Hyrimoz®
adalimumab-adaz

AN ADALIMUMAB BIOSIMILAR TREATMENT OPTION

Office Handbook

Your guide to starting patients on treatment

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.

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.

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

Team HYRIMOZ® is here for you

HYRIMOZ has a dedicated team of industry professionals to support you and your patients.

Contact your **HYRIMOZ Immunology Sales Specialist** for questions related to:

- Clinical information
  - Efficacy and safety
  - Indications
  - Dosing
  - Administration
- Samples
- Insurance coverage
- In-office educational resources
- Sandoz One Source patient support programs

Contact your **HYRIMOZ Field Reimbursement Manager** for questions related to:

- Patient-level[a] reimbursement support
- Patient-level[a] insurance coverage
- In-office educational materials
- Sandoz One Source patient support programs
  - Injection training
  - Nurse Ambassadors
  - Financial assistance
  - Specialty pharmacy network
  - Prior authorization and appeal support

[a]Patient consent must be on file.

You can also contact a Sandoz **Medical Science Liaison** if you would like more information about the science behind biosimilars or HYRIMOZ.

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

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

RA — RHEUMATOID ARTHRITIS (RA)
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.

JIA — JUVENILE IDIOPATHIC ARTHRITIS (JIA)
Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.

PsA — PSORIATIC ARTHRITIS (PsA)
Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.

AS — ANKYLOSING SPONDYLITIS (AS)
Reducing signs and symptoms in adult patients with active AS.

CD — CROHN'S DISEASE (CD)
Treatment of moderately to severely active Crohn's disease in adult and pediatric patients 6 years of age and older.

UC — ULCERATIVE COLITIS (UC)
Treatment of moderately to severely active ulcerative colitis in adult patients.
Limitations of use: effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.

Ps — PLAQUE PSORIASIS (Ps)
Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

HS — HIDRADENITIS SUPPURATIVA (HS)
Treatment of moderate to severe hidradenitis suppurativa in adult patients.

IMPORTANT SAFETY INFORMATION (cont'd):

WARNINGS AND PRECAUTIONS

Serious Infections

- Do not start HYRIMOZ 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

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

HYRIMOZ® offers 2 options for dose administration

Prefilled Sensoready® pen

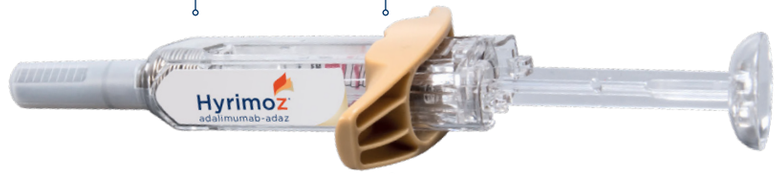
Ergonomic device with triangular shape

360° viewing window
for visual feedback

Buttonless activation for self-administration

Prefilled syringe with retractable needle

Viewing window for visual feedback



Large finger flange

NOTE: The 10-mg and 20-mg high concentration formulation doses are available in a prefilled syringe without a retractable needle.

IMPORTANT SAFETY INFORMATION (cont'd):

WARNINGS AND PRECAUTIONS (cont'd)

Malignancies (cont'd)

- 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

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

Learn more about injecting HYRIMOZ®

The Sensoready® pen

To learn how to administer HYRIMOZ using the prefilled Sensoready pen, please see the the Sensoready pen training video.

Prefilled syringe with retractable needle

For instructions on using the prefilled syringe with retractable needle, please see the Instructions for Use in the Prescribing Information.

For complete information on how to inject HYRIMOZ, please see the Instructions for Use section of the Prescribing Information.

To report a defective device and **request a replacement dose**, patients or providers should contact the **Novartis Customer Interaction Center: 1-800-525-8747**.

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 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

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

HYRIMOZ® Packaging Information[1]

HYRIMOZ is administered using either a prefilled Sensoready® pen or a prefilled syringe with retractable needle. The following packaging configurations are available for HYRIMOZ:

PACKAGE STRENGTH	PACKAGE SIZE	NDC NUMBER
80 mg/0.8 mL single-dose prefilled Sensoready Pen[a]	Carton of 2	61314-454-20
80 mg/0.8 mL single-dose prefilled Sensoready Pen[a]	Starter Pack for CD, UC, or HS Carton of 3	61314-454-36
80 mg/0.8 mL and 40 mg/0.4 mL single-dose prefilled Sensoready Pens[a]	Starter Pack for Ps Carton of 3 (1x 80 mg/0.8 mL, 2x 40 mg/0.4 mL)	61314-517-36
80 mg/0.8 mL single-dose prefilled syringe[b]	Starter Pack for Pediatric CD Carton of 3	61314-454-68
80 mg/0.8 mL and 40 mg/0.4 mL single-dose prefilled syringe[b]	Starter Pack for Pediatric CD Carton of 2	61314-531-64

[a]With a fixed 29-gauge, ½-inch needle.

