PROGRAM APPLICATION

# Adalimumab-aaty



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

Required fields are indicated in **bold** on this form.

Complete online and print, then sign form.  
Fax all pages to Celltrion CONNECT®: 614-633-2259

## 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

If preferred shipping site has a different address than the patient's address above, please complete the following:

Shipping Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

## 2. PATIENT INSURANCE INFORMATION

Patient Does Not Have Insurance

Pharmacy Insurance Carrier: \_\_\_\_\_ Policy/ID#: \_\_\_\_\_

Group #: \_\_\_\_\_ BIN: \_\_\_\_\_ PCN: \_\_\_\_\_ Phone: (\_\_\_\_) \_\_\_\_ - \_\_\_\_\_

Primary Medical Insurance Carrier (if applicable): \_\_\_\_\_ 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.

Patient or Patient Authorized Representative Signature: \_\_\_\_\_ Date: MM / DD / YYYY

 SIGN & DATE

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 ASSISTANCE PROGRAM (PAP) CONSENT

I certify that I cannot afford my medication, and I affirm that my answers and my proof-of-income documents are complete, true, and accurate to the best of my knowledge. I will promptly contact the Celltrion Patient Assistance Program within thirty (30) days if my financial status or health insurance coverage changes. I will not seek to have this medicine or any cost from it counted in my Medicare Part D out-of-pocket expenses for prescription drugs. I will not seek reimbursement or credit for the medicine(s) from my prescription insurance provider, payor, or government health benefit program, including Medicare Part D plans, for Celltrion medications that I receive from the Celltrion Patient Assistance Foundation. I will notify my insurance provider of the receipt of any medicines through the Celltrion Patient Assistance Program. I have a signed copy of a current and completed Patient Authorization to Share Health Information on record with my healthcare provider so that my healthcare provider may share health information about me with Celltrion's assistance programs, Celltrion USA, Inc., and the Celltrion Patient Assistance Foundation.

I understand that the information I provide will be used by Celltrion, the Celltrion Patient Assistance Foundation, and parties acting on their behalf to determine eligibility, to manage and improve Celltrion's assistance programs, to communicate with me about my experience with Celltrion's assistance programs, to help me understand my insurance coverage and help me access certain Celltrion medicines through my insurance, and/or to send materials and other helpful information and updates relating to Celltrion programs.

I understand that: Completing this enrollment form does not guarantee that I will qualify for Celltrion's assistance programs. Celltrion may contact my insurer, to help me understand my insurance coverage for certain products and may provide me support to obtain coverage through my insurer, including prior authorization and appeals support (if necessary and available). Celltrion may verify the accuracy of the information I have provided and may ask for more financial and insurance information. Any medicines supplied by Celltrion's assistance programs shall not be sold, traded, bartered, or transferred. Celltrion reserves the right to change or cancel Celltrion's assistance programs, or terminate my enrollment, at any time, except that if I am enrolled in a Medicare Part D plan, my benefits will continue until the end of the calendar year. I understand that if I am currently enrolled in a Medicare Part D plan, I cannot utilize my Part D plan benefits for medications received through the Celltrion Patient Assistance Foundation for the duration of my enrollment. The support provided through this program is not contingent on any future purchase. If I decide to enroll in a Medicare Part D plan and am eligible for the Celltrion Patient Assistance Program, I will inform the Celltrion Patient Assistance Foundation by calling 1-877-81CONNC (1-877-812-6662). If I receive notice that I have been auto enrolled in a Medicare Part D plan, I will immediately notify the Celltrion Patient Assistance Foundation.

By checking this box, the patient agrees to PAP consent and agrees to the Terms and Conditions specified here.


#### 5. 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 1-877-81CONNC (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: (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

#### 6. PATIENT FINANCIAL VERIFICATION AUTHORIZATION

I understand that by checking the "I Agree" box immediately following this notice, I am providing "written instructions" to Celltrion CONNECT® and/or its agents and contractors under applicable federal and/or state law authorizing them to perform electronic income verification by obtaining information from my personal credit profile or other information from Experian Health. I authorize Celltrion CONNECT® and/or their agents and contractors to obtain such information solely to validate my income for the purposes of determining my eligibility for patient assistance. As a soft credit check, it will not impact my credit score.

