Hyrimoz®
adalimumab-adaz

3 simple steps

to access support from Sandoz for HYRIMOZ®

1 **COMPLETE**
the appropriate form

2 **SIGN & DATE**
the form
(must have an e-signature from a healthcare provider)

3 **SUBMIT**
the form online

Questions? Call 1-833-HYRIMOZ (1-833-497-4669)

Important Safety Information:

WARNING: SERIOUS INFECTIONS AND MALIGNANCY

SERIOUS INFECTIONS

Patients treated with adalimumab products, including HYRIMOZ (adalimumab-adaz), 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 HYRIMOZ 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 HYRIMOZ use and during therapy. Initiate treatment for latent TB prior to HYRIMOZ 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 HYRIMOZ prior to initiating therapy in patients with chronic or recurrent infection.

Monitor patients closely for the development of signs and symptoms of infection during and after treatment with HYRIMOZ, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Please see Important Safety Information throughout and full Prescribing Information for HYRIMOZ, including Boxed Warning and Medication Guide.

Phone 1-833-497-4669

ADULT ENROLLMENT AND PRESCRIPTION FORM

Hyrimoz® adalimumab-adaz | Sandoz one source®

Phone 1-833-497-4669 **Fax** 1-844-600-0449 **Website** HYRIMOZpro.com
Hours Monday through Friday 8 AM–8 PM ET ***Required field**

Information requested is necessary to enroll in Sandoz One Source for HYRIMOZ® per patient services request. **This form should be filled out completely by the healthcare professional and the patient or their legally authorized person.**

☐ New ☐ Switch ☐ Restart

1 | SELECT SERVICES

By completing this form, I am requesting services on behalf of the patient. I would like the following services completed:

☐ All Services OR (select desired services) ☐ Benefits Investigation ☐ Prior Authorization/Appeal Support ☐ QuickStart Program
☐ Co-pay Program ☐ Other Financial Assistance ☐ Welcome Packet ☐ Injection Training

2 | PATIENT INFORMATION Please print clearly.

*First Name *Last Name *DOB / / Sex ☐ M ☐ F

*Address *City *State *ZIP

Home Phone *Mobile Phone ☐ Interpreter Needed ☐ Hearing Impaired

*Email Address Language

Once enrolled in Sandoz One Source, you may be assigned a personal Nurse Ambassador. Nurse Ambassadors work on behalf of Sandoz One Source, not under the direction of your healthcare professional. They will not give medical advice and will direct you to your healthcare professional for any treatment-related matters, including referrals. Visit the Sandoz One Source HUB to learn about privacy practices and your options.

3 | INSURANCE INFORMATION Please complete this section or attach a copy of your insurance cards. ☐ Documents Included

What type of insurance do you have? ☐ Commercial/Private† ☐ Medicare ☐ Medicaid, Government-Funded Plan, or VA‡ ☐ Not Insured

†Insurance that you or a family member have through an employer or purchased privately. ‡An example would be a Department of Defense program or TRICARE.

Beneficiary/Cardholder Name Prescription Insurance

Medical Insurance Rx Group # Rx ID #

Medical Insurance ID # Group # Rx BIN # Rx PCN #

FOR HEALTH CARE PROFESSIONAL USE ONLY

4 | DIAGNOSIS*

☐ Rheumatoid Arthritis (RA) ☐ Psoriatic Arthritis (PsA) ☐ Ankylosing Spondylitis (AS) ☐ Crohn's Disease (CD)
☐ Ulcerative Colitis (UC) ☐ Plaque Psoriasis (Ps) ☐ Hidradenitis Suppurativa (HS)

5 | PRESCRIBER INFORMATION I would like a copy of: ☐ Prior Authorization Form ☐ Benefits Verification Summary

*Prescriber's Name (First, Last) *Office Contact Name

*Site Name *Address *City *State

*ZIP *Office Phone *Office Fax *NPI #

6 | PHARMACY PRESCRIPTION Please choose the medication, and complete and sign the corresponding prescription.

*Number of refills Patient's preferred Specialty Pharmacy ☐ Do not send to Specialty Pharmacy

RHEUMATOID ARTHRITIS

Choose 1 Recommended Dose:
☐ Every other week: 40 mg SC inj.
☐ Every week: 40 mg SC inj.[a]
☐ Every other week: 80 mg SC inj.[a]

Choose 1 Presentation:
☐ Sensoready pen 40 mg/0.4 mL
☐ Prefilled syringe 40 mg/0.4 mL
☐ Sensoready pen 80 mg/0.8 mL

[a] Only for patients not taking concomitant MTX.

