Esbriet Statement of Medical Necessity (SMN)

SUBMIT SMN AND PAN FORMS ONLY

Genentech-Access.com/Esbriet

Phone: (844) 372-7438 **Fax: (844) 372-7444**

Esbriet (pirfenidone) tablets | ACCESS SOLUTIONS®

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BY COMPLETING THIS FORM, I am requesting services on behalf of the patient, which may include benefits investigation, help navigating the prior authorization (PA) process and appeals support.

☐ Refer Patient to Co-pay Assistance
☐ GATCF* Patient Assistance

Step 1: Patient Information

Last name: _____ First name: _____ DOB: ____/____/____ Gender: ☐ M ☐ F

Street: _____ City: _____ State: _____ ZIP: _____

Home phone: (____)____ - _____ Work/cell: (____)____ - _____ Email: _____

Patient preferred language (if other than English): _____

Alternate contact name: _____ Relationship: _____ Alternate phone: (___)____ - _____

Step 2: Insurance Information *Please do not send a copy of the patient's insurance card.*

☐ **No Insurance**

Primary insurance name: _____

Phone: (___)____ - _____ Subscriber name: _____

Subscriber ID #: _____

Group #: _____

Secondary insurance name: _____

Phone: (___)____ - _____ Subscriber name: _____

Subscriber ID #: _____

Group #: _____

Step 3 : Diagnosis Information

☐ Idiopathic pulmonary fibrosis (J84.112) (ICD-10-CM)

☐ Other (ICD-10-CM) _____

Step 4: Prescriber Information

Last name: _____ First name: _____ Practice name: _____

Street: _____ Suite #: _____ City: _____ State: _____ ZIP: _____

Prescriber tax ID #: _____ Prescriber NPI† #: _____ Group NPI #: _____

Office contact: _____ Office contact phone: (____)_____ - _____ Fax: (____)_____ - _____

Step 5: Esbriet Prescription Information

Initial Tablet Titration

☐ Esbriet 267 mg 30-day supply (207 tablets)

Treatment Days	Dosing Instruction From PI
Days 1–7	1 tablet by mouth 3 times/day with meals
Days 8–14	2 tablets by mouth 3 times/day with meals
Days 15+	3 tablets by mouth 3 times/day with meals

Maintenance Tablet Dose

☐ Esbriet 267 mg 30-day supply (270 tablets) _____ Refills
Directions: 3 tablets by mouth 3 times/day with meals

☐ Esbriet 801 mg 30-day supply (90 tablets) _____ Refills
Directions: 1 tablet by mouth 3 times/day with meals

Maintenance Capsule Dose

☐ Esbriet 267 mg 30-day supply (270 capsules) _____ Refills
Directions: 3 capsules by mouth 3 times/day with meals

Other special instructions: _____

Preferred specialty pharmacy: _____

Step 6: Start Now Program

☐ **I approve the dispense of up to a 30-day free supply of Esbriet 267 mg to my patient if they experience an insurance coverage delay and otherwise meet eligibility criteria. For full eligibility criteria, please visit Genentech-Access.com/Esbriet or speak to your Esbriet representative.**

Step 7: Sign and Date Form

PHYSICIAN CERTIFICATION: By signing below, I certify: (a) the above therapy is medically necessary, (b) I received the authorization to release the information above and other protected health information (as defined by the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) to Genentech, Inc., Genentech Access Solutions, the contracted dispensing pharmacy, or other contractors for the purpose of requesting reimbursement support, assisting in initiating or continuing therapy and/or the evaluation of the patient's eligibility for GATCF, as a break in treatment would negatively impact the patient's therapeutic outcome and (c) I will not attempt to seek reimbursement for free product provided to the patient. I request Genentech Access Solutions convey to the pharmacy chosen by the above-named patient the prescription described herein.

I agree to comply with the Genentech, Inc. program guidelines and understand that GATCF, at its sole discretion, reserves the right to modify or discontinue the program at any time and to verify the accuracy of the information submitted. I further understand that Genentech will provide vial replacement in a configuration that will create the least wastage. If applying for GATCF, I certify that (a) this patient has no medical insurance coverage or otherwise meets the financial criteria for the prescribed therapy, and is not eligible for other product financial support programs, and (b) the therapy identified above will not be used in a clinical trial. Note: Prescribers in all states must follow applicable law for a valid prescription and who is considered an authorized prescriber. For prescribers in states with official prescription form requirements, such as New York, please submit prescriptions on an official state prescription blank along with this form.

Unapproved Use Warning: Please read the FDA-approved label for Genentech products before prescribing. If the indication for which you are prescribing a Genentech product is not listed in the FDA-approved label, you are prescribing the medication for an "unapproved" use, meaning that the FDA has not approved the efficacy, dosage amount or safety of this medication when used for such a use. Nevertheless, GATCF will consider providing the medication for your patient with this admonition, based upon your medical order, within program requirements.

Sign and date here, then fax to (844) 372-7444

Prescriber's Signature: _____ **Date:** ____ /____ /_____

(Original signature required. This form cannot be processed without a prescriber's signature.)

