Tecfidera® (dimethyl fumarate) delayed-release capsules 240 mg

TEC-US-0298 v9 01/20

Instructions for Healthcare Providers

To prescribe TECFIDERA, please follow these steps:

1. **After discussing TECFIDERA with your patient, have your patient read the Patient Consent Information and, if interested, sign the indicated areas on the accompanying Start Form.**

   Biogen takes your patient's confidentiality very seriously. While patients are not required to sign the Start Form in order to receive TECFIDERA, signing both lines will expedite their enrollment in Biogen support services, such as the QuickStart Program and **$0 Copay Program** (call 1-800-456-2255 for eligibility guidelines). In addition, with both signatures, Biogen will have access to your patient's prescription status should you or your patient need assistance.

2. **Complete the rest of the Start Form.**

   Copy both sides of the patient's medical insurance card and pharmacy benefit card, if available. In some cases, the medical and pharmacy cards may be the same.

3. **Give your patient the Instructions for Patients and Patient Consent Information pages.**

   Then, fax the Start Form to 1-855-474-3067. Prescriptions are only valid when received via fax.

Your patient will be contacted by a pharmacy in the TECFIDERA Pharmacy Network to arrange for delivery of the prescription.

Please be sure to fill out all of the sections of the Start Form. Incomplete areas may delay the start of treatment.

If you have any questions or want to learn more about TECFIDERA, please call 1-800-456-2255 or visit TECFIDERAHCP.com.

Biogen
225 Binney Street
Cambridge, MA 02142
(800) 456-2255
Tecfidera.com

Please see Important Safety Information on page 2 and accompanying full Prescribing Information, including Patient Information.

Instructions for Patients

How do I get started?

1. **Read the Patient Consent Information and sign as indicated in Sections A, B, and C of the Start Form.**
   This will enable you to enroll in Biogen support services, such as the QuickStart Program and **$0 Copay Program** (call 1-800-456-2255 for eligibility guidelines).

2. **Be sure to include your email address in the space provided.**
   By giving us your email address, you can stay up-to-date on the latest news about TECFIDERA.

3. **Your healthcare provider fills out the rest of the Start Form.**
   You're done. Your healthcare provider will fax us the Start Form.

What happens next?

- You can expect to receive several important phone calls. These calls will come from a Biogen support coordinator and a TECFIDERA pharmacy.
  - **You'll see 919-993-7000, a 1-800 number, or "unknown" on your caller ID. Please be sure to answer when you see these calls.** They are intended to help you in getting started on TECFIDERA as smoothly and quickly as possible.
- Your prescription can be shipped directly to your home.

If you have any questions or want to learn more about TECFIDERA, please call 1-800-456-2255 or visit TECFIDERA.com.

WHAT IS TECFIDERA® (dimethyl fumarate)?

- TECFIDERA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- It is not known if TECFIDERA is safe and effective in children under 18 years of age

IMPORTANT SAFETY INFORMATION

Who should not take TECFIDERA® (dimethyl fumarate)?

- Do not use TECFIDERA if you have had an allergic reaction (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing) to TECFIDERA or any of its ingredients

Before taking and while you take TECFIDERA, tell your healthcare provider if you have or have had:

- low white blood cell counts or an infection
- any other medical conditions

Tell your healthcare provider if you are:

- pregnant or plan to become pregnant. It is not known if TECFIDERA will harm your unborn baby
  - If you become pregnant while taking TECFIDERA, talk to your healthcare provider about enrolling in the TECFIDERA Pregnancy Registry. You can enroll in this registry by calling 1-866-810-1462 or visiting www.tecfiderapregnancyregistry.com. The purpose of this registry is to monitor the health of you and your baby
- breastfeeding or plan to breastfeed. It is not known if TECFIDERA passes into your breast milk. You and your healthcare provider should decide if you will take TECFIDERA or breastfeed
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements

What are the possible side effects of TECFIDERA?

TECFIDERA may cause serious side effects, including:

- **allergic reaction** (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing)
- **PML** a rare brain infection that usually leads to death or severe disability
- **decreases in your white blood cell count** Your healthcare provider should do a blood test before you start treatment with TECFIDERA and while on therapy
- **liver problems.** Your healthcare provider should do blood tests to check your liver function before you start taking TECFIDERA and during treatment if needed. Tell your healthcare provider right away if you get any of these symptoms of a liver problem during treatment
  - severe tiredness
  - loss of appetite
  - pain on the right side of your stomach
  - have dark or brown (tea color) urine
  - yellowing of your skin or the white part of your eyes
- **herpes zoster infections (shingles),** including central nervous system infections
- **other serious infections**

The most common side effects of TECFIDERA include:

- flushing, redness, itching, or rash
- nausea, vomiting, diarrhea, stomach pain, or indigestion
- Flushing and stomach problems are the most common reactions, especially at the start of therapy, and may decrease over time. Taking TECFIDERA with food may help reduce flushing. Call your healthcare provider if you have any of these symptoms and they bother you or do not go away. Ask your healthcare provider if taking aspirin before taking TECFIDERA may reduce flushing

These are not all the possible side effects of TECFIDERA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov.**

Please see full Prescribing Information, including Patient Information.