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

Not all strengths are represented. Please refer to Prescribing Information for complete list.

Reference:

1. HYRIMOZ [prescribing information]. Princeton, NJ: Sandoz Inc.

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

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

HYRIMOZ® Packaging Information[1] (cont'd)

PACKAGE STRENGTH	PACKAGE SIZE	NDC NUMBER
40 mg/0.4 mL single-dose prefilled syringe[b]	Carton of 2	61314-473-64
40 mg/0.4 mL single-dose prefilled Sensoready Pen[a]	Carton of 2	61314-473-20
20 mg/0.2 mL single-dose prefilled syringe[a]	Carton of 2	61314-476-64
10 mg/0.1 mL single-dose prefilled syringe[a]	Carton of 2	61314-509-64

[a]With a fixed 29-gauge, ½-inch needle.

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

Not all strengths are represented. Please refer to Prescribing Information for complete list.

Reference:

1. HYRIMOZ [prescribing information]. Princeton, NJ: Sandoz Inc.

IMPORTANT SAFETY INFORMATION (cont'd):

INDICATIONS (cont'd):

- **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

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.

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

Sandoz One Source for HYRIMOZ® offers support for office staff and patients

HYRIMOZ Field Reimbursement Managers

- Available to answer questions about patient-level[a] **reimbursement support and insurance coverage**

Nurse Ambassadors

- Navigate the **insurance process**
- Identify ways to **save on prescription costs**
- Provide support for **injection training**

Reimbursement Support

- HYRIMOZ Care Specialists **assist with benefits investigations and the prior authorization (PA) process**
- Use **CoverMyMeds**® to complete a PA request via CoverMyMeds (CMM) account

QuickStart Program

- Addresses **PA and appeal delays**
- Provides **product support** for PA and appeal delays

Injection Training

- 1:1 **in-person and virtual** options available
- A **video** highlighting the Sensoready® pen injection experience

Co-Pay Card

- **Co-pay offer may be as little as $0 for eligible, commercially insured patients.** Terms and conditions apply.

In-Home Support

- Phone or text **refill reminders**
- **Welcome packets and sharps containers** delivered directly to patients' homes

Demonstration Kits

- **Experience the Sensoready pen** 2-click technology with buttonless activation for yourself
- Show your patients that the Sensoready pen was **designed with them in mind**

It's Easy to Enroll Your Patients in Sandoz One Source for HYRIMOZ

SANDOZ one source®

3 easy ways to enroll beginning July 1:

- **Complete** the online Sandoz One Source patient enrollment and prescription form
- **Print and fax** the completed Sandoz One Source patient enrollment and prescription form to 1-844-600-0449
- **Call** 1-833-HYRIMOZ (1-833-497-4669) to speak with a live Sandoz One Source for HYRIMOZ Case Manager

[a]Patient consent must be on file.

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

The Sandoz One Source patient enrollment and prescription form:

- Allows Sandoz One Source to assist with the PA process, status monitoring, and appeals support
- Allows you to enroll patients in a variety of services, including nurse support and benefits investigations
- Provides the specialty pharmacy with important information about the patient's diagnosis and treatment history

Please note that there are both **adult** and **pediatric** enrollment and prescription forms.

Visit **HYRIMOZ.com/pro/PEF** to complete the Sandoz One Source patient enrollment and prescription form online.

Please check the desired services or "All Services" as appropriate. Services such as the QuickStart Program **are not automatic**—eligible patients must be enrolled using this form.

Please ensure that the patient's **medical and prescription insurance information** have both been completed.

Please select the **patient's diagnosis**.

Prescriber signature is required.

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.**

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
*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.*
☐ Every other week: 80 mg SC inj.*
*Only for patients not taking concomitant MTX.

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

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.