PSORIATIC ARTHRITIS or ANKYLOSING SPONDYLITIS

Recommended Dose:
☐ Every other week: 40 mg SC inj.

Choose 1 Presentation:
☐ Sensoready pen 40 mg/0.4 mL
☐ Prefilled syringe 40 mg/0.4 mL

CROHN'S DISEASE or ULCERATIVE COLITIS

INITIAL Therapy
Day 1: 160 mg SC inj. (single dose or split over 2 consecutive days)
Day 15: 80 mg SC inj.

Choose 1 Presentation:
☐ Sensoready pen Starter Pack 80 mg/0.8 mL
☐ Prefilled syringe Starter Pack 80 mg/0.8 mL

CONTINUING Therapy
Every other week starting on Day 29:
40 mg SC inj.

Choose 1 Presentation:
☐ Sensoready pen 40 mg/0.4 mL
☐ Prefilled syringe 40 mg/0.4 mL

PLAQUE PSORIASIS

INITIAL Therapy
Day 1: 80 mg SC inj.

Choose 1 Presentation:
☐ Sensoready pen Starter Pack 80 mg/0.8 mL, 40 mg/0.4 mL
☐ Prefilled syringe Starter Pack 40 mg/0.4 mL

CONTINUING Therapy
Starting 1 week after initial dose, every other week: 40 mg SC inj.

Choose 1 Presentation:
☐ Sensoready pen 40 mg/0.4 mL
☐ Prefilled syringe 40 mg/0.4 mL

HIDRADENITIS SUPPURATIVA

INITIAL Therapy
Day 1: 160 mg SC inj. (single dose or split over 2 consecutive days)
Day 15: 80 mg SC inj.

Choose 1 Presentation:
☐ Sensoready pen Starter Pack 80 mg/0.8 mL
☐ Prefilled syringe Starter Pack 80 mg/0.8 mL

CONTINUING Therapy (Choose 1:)
☐ Every week starting on Day 29: 40 mg SC inj.
☐ Every other week starting on Day 29: 80 mg SC inj.

Choose 1 Presentation:
☐ Sensoready pen 40 mg/0.4 mL
☐ Prefilled syringe 40 mg/0.4 mL
☐ Sensoready pen 80 mg/0.8 mL
☐ Prefilled syringe 80 mg/0.8 mL

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. By completing and submitting this form, I certify that my patient is aware of the disclosure of their personal health information to Sandoz and its business partners for Sandoz's patient support services, including reimbursement and verification services and the services provided by field reimbursement professionals in my office, as part of the patient's treatment with this product. I certify that I have obtained any required patient authorization. I further certify that (a) any service provided through Sandoz One Source on behalf of any patient is not made in exchange for any expressed or implied agreement or understanding that I would recommend, prescribe, or use HYRIMOZ or any other Sandoz product or service for anyone, and that (b) my decision to prescribe HYRIMOZ was based solely on my determination of medical necessity as set forth herein, and that (c) I will not seek reimbursement for any medication or service provided by or through Sandoz One Source for any government program or third-party insurer. For the purposes of transmitting prescriptions, I authorize SPA (Sandoz Patient Assistance), Sandoz, and its affiliates, business partners, and agents to forward these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies on my behalf.

Prescriber's Signature (REQUIRED) Date / /

Please see Important Safety Information throughout and full Prescribing Information for HYRIMOZ, including Boxed Warning and Medication Guide.

PEDIATRIC ENROLLMENT AND PRESCRIPTION FORM

Hyrimoz® adalimumab-adaz | SANDOZ one source®

Phone 1-833-497-4669 **Fax** 1-844-600-0449 **Website** HYRIMOZpro.com
Hours Monday through Friday 8 AM–8 PM ET ***Required field**

Information requested is necessary to enroll in Sandoz One Source for HYRIMOZ® per patient services request. **This form should be filled out completely by the healthcare professional and the patient's parent or legal guardian.**

1 | SELECT SERVICES ☐ New ☐ Switch ☐ Restart

By completing this form, I am requesting services on behalf of the patient. I would like the following services completed:

☐ All Services OR (select desired services) ☐ Benefits Investigation ☐ Prior Authorization/Appeal Support ☐ QuickStart Program
☐ Co-pay Program ☐ Other Financial Assistance ☐ Welcome Packet ☐ Injection Training

2 | PATIENT INFORMATION Please print clearly.