**I AGREE** to the terms above for electronic income verification using Experian Health.

**I DO NOT AGREE** with the terms above and do not wish to have my income verified by using Experian Health. I understand that I will be asked to provide supporting documentation to authenticate my income and eligibility. If additional income documentation is required, the following documents are acceptable for income verification:

- Social Security/Disability benefit statement, monthly check, or 1099
- Previous year tax return or W-2 statement
- Unemployment or disability determination letter

#### 7. PATIENT INCOME VERIFICATION

Annual Gross Income (Including salary/wages, Social Security income, disability income, and any other income): \_\_\_\_\_ Household Size (Number of members including you): \_\_\_\_\_

By checking this box, the patient agrees to income information specified here.

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

## PATIENTS ELIGIBLE FOR THE CELLTRION CONNECT® PATIENT ASSISTANCE PROGRAM

### Description

The Celltrion CONNECT® Patient Assistance Program (PAP) is designed to provide free product to qualified individuals who are uninsured or are functionally uninsured, who have no applicable drug coverage, or who express financial hardship affording their medication. Celltrion CONNECT® will help activate PAP for eligible participants.

### Eligibility Criteria

Patient Assistance Program eligibility: To receive PAP benefits, the patient must enroll in the program and meet the following eligibility requirements:

- a. Patient has no insurance or is functionally uninsured:
  - Patients who do not have insurance (uninsured) or are insured, but product is not covered by their plan (Patient is responsible for 100% of product cost) (functionally uninsured).
    - Functionally uninsured includes all payor types:
      - For commercial patients who have exhausted their co-pay benefits through Celltrion CARES™ Co-pay Assistance Program.
    - In order to be considered functionally uninsured:
      - The patient has pharmacy benefits but the payor/pharmacy benefit manager (PBM) will not approve or pay for either the entirety or any portion of the medication.
        - The payor/PBM must deny one level of appeal of an initial coverage denial.
      - The patient is uninsured or their insurance plan excludes Adalimumab-aaty and its reference/generic/biosimilar.
  - Medicare Part D patients with coverage for Adalimumab-aaty who cannot afford their out-of-pocket costs may be eligible. It is required that the patient is able to demonstrate:
    - Inability to afford the medicine.
    - Ineligibility for Medicaid or Medicare's low-income subsidy (extra help).
    - Satisfied all payer guidelines and prior authorization (PA) requirements prior to applying for assistance.
    - Does not have any other financial support options.
- b. Patient must have a valid prescription from a licensed healthcare provider (HCP) for an on-label indication. Please see the full Prescribing Information [here](#) for a complete list of FDA-approved indications.
- c. Patient must have an adjusted annual household income of ≤500% of the federal poverty level (FPL).
- d. Income verification:
  - If the electronic income check fails or the patient has not provided consent for income credit check, then Celltrion CONNECT® will request income documentation from the patient.
  - Income documentation accepted includes tax returns (1040, 1099), W-2s, 30 days of pay stubs, unemployment letters and unemployment government assistance, if applicable. Social Security statements or Social Security verification letter.
- e. Patient must reside in the United States or the Commonwealth of Puerto Rico for at least 6 months and product must be administered and shipped to locations in the United States or the Commonwealth of Puerto Rico.
- f. Diagnosis and dosing are consistent with FDA-approved indication for Adalimumab-aaty.
- g. Patients with insurance plans or employers participating in an alternate funding program (also sometimes referred to as patient advocacy programs, specialty networks, SHARx, Paydhealth, or PayerMatrix, among other names) are not eligible for PAP.
  - These programs require patients to apply to a manufacturer's PAP or otherwise pursue specialty drug prescription coverage through an alternate funding vendor as a condition of, requirement for, or prerequisite to coverage of relevant products, or that otherwise denies, restricts, eliminates, delays, alters, or withholds any insurance benefits or coverage contingent upon application to, or denial of eligibility for, specialty drug prescription coverage through the alternate funding program.
  - Patients must promptly contact the Celltrion CONNECT® PAP if their financial status or insurance coverage changes.
- h. If the patient is approved through PAP, they must remain in PAP and receive free drug through the Celltrion CONNECT® PAP until the end of the calendar year that they were approved for. For example, if the patient was approved for PAP in July, they will remain enrolled in PAP until December 31st of the same calendar year.

