Hyrimoz®
adalimumab-adaz
40 mg/0.4 mL for injection

adalimumab-adaz
40 mg/0.4 mL for injection

Pediatric Enrollment and Prescription Form

3 simple steps

to access support from Sandoz One Source

1. **COMPLETE** the form in full
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, 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

PEDIATRIC ENROLLMENT AND PRESCRIPTION FORM

Hyrimoz® adalimumab-adaz 40 mg/0.4 mL for injection | adalimumab-adaz 40 mg/0.4 mL for injection | SANDOZ one source®

Phone 1-833-497-4669 **Fax** 1-844-600-0449
Website HYRIMOZ.com/pro **Hours** M-F, 8 AM - 8 PM ET

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

☐ New ☐ Restart
☐ Switch from:_____

***Required field.**

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
☐ Sharps Container ☐ Co-Pay Program ☐ Other Financial Assistance ☐ Injection Training

2 | PATIENT INFORMATION Please print clearly.

*First Name Middle Initial *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

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 HEALTHCARE PROFESSIONAL USE ONLY

4 | *DIAGNOSIS

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

5 | PRESCRIBER INFORMATION

*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.

Patient's preferred Specialty Pharmacy ☐ Do not send to Specialty Pharmacy

Available as HYRIMOZ® and adalimumab-adaz

PEDIATRIC CROHN'S DISEASE (6 years of age and older)

PRESENTATION	STRENGTH	DOSE AND DIRECTIONS	QUANTITY/REFILLS
Initial Therapy			
☐ HYRIMOZ	☐ Prefilled Syringe Starter Pack 80 mg/0.8 mL, 40 mg/0.4 mL	**17 kg (37 lb) to <40 kg (88 lb)** ☐ Inject 80 mg SC on Day 1, then 40 mg SC on Day 15	**QTY:** ☐ 1 kit (Carton of 2: 1 x 80 mg/0.8 mL, 1 x 40 mg/0.4 mL) **Refills:** 0
☐ HYRIMOZ	☐ Prefilled Syringe Starter Pack 80 mg/0.8 mL	**40 kg (88 lb) and greater** ☐ Inject 160 mg SC on Day 1 (given in one day or split over two consecutive days), then 80 mg SC on Day 15	**QTY:** ☐ 1 kit (Carton of 3: 3 x 80 mg/0.8 mL) **Refills:** 0
☐ HYRIMOZ ☐ adalimumab-adaz	☐ Sensoready® Pen 40 mg/0.4 mL ☐ Prefilled Syringe 40 mg/0.4 mL		**QTY:** ☐ 1 month ☐ 3 months **Refills:**_____
Maintenance Therapy			
☐ HYRIMOZ ☐ adalimumab-adaz	☐ Prefilled Syringe 20 mg/0.2 mL	**17 kg (37 lb) to <40 kg (88 lb)** ☐ Inject 20 mg SC every other week starting on Day 29	**QTY:** ☐ 1 month ☐ 3 months **Refills:**_____
☐ HYRIMOZ ☐ adalimumab-adaz	☐ Sensoready Pen 40 mg/0.4 mL	**40 kg (88 lb) and greater** ☐ Inject 40 mg SC every other week starting on Day 29	
☐ HYRIMOZ ☐ adalimumab-adaz	☐ Prefilled Syringe 40 mg/0.4 mL		

SC=subcutaneous.

Continued on the following page.

PEDIATRIC ENROLLMENT AND PRESCRIPTION FORM

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Website HYRIMOZ.com/pro **Hours** M-F, 8 AM - 8 PM ET

*__Required field.__

*Patient Full Name _____ *DOB ___/___/___ *Parent/Guardian Mobile Phone _____

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

JUVENILE IDIOPATHIC ARTHRITIS (2 years of age and older)				
PRESENTATION	**STRENGTH**	**DOSE AND DIRECTIONS**		**QUANTITY/REFILLS**
☐ **HYRIMOZ®** ☐ **adalimumab-adaz**	☐ **Prefilled Syringe 10 mg/0.1 mL**[a]	**10 kg (22 lb) to <15 kg (33 lb)**	☐ Inject 10 mg SC every other week	**QTY:** ☐ 1 month ☐ 3 months **Refills:**_____
	☐ **Prefilled Syringe 20 mg/0.2 mL**	**15 kg (33 lb) to <30 kg (66 lb)**	☐ Inject 20 mg SC every other week	
	☐ **Sensoready® Pen 40 mg/0.4 mL**	**30 kg (66 lb) and greater**	☐ Inject 40 mg SC every other week	
	☐ **Prefilled Syringe 40 mg/0.4 mL**			

[a]Adalimumab-adaz presentation available in 2025.
SC=subcutaneous.