*First Name *Last Name *DOB / / Sex ☐ M ☐ F

*Parent/Guardian Name *Relationship to Patient

*Address *City *State *ZIP

Home Phone *Parent/Guardian Mobile Phone ☐ Interpreter Needed ☐ Hearing Impaired

*Parent/Guardian Email Address Language

Once enrolled in Sandoz One Source, you may be assigned a personal Nurse Ambassador. Nurse Ambassadors work on behalf of Sandoz One Source, not under the direction of your healthcare professional. They will not give medical advice and will direct you to your healthcare professional for any treatment-related matters, including referrals. Visit the Sandoz One Source HUB to learn about privacy practices and your options.

3 | INSURANCE INFORMATION Please complete this section or attach a copy of your insurance cards. ☐ Documents Included

What type of insurance do you have? ☐ Commercial/Private† ☐ Medicaid, Government-Funded Plan, or VA‡ ☐ Not Insured

†Insurance that you or a family member have through an employer or purchased privately. ‡An example would be a Department of Defense program or TRICARE.

Beneficiary/Cardholder Name Prescription Insurance

Medical Insurance Rx Group # Rx ID #

Medical Insurance ID # Group # Rx BIN # Rx PCN #

FOR HEALTH CARE PROFESSIONAL USE ONLY

4 | DIAGNOSIS*

☐ Juvenile Idiopathic Arthritis (JIA) ☐ Pediatric Crohn's Disease (CD)

5 | PRESCRIBER INFORMATION I would like a copy of: ☐ Prior Authorization Form ☐ Benefits Verification Summary

*Prescriber's Name (First, Last) *Office Contact Name

*Site Name *Address *City *State

*ZIP *Office Phone *Office Fax *NPI #

6 | PHARMACY PRESCRIPTION Please choose the medication, and complete and sign the corresponding prescription.

*Number of refills Patient's preferred Specialty Pharmacy ☐ Do not send to Specialty Pharmacy

JUVENILE IDIOPATHIC ARTHRITIS (2 years of age and older)		
☐ **10 kg (22 lbs) to <15 kg (33 lbs)**	**Every other week 10 mg SC inj.**	Confirm dosage strength: ☐ Prefilled syringe 10 mg/0.1 mL
☐ **15 kg (33 lbs) to <30 kg (66 lbs)**	**Every other week 20 mg SC inj.**	
☐ **≥30 kg (66 lbs)**	**Every other week 40 mg SC inj.**	Choose 1 Presentation: ☐ Sensoready pen 40 mg/0.4 mL ☐ Prefilled syringe 40 mg/0.4 mL

PEDIATRIC CROHN'S DISEASE (6 years of age and older)		
☐ **17 kg (37 lbs) to <40 kg (88 lbs)**	**INITIAL Therapy:** Day 1: 80 mg SC inj. Day 15: 40 mg SC inj.	**CONTINUING Therapy:** Every other week starting on Day 29: 20 mg SC inj. Confirm dosage strength: ☐ Prefilled syringe 20 mg/0.2 mL
☐ **40 kg (88 lbs) and greater**	**INITIAL Therapy:** Day 1: 160 mg SC inj. (single dose or split over 2 consecutive days) Day 15: 80 mg SC inj.	**CONTINUING Therapy:** 40 mg SC inj. every other week starting on Day 29 Choose 1 Presentation: ☐ Sensoready pen 40 mg/0.4 mL ☐ Prefilled syringe 40 mg/0.4 mL

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. By completing and submitting this form, I certify that my patient and/or their parent or legal guardian is aware of the disclosure of their personal health information to Sandoz and its business partners for Sandoz's patient support services, including reimbursement and verification services and the services provided by field reimbursement professionals in my office, as part of the patient's treatment with this product. I certify that I have obtained any required patient authorization. I further certify that (a) any service provided through Sandoz One Source on behalf of any patient is not made in exchange for any expressed or implied agreement or understanding that I would recommend, prescribe, or use HYRIMOZ or any other Sandoz product or service for anyone, and that (b) my decision to prescribe HYRIMOZ was based solely on my determination of medical necessity as set forth herein, and that (c) I will not seek reimbursement for any medication or service provided by or through Sandoz One Source for any government program or third-party insurer. For the purposes of transmitting prescriptions, I authorize SPA (Sandoz Patient Assistance), Sandoz, and its affiliates, business partners, and agents to forward these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies on my behalf.