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

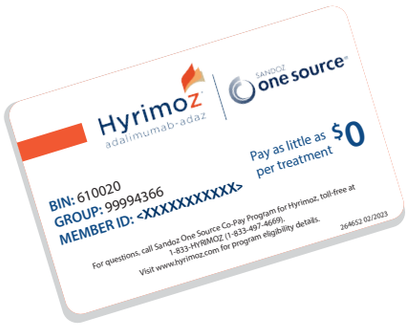
Financial options for patients

Hyrimoz® PATIENT TRANSITION PROGRAM

Supporting your patients—right from the start

To help offset the cost of switching from Humira®, the HYRIMOZ® Patient Transition program will provide a one-time reimbursement of **$200** to eligible patients[a] in 3 simple steps:

1. **Complete the eligibility information at portal.trialcard.com/sandoz/hyrimoz.**
2. **Upload proof of their valid HYRIMOZ prescription, filled within the last 90 days, for an approved indication.**
3. **Submit their complete information. Once their eligibility has been verified, they will receive a $200 healthcare debit card in the mail.**



Sandoz One Source Co-Pay Program for HYRIMOZ

Eligible patients[b] with commercial coverage may pay **as little as $0** per treatment.

- Patients should present this card with their insurance card and prescription at the pharmacy
- Providers should submit the information on this card as a secondary payer on the patient's claim

Questions about the co-pay card?
Call **1-833-497-4669**
Monday–Friday | 8 AM–8 PM ET

[a]**The HYRIMOZ® Patient Transition Program** provides a one-time reimbursement of costs to patients who transition from Humira® to HYRIMOZ, in the form of a $200 debit card that the patient must certify will be used for healthcare-related expenses. The following are acceptable merchant codes at which the debit cards can be used: 5912 DRUG STORES, PHARMACIES; 8011 DOCTORS – NOT ELSEWHERE CLASSIFIED; 8050 NURSING AND PERSONAL CARE FACILITIES; 8062 HOSPITALS; 8071 DENTAL AND MEDICAL LABORATORIES; and 8099 HEALTH PRACTITIONERS/MED SVCS UNCLASSIFIED. To qualify, a patient must provide proof of a filled HYRIMOZ prescription for an approved indication dated no more than 90 days prior to applying for the Patient Transition Program. Residents of Illinois, Massachusetts, Michigan, Minnesota, Mississippi, and Rhode Island are not eligible. A patient is not eligible if the patient's prescription is paid for, in whole or in part, by any state or federally funded programs, including but not limited to Medicare (including Part D, even in the coverage gap) or Medicaid, Medigap, VA, DOD, or TRICARE, or private indemnity, or HMO insurance plans that reimburse the patient for the entire cost of the patient's prescription drugs, or where prohibited by law. Sandoz reserves the right to rescind, revoke, or amend this offer at any time and without further notice.

[b]**HYRIMOZ Copay** Terms and Conditions: Limitations apply. Valid only for those with private insurance. Prescription must be for an approved indication. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and US Territories (Puerto Rico, Guam, Northern Mariana Islands, and Virgin Islands). This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Sandoz reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

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

Frequently asked questions

Q: What is Sandoz One Source for HYRIMOZ®?

A: Sandoz One Source for HYRIMOZ offers support services for office staff and eligible patients. For more information, please visit **HYRIMOZ.com/pro** or call **1-833-HYRIMOZ (1-833-497-4669)**.

Q: Does Sandoz One Source for HYRIMOZ have income requirements for patients to qualify for the Co-Pay Program?

A: No. The Sandoz One Source Co-Pay Program for HYRIMOZ is available to eligible, commercially insured patients, irrespective of their income levels. Terms and conditions apply.

Q: Is there support for Medicare and Medicaid patients?

A: No, co-pay coupons and other assistance are unavailable for federal healthcare program recipients; however, foundational support may be available to assist these patients. Sandoz One Source for HYRIMOZ can provide a list of foundations that may have funding available.

Q: Which support services are available to patients prescribed HYRIMOZ?

A: Sandoz One Source for HYRIMOZ provides the following services for eligible patients:

- Co-Pay Card[a]
- Nurse Ambassadors
- Patient Welcome Packets
- 1:1 Injection Training
- Sharps Disposal and Mail-Back Program
- Refill Reminders

Please see Sandoz One Source Patient Support on page 8 for details about support services.

Q: If eligible, how can commercially insured patients enroll in the Sandoz One Source Co-Pay Program for HYRIMOZ?

A: Beginning July 1, patients can enroll in 1 of 3 ways:

- Fill out the form online at **HYRIMOZ.com**
- Text[b] **COPAY to 1-833-HYRIMOZ**
- Call **1-833-HYRIMOZ**

[a]For eligible patients.

[b]Message and data rates may apply.

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

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.

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
- 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

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Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

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

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Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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):** 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

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.