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 be sure to submit BOTH pages of this form when enrolling a patient, regardless of indication.

MLR-0060-US 10/2024

HYRIMOZ® and adalimumab-adaz Packaging Information

Available in 2 presentations of the same medicine: branded HYRIMOZ as well as authorized unbranded adalimumab-adaz. Offering 2 presentations ensures broader access for your patients. Insurance coverage will determine whether your patient receives HYRIMOZ or adalimumab-adaz.

HYRIMOZ Package Strength	Package Size	NDC Number
80 mg/0.8 mL single-dose prefilled Sensoready® Pen[a]	Carton of 2	61314-0454-20
80 mg/0.8 mL single-dose prefilled Sensoready Pen[a]	Starter Pack for Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa Carton of 3	61314-0454-36
80 mg/0.8 mL and 40 mg/0.4 mL single-dose prefilled Sensoready Pens[a]	Starter Pack for Plaque Psoriasis or Uveitis Carton of 3 (1 x 80 mg/0.8 mL, 2 x 40 mg/0.4 mL)	61314-0517-36
80 mg/0.8 mL single-dose prefilled syringe[b]	Starter Pack for Pediatric Crohn's Disease Carton of 3	61314-0454-68
80 mg/0.8 mL and 40 mg/0.4 mL single-dose prefilled syringe[b]	Starter Pack for Pediatric Crohn's Disease Carton of 2	61314-0531-64
40 mg/0.4 mL single-dose prefilled syringe[b]	Carton of 2	61314-0473-64
40 mg/0.4 mL single-dose prefilled Sensoready Pen[a]	Carton of 2	61314-0473-20
20 mg/0.2 mL single-dose prefilled syringe[a]	Carton of 2	61314-0476-64
10 mg/0.1 mL single-dose prefilled syringe[a]	Carton of 2	61314-0509-64
Adalimumab-adaz Package Strength	**Package Size**	**NDC Number**
80 mg/0.8mL single-dose prefilled Sensoready Pen[a,c]	Carton of 2	61314-0325-20
40 mg/0.4 mL single-dose prefilled Sensoready Pen[a]	Carton of 2	61314-0327-20
40 mg/0.4 mL single-dose prefilled syringe[b]	Carton of 2	61314-0327-64
20 mg/0.2 mL single-dose prefilled syringe[a]	Carton of 2	61314-0332-64
10 mg/0.1 mL single-dose prefilled syringe[a,c]	Carton of 2	61314-0342-64

[a]With a fixed, 29-gauge, ½-inch needle.
[b]With a fixed, 29-gauge, ½-inch needle and with BD UltraSafe Passive™ Needle Guard.
[c]Available in 2025.

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 during an active infection, including localized infections

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Phone 1-833-497-4669

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Serious Infections (cont'd)

- 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

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 for patients with these disorders; discontinuation of HYRIMOZ should be considered if any of these disorders develop
- There is a known association between intermediate uveitis and central demyelinating disorders

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

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Important Safety Information (cont'd)

ADVERSE REACTIONS

The most common adverse reactions (incidence >10 %): infections (eg, upper respiratory, sinusitis), injection site reactions, headache, and rash.

INDICATIONS: HYRIMOZ (adalimumab-adaz) 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):** 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):** Treatment of moderate to severe HS in adult patients
- **Uveitis:** Treatment of non-infectious intermediate, posterior, and panuveitis in adult patients

IMPORTANT SAFETY INFORMATION:

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SERIOUS INFECTIONS

Patients treated with adalimumab products, including HYRIMOZ, 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.

See full Boxed Warning on pages 1 and 4.

Please see 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.

SANDOZ

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