This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

Please read the following. If you agree, sign and date the corresponding section on the following page.

I. Authorization to Share Health Information

By signing this Authorization, I authorize my healthcare provider, my health insurance company, and my pharmacy providers ("Healthcare Entities") to disclose to Biogen, and companies working with Biogen (collectively, "Biogen"), health information relating to my medical condition, treatment, and insurance coverage for Biogen to provide me with (i) support services (and related information and materials) related to any of Biogen's products, including but not limited to, online support, financial assistance services, compliance and persistency and other therapy support services, (ii) conduct data analytics, market research and other internal business activities, and (iii) information about Biogen's products, services, and programs and other topics of interest for marketing, educational or other purposes. Once my health information has been disclosed to Biogen, I understand that federal privacy laws no longer protect the information. However, Biogen agrees to protect my health information by using and disclosing it only for purposes authorized in this Authorization or as required by law or regulations. I understand that my pharmacy provider may receive remuneration from Biogen in exchange for the health information and/or for any therapy support services provided to me.

I understand that I may refuse to sign this Authorization. I further understand that my treatment (including with a Biogen product), payment for treatment, insurance enrollment or eligibility for insurance benefits are not conditioned upon my agreement to sign this Authorization; but if I do not sign it or later cancel it, I will not be able to receive Biogen's therapy support services.

I may cancel this Authorization at any time by mailing a letter to: Biogen, 5000 Davis Drive, PO Box 13919, Research Triangle Park, NC, 27709 or visiting *biogen.com/privacy*. Canceling this Authorization will end my consent to further disclosure of my health information to Biogen by my Healthcare Entities after they are notified of my cancellation, but will not affect previous disclosures by them pursuant to this Authorization. Canceling this authorization will not affect my ability to receive treatment, payment for treatment, or my eligibility for health insurance.

This Authorization expires ten (10) years, or such shorter timeframe required by applicable law, from the day I sign it as indicated by the date next to my signature unless otherwise canceled earlier as set forth above.

Please sign in the space in Section A on the following page to authorize your consent.

II. Patient Services and Marketing/Other Communications Authorization

Patient Services

I authorize Biogen, and companies working with Biogen, to provide me with support services related to any of Biogen's products, including but not limited to: online support, financial assistance services, compliance and persistency and other therapy support services, as well as any information or materials related to such services. I agree and authorize that any nurse providing such support services is not employed by my healthcare professional. I authorize Biogen, and companies working with Biogen, to contact me to provide such services and information by mail, email, fax, telephone call, text message (including calls and text messages made with an automatic telephone dialing system or a prerecorded voice), and other mutually agreed upon means. I also authorize Biogen, and companies working with Biogen, to use my health information in connection with the services, including, without limitation, sharing such information with my healthcare provider, insurance provider, or pharmacy. I also authorize the disclosure of my health information to specific individuals that I have designated.

Marketing/Other Communications

I further authorize Biogen, and companies working with Biogen, to contact me by mail, email, fax, telephone call, and text message for marketing purposes or otherwise provide me with information about Biogen's products, services, and programs or other topics of interest, conduct market research or otherwise ask me about my experience with or thoughts about such topics. I understand and agree that any information that I provide may be used by Biogen to help develop new products, services, and programs. Note that Biogen will not sell or transfer your personal data to any unrelated third party for marketing purposes without your express permission. I understand that I may revoke this authorization and choose not to receive services or information from Biogen by mailing a letter to the address above or visiting *biogen.com/privacy*.

Please sign in the space in Section B on the following page to authorize your consent.

III. Opt-in for Automated Marketing Calls and Text Messages

I also consent to receive autodialed and prerecorded marketing calls and text messages from Biogen, and companies working with Biogen, at the telephone number(s) that I provide. I understand that my consent is not required as a condition of purchasing or receiving any goods or services from Biogen. I understand that I may revoke this authorization and choose not to receive automated marketing calls and text messages from Biogen by mailing a letter to the address above or visiting *biogen.com/privacy*.