Prescriber's Signature (REQUIRED) Date / /

Please see Important Safety Information throughout and full Prescribing Information for HYRIMOZ, including Boxed Warning and Medication Guide.

Important Safety Information (cont'd)

WARNING: SERIOUS INFECTIONS AND MALIGNANCY (cont'd)

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Post-marketing 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 products. 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 these patients had received treatment with azathioprine or 6-mercaptopurine (6–MP) 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.

WARNINGS AND PRECAUTIONS

Serious Infections

- Do not start HYRIMOZ® (adalimumab-adaz) during an active infection, including localized infections
- If an infection develops, monitor carefully, and stop HYRIMOZ if infection becomes serious. Drug interactions with biologic products: A higher rate of serious infections has been observed in RA patients treated with rituximab who received subsequent treatment with a 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 HYRIMOZ with other biologic DMARDs (eg, anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions
- Patients 65 years of age and older, patients with co-morbid conditions and/or patients taking concomitant immunosuppressants, may be at greater risk of infection
- *Invasive fungal infections:* For patients who develop a systemic illness on HYRIMOZ, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic

Malignancies

- In clinical trials, incidence of malignancies was greater in adalimumab-treated patients than in controls
- Consider the risks and benefits of TNF blocker-treatment, including HYRIMOZ, prior to initiating therapy in patients with known malignancy
- 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 PUVA therapy for the presence of NMSC prior to and during treatment with HYRIMOZ
- In the adalimumab clinical trials there was an approximate 3-fold higher rate of lymphoma than expected in the general US population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at a higher risk than the general population for the development of lymphoma, even in the absence of TNF blockers
- Post-marketing cases of acute and chronic leukemia have been reported in association with TNF-blocker use. Approximately half of the post-marketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases represented a variety of different malignancies and included rare malignancies usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents

Hypersensitivity Reactions

- Anaphylaxis or serious allergic reactions have been reported following administration of adalimumab products. If an anaphylactic or other serious hypersensitivity reaction occurs, immediately discontinue administration of HYRIMOZ and institute appropriate therapy

Hepatitis B Virus Reactivation

- Use of TNF blockers, including HYRIMOZ, 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 identified as carriers of HBV and closely monitor during and after HYRIMOZ treatment
- In patients who develop HBV reactivation, stop HYRIMOZ and initiate effective anti-viral therapy. Exercise caution when resuming HYRIMOZ after HBV treatment

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (CONT'D)

Neurologic Reactions

- Use of TNF-blocking agents, including adalimumab products, has been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating disease, including multiple sclerosis (MS), optic neuritis, and Guillain-Barré syndrome
- Exercise caution when considering HYRIMOZ® (adalimumab-adaz) for patients with these disorders; discontinuation of HYRIMOZ should be considered if any of these disorders develop

Hematological Reactions

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

Heart Failure

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

Autoimmunity

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

Immunizations

- Patients on HYRIMOZ should not receive live vaccines
- Pediatric patients, if possible, should be brought up to date with all immunizations prior to initiating HYRIMOZ 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 adalimumab products *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 (incidence >10 %): infections (eg, upper respiratory, sinusitis), injection site reactions, headache, and rash.

Please see Important Safety Information throughout and full Prescribing Information for HYRIMOZ, including Boxed Warning and Medication Guide.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

INDICATIONS: HYRIMOZ® injection for subcutaneous use, a prescription medication, is a tumor necrosis factor (TNF)-blocker indicated for:

- **Rheumatoid Arthritis (RA):** Alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (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 RA
- **Juvenile Idiopathic Arthritis (JIA):** Alone or in combination with methotrexate for reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older
- **Psoriatic Arthritis (PsA):** 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 PsA
- **Ankylosing Spondylitis (AS):** Reducing signs and symptoms in adult patients with active AS
- **Crohn's Disease (CD):** Treatment of moderately to severely active CD in adults and pediatric patients 6 years of age and older
- **Ulcerative Colitis (UC):** Treatment of moderately to severely active UC in adult patients
  Limitations of Use: The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers.
- **Plaque Psoriasis (Ps):** The treatment of adult patients with moderate to severe chronic Ps who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. HYRIMOZ should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician
- **Hidradenitis Suppurativa (HS):** HYRIMOZ is indicated for the treatment of moderate to severe HS in adults