These eligibility requirements are subject to change. Please see [www.CelltrionConnect.com](http://www.CelltrionConnect.com) for any updated requirements.

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

## 8. 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:** (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

## 9. PHARMACY PRESCRIPTION INFORMATION

**Patient First Name:** \_\_\_\_\_ **Patient Last Name:** \_\_\_\_\_ **Patient Date of Birth:** MM / DD / YYYY  
 Patient's Preferred 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	9a. Select Supply	Adalimumab-aaty Prefilled Auto-Injector	Adalimumab-aaty Prefilled Syringe with Safety Guard
	9b. Select Indication and Instructions		

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

Starting Dose:	Maintenance Dose:
<b>Adalimumab-aaty 80 mg/0.8 mL:</b> 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	<b>Adalimumab-aaty 40 mg/0.4 mL:</b> 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:
<b>Adalimumab-aaty 40 mg/0.4 mL:</b> 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	<b>Adalimumab-aaty 20 mg/0.2 mL:</b> 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:
<b>Adalimumab-aaty 80 mg/0.8 mL:</b> 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	<b>Adalimumab-aaty 40 mg/0.4 mL:</b> Starting on Day 29: Administer 1 injection (40 mg) SQ every week. Quantity (1 month): 4 injections <b>Adalimumab-aaty 80 mg/0.8 mL:</b> 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:
<b>Adalimumab-aaty 40 mg/0.4 mL:</b> 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	<b>Adalimumab-aaty 40 mg/0.4 mL:</b> 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:
<b>Adalimumab-aaty 80 mg/0.8 mL:</b> 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	<b>Adalimumab-aaty 40 mg/0.4 mL:</b> Starting on Day 29: Administer 1 injection (40 mg) SQ every other week. Quantity (1 month): 2 injections*

**Juvenile Idiopathic Arthritis  $\geq 2$  years of age and 15 kg (33 lbs) to  $< 30$  kg (66 lbs)**

**Juvenile Idiopathic Arthritis  $\geq 2$  years of age and  $> 30$  kg (66 lbs)**

<b>Adalimumab-aaty 20 mg/0.2 mL:</b> Administer 1 injection (20 mg) SQ every other week. Quantity (1 month): 2 injections	<b>Adalimumab-aaty 40 mg/0.4 mL:</b> 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)**

<b>Adalimumab-aaty 40 mg/0.4 mL:</b> Administer 1 injection (40 mg) SQ every other week. Quantity (1 month): 2 injections <b>Adalimumab-aaty 40 mg/0.4 mL:</b> Administer 1 injection (40 mg) SQ every week. <sup>†</sup> Quantity (1 month): 4 injections <b>Adalimumab-aaty 80 mg/0.8 mL:</b> Administer 1 injection (80 mg) SQ every other week. <sup>†</sup> Quantity (1 month): 2 injections	*Discontinue in patients without evidence of clinical remission by 8 weeks (Day 57). <sup>†</sup> 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.
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**9c. Select Refills** Maintenance Refills: \_\_\_\_\_

## 10. PRESCRIBER ATTESTATION/AUTHORIZATION

 **SIGN & DATE**

By signing this document, the prescriber has certified that they have prescribed Adalimumab-aaty for an on-label diagnosis based on their professional judgment of medical necessity and that they will supervise the patient's medical treatment. The prescriber has also read and agrees to the terms, conditions, and authorizations and that all information provided in this application is complete and accurate to the best of their knowledge.

**Prescriber Signature:** \_\_\_\_\_ **Date:** MM / DD / YYYY

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

## 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](#).