*Genentech® Access to Care Foundation. †National Provider Identifier.

TWO OPTIONS to Help Patients Get Esbriet

Option 1

Esbriet Access Solutions offers a range of access and reimbursement support for your patients and practice.

- **Full benefits investigations** (BIs)
- **Resources** for appeals
- **Prior authorization** (PA) resources
- **Patient assistance** options

Enroll your patients now

To get started, fax the Statement of Medical Necessity (SMN) **and** the Patient Authorization and Notice of Release of Information (PAN) to **(844) 372-7444**. Please submit SMN **and** PAN forms only—additional documentation not needed.

Option 2

Work directly with one of the following **specialty pharmacies***:

Name	Phone	Fax
Accredo Specialty Pharmacy	(888) 608-9010	(888) 302-1028
Acro Pharmaceutical Services	(800) 906-7798	(877) 381-3806
Advanced Care Scripts	(866) 681-7131	(866) 679-7131
BriovaRx	(800) 850-9122	(800) 218-3221
Cigna Specialty Pharmacy	(800) 351-3606	(800) 351-3616
CVS/Specialty	(800) 237-2767	(800) 323-2445
Diplomat Specialty Pharmacy	(877) 977-9118	(800) 550-6272
Humana Specialty Pharmacy	(800) 486-2668	(877) 405-7940
Orsini Healthcare	(800) 355-9366	(877) 358-9246
Prime Therapeutics Specialty Pharmacy	(877) 627-6337	(877) 828-3939
Walgreens Specialty Pharmacy	(888) 347-3416	(877) 231-8302

Genentech does not influence or advocate the use of any one specialty distributor or specialty pharmacy. We make no representation or guarantee of service or coverage of any item. To view the most recent list of specialty pharmacies, visit Genentech-Access.com/Esbriet.

*Individual payer policies may vary. Some payers may require the use of certain specialty pharmacies.

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Patient Authorization and Notice of Request for Transmission of Health Information to Genentech Access Solutions and Genentech® Access to Care Foundation (PAN)

Phone: (866) 4ACCESS/(866) 422-2377 **Fax:** (866) 480-7762 **Genentech-Access.com**

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Genentech Access Solutions is a free program for you from Genentech.

Genentech Access Solutions works to help you understand how to pay for your Genentech product. We assist people who have a health care plan as well as those who don't.

If you don't have a health care plan, or your plan won't pay for your Genentech products, Genentech might be able to help. If you meet certain criteria, we can supply free medicine. This is done through the Genentech Access to Care Foundation (GATCF).

Genentech Access Solutions and GATCF take patient privacy seriously. We recognize that your health information is sensitive and take steps to protect it and keep it confidential. In order for Genentech Access Solutions to help you, we will need to look at, use, and disclose some of your personally identifiable information (PII) including health information. By signing this form, you are directing your health care provider and health care plan to transmit certain PII to us and you are authorizing us to use and further disclose your PII as necessary to assist you. Once you sign this form and it is sent back to us, or it is submitted electronically by you or your health care provider on your behalf, we can start assisting you. You can choose not to sign this form; however, please note that we cannot assist you without it.

Please read through this form carefully.
If you have any questions, talk to your health care provider's office or call us at the phone number listed at the top of this page.

1 Information that may be used or disclosed

I am directing my health care provider(s) and/or health care plan(s) to share the following information with Genentech Access Solutions and/or GATCF:

- Health information related to my treatment with Genentech products, including relevant diagnoses and prescriptions
- Information about my health care plan benefits, including my deductibles and anticipated annual and lifetime out-of-pocket costs

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2 Who may see and use my PII

I authorize Genentech Access Solutions and/or GATCF to use and further disclose my PII to Agents, affiliates and vendors who are assisting Genentech Access Solutions and/or GATCF; and my health care provider(s), health care entities, pharmacies and health plan(s) for the purpose of facilitating my access to Genentech products, including:

- Coordinating with my health care plan for understanding coverage for Genentech products
- Applying to GATCF
- Determining my eligibility for alternative forms of coverage and sources of funding for my Genentech medicines
- Coordinating fulfillment of my prescription through a pharmacy
- For administrative purposes that support Genentech Access Solutions and GATCF

3 Notices

This PAN shall be in effect for 3 years from the date of my signature, or the date of last enrollment, whichever comes first, unless a shorter period is required by law.

I understand that if I am a resident of the state of Maryland, this authorization will be valid for no longer than 1 year from the date I signed it.

Once I sign this PAN form and my PII is transmitted to Genentech Access Solutions and/or GATCF, I understand that the Health Insurance Portability and Accountability Act (HIPAA) may no longer protect the PII disclosed to Genentech Access Solutions and/or GATCF by my health care provider or others covered by the HIPAA laws because Genentech Access Solutions and GATCF are not covered by HIPAA. I understand that Genentech Access Solutions and GATCF are committed to protecting my information and keeping it secure and confidential while it is being collected or used to assist me and that the use and disclosure of my information will be limited to that described above.