Please check the box in Section C on the following page to authorize your consent.

Please see Important Safety Information on page 2 and accompanying full Prescribing Information, including Patient Information.

START FORM

Phone: 1-800-456-2255 Fax: 1-855-474-3067

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I. Authorization to Share Health Information

I have read and understand the *Authorization to Share Health Information* and agree to the terms.

A

Signature of patient or patient representative | Date

If signed by patient representative, please explain authority to act on behalf of the patient:

II. Patient Services and Marketing/Other Communications Authorization

I have read and understand the *Patient Services and Marketing/Other Communications Authorization* and agree to the terms.

B

Signature of patient or patient representative | Date

In addition, I authorize the disclosure of my health information to the following designated individual(s) (optional):

Care partner (print name) | Relationship

Care partner email | Phone

III. Opt-in for Automated Marketing Calls and Text Messages

C

☐ I have read and understand the *Opt-in for Automated Marketing Calls and Text Messages* and hereby agree to receive such information from Biogen (optional).

Patient Information

☐ Male ☐ Female

First name | Last name

Address

City | State | Zip

Date of birth | Email address

Home phone (patient) ☐ Preferred number ☐ OK to leave voicemail and/or text message

Cell phone (patient) ☐ Preferred number ☐ OK to leave voicemail and/or text message

Best time to reach me: ☐ Morning ☐ Afternoon ☐ Evening

Patient preferred language

THE FOLLOWING INFORMATION SHOULD BE FILLED OUT BY YOUR HEALTHCARE PROVIDER

☐ **Samples were provided to patient for 120 mg dose**

Prescription for TECFIDERA

Month 1

☐ **Titration Starter Pack Rx for TECFIDERA:**

120mg PO BID	x7 days	#14 capsules
240mg PO BID	x23 days	#46 capsules

No refills

Months 2–13

Maintenance Rx for TECFIDERA:

☐ 240mg PO BID	x90 days	#180 capsules	3 refills
☐ 240mg PO BID	x30 days	#60 capsules	11 refills

See below or attached for Healthcare Provider Instructions:

Statement of Medical Necessity

Primary diagnosis: ICD 10: G35

Current or most recent therapy | Dates/Duration

Other therapy (not including TECFIDERA samples) ☐ No prior disease-modifying therapies

Height: inches/cm | Weight: lbs/kg | Allergies

Prescriber Information

First name | Last name

Address

City | State | Zip

Phone | Fax

NPI # | Tax ID #

Clinical/Hospital affiliation | Office contact name

Best time to contact: ☐ Morning ☐ Afternoon

QuickStart Program (Optional, at no cost to patient; for commercially insured patients only*)

☐ Yes, I authorize Biogen to provide up to 3 months of TECFIDERA to my patient at no cost (one titration starter pack and ongoing Maintenance Rx, as needed) until the patient's prescription coverage is secured. I authorize Biogen to forward this prescription to the QuickStart Program designated pharmacy to dispense TECFIDERA directly to the above-named patient. Patient signatures are needed for (A) and (B) above to expedite enrollment in the QuickStart Program.

*Patients insured through Medicaid, Medicare, VA, DoD, TRICARE®, and other governmental insurance are NOT eligible for this program. TRICARE® is a registered trademark of the Department of Defense, DHA. All rights reserved.

QuickStart Rx for TECFIDERA:

Titration Rx

120mg PO BID	x7 days	#14 capsules	
240mg PO BID	x7 days	#14 capsules	

Maintenance Rx

240mg PO BID	x14 days	#28 capsules	10 refills

Medical Benefit Information

Primary insurance | Policy #

Group # | Insurance company phone

Policyholder first name | Policyholder last name

Pharmacy Benefit Information

Attach copies of both sides of patient's pharmacy benefit card(s).

☐ Check if no coverage ☐ Check if patient has secondary insurance

Amber Pharmacy

Patient preferred specialty pharmacy

Prescriber Authorization*

I authorize Biogen as my designated agent and on behalf of my patient to (1) forward the above statement of medical necessity and furnish any information on this form to the insurer of the above-named patient and (2) forward the above prescription, by fax or other mode of delivery, to the pharmacy chosen by the above-named patient. I certify that the rationale for prescribing TECFIDERA therapy is for a primary diagnosis of ICD-10: G35, and I will be supervising the patient's treatment accordingly.

Prescriber signature (Substitution Permitted) Signature stamps not acceptable.

Date

Prescriber signature (Dispense as written) Signature stamps not acceptable.

Date

*In New York, please attach copies of all prescriptions on Official New York State Prescription forms.