I understand that I can refuse to sign this PAN form. I also understand that I can cancel this PAN form at any time and for any reason. I understand that this cancellation means that Genentech Access Solutions and/or GATCF will no longer use or share my PII, but does not apply to PII already used or shared. To cancel this PAN form, I must send a written notice to Genentech. It can be sent by fax or by mail to the address on this page. If I cancel this PAN form, I understand that Genentech Access Solutions and GATCF will no longer be able to assist me with access to my Genentech product(s).

The address for Genentech Access Solutions and GATCF is 1 DNA Way, Mail Stop #858a, South San Francisco, CA 94080-4990. The fax number for Genentech Access Solutions and GATCF is (866) 480-7762.

I understand that I, as the patient or signer, have a right to obtain a copy of this signed PAN form during the period it is in effect.

4 Distribution acceptance

If I receive free product from GATCF, I will not sell or distribute Genentech products. I understand it is unlawful to do this. I am responsible for ensuring any Genentech product is sent to a secure address when it is shipped to me. I know it is my duty to control any Genentech product while it stays in my possession.

Section 5 on the next page is required.
This written notice must be signed, dated, and mailed, faxed or electronically submitted to:

Genentech Access Solutions
1 DNA Way, Mail Stop #858a, South San Francisco, CA 94080-4990
Fax: (866) 480-7762

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5 Signature and date

(Required in order to obtain the assistance of Genentech Access Solutions and the Genentech Access to Care Foundation)*

Please fill in all information below. Be sure to sign and date this form. If you don't, it could hold up the process for helping you.

Required:	Optional:

Print patient name

Last Name _____ First Name _____ Date of Birth _____

Signature of Patient/Legally Authorized Person _____ Date Signed _____

Print name of person signing (if not the patient)

Last Name _____ First Name _____ Relationship to Patient _____

☐ **OK to leave a detailed message†:**

I authorize Genentech Access Solutions/ GATCF to leave a detailed message at the following number:

_____

*If an error is made, the person signing the PAN form must correct the information by putting a single line through the mistake and initialing it. Rewrite the correct information next to the mistake. Other forms of correction, such as crossing out words or white-out will not be accepted.

†By providing my phone number, I authorize Genentech to use auto-dialers, prerecorded messages, and artificial voice messages to contact me. I understand that these calls/texts may mention the name of Genentech products or services, details about my insurance coverage, and my doctor's name. I understand that I am not required to consent to being contacted by phone or text message as a condition of any purchase of Genentech products or enrollment in Genentech Access Solutions or GATCF.

6 Financial information (GATCF only)

Total household income for the previous calendar year: $ _____

Read the following attestation: I understand that to qualify for free medicine, GATCF has criteria that must be met, including income. I certify the above statement of my total annual household income for the previous calendar year is true, and I do not have the financial resources or insurance coverage to pay for Genentech products. I know that GATCF could ask me for a copy of my IRS 1040 form or other proof of income for the purpose of an audit. I agree to provide my financial documentation in a timely manner, if so requested. In addition, I will notify GATCF immediately if my insurance situation changes. Please note that GATCF will pursue all appropriate legal remedies, including seeking damages in litigation, in the event GATCF determines that this certification is false or that the financial attestation is false or inaccurate. By signing this attestation, I certify that the above statement of my annual household income amount is true and accurate, to the best of my knowledge.

Choose to enroll by signing and dating here

Signature of Patient/Legally Authorized Person _____ Date Signed _____

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7 Genentech marketing consent

I want to enroll in optional and free programs sponsored by Genentech, related to the use of Genentech products. These programs may include co-pay assistance, other patient support programs, providing me with information or marketing materials about other products or services available from Genentech and its affiliates, or opportunities to participate in surveys or provide feedback. I understand my personally identifiable information (PII), including information about my use of Genentech products, may be needed for me to be a part of these programs. I understand by enrolling in these programs, Genentech may share information concerning my health with those who are responsible for administering these programs. I may choose to be contacted by mail, email, phone and/or text message. I understand the use and disclosure of my PII will be limited to Genentech, its successors, and its Agents, except as required by law. I agree to let Genentech, its successors, or its Agents contact me in the future about these programs.

I understand the following:

- This consent to enroll in these programs or receive marketing information is voluntary,
- I can get assistance from Genentech Access Solutions even if I do not sign this consent,
- I can get my medicine even if I do not sign this consent, and
- I may cancel my enrollment or consent to marketing at any time.

To cancel, I can call (877) 436-3683 toll free.

Preferred way to contact me

(Please check all boxes that apply.):

☐ Email: _____

☐ Phone number (voice message): _____ OK to leave a message? ☐Yes ☐No

☐ Phone number (text message): _____

By checking one or more of the above boxes to receive voice messages and/or text messages, I authorize Genentech to use auto-dialers, prerecorded messages, and artificial voice messages to contact me. I understand that these voice calls and text messages may market or advertise Genentech products, goods or services. I understand that I am not required to consent to being contacted by phone or text message as a condition of any purchase of goods or services.

☐ Address: _____

_____

_____

Choose to enroll by signing and dating here

_____ _____

Signature of Patient/Legally Authorized Person
(You must sign here to enroll in the programs related to Genentech products as described above.)

Date Signed

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