

The first and only FDA-approved treatment for Friedreich ataxia (FA) in patients 16 years and older

If your goal is slowing FA progression,
MAKE MOVES TO CHOOSE SKYCLARYS*

SKYCLARYS was shown
to reduce FA's impact on
physical function over time*

*In a 48-week clinical trial, treatment with SKYCLARYS resulted in less physical impairment over time versus placebo, as measured by the modified Friedreich Ataxia Rating Scale.

Matt: Avid cyclist, professional writer

Taking SKYCLARYS since 2023

Patients featured are paid spokespersons for Biogen.

SKYCLARYS[®]
(omaveloxolone) 50 mg
capsules

WHAT IS SKYCLARYS?

- ▶ SKYCLARYS[®] (omaveloxolone) is used for the treatment of Friedreich ataxia in adults and children aged 16 years and older. It is not known if SKYCLARYS is safe and effective for use in children younger than 16 years of age

IMPORTANT SAFETY INFORMATION

What are the possible side effects of SKYCLARYS?

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Please see Important Safety Information throughout and accompanying full Prescribing Information, including Patient Information.

Understanding the disease and how it progresses



What is Friedreich ataxia (FA)?

FA is a rare, genetic, and progressive disease that damages the nervous system, causing you to lose control of your muscles over time. It happens when a specific gene, called the frataxin gene (or *FXN*), does not function properly and cannot help nerve cells work the way they should. Ultimately, this leads to irreversible cell death.



How is FA diagnosed?

On average, diagnosing FA takes about 3 years. An FA diagnosis can be confirmed with a genetic test. It is important that the test include a Friedreich ataxia repeat expansion analysis. Your doctor can provide additional information about the specific test needed.



How is progression measured?

One way to measure FA progression is with the modified Friedreich Ataxia Rating Scale (mFARS) neurological exam, which is commonly used in clinical trials to evaluate how well potential FA treatments work. mFARS is made up of 4 parts that look at some of the different types of skills you may use. Together they paint a picture of your overall physical function.

Key mFARS areas	Possible activities affected
Lower limb coordination	Putting on socks and shoes
Upright stability	Walking, sitting in a car, standing in a line, or showering
Upper limb coordination	Getting dressed, eating, brushing teeth, typing, pointing, reaching, or turning a doorknob
Mouth and throat function	Speaking clearly and coughing

mFARS scores range from 0 to 93 points. **A lower mFARS score means less physical impairment, while a higher score indicates poorer functional ability.**

Understanding that mFARS scores can vary is important when discussing the rate of FA progression.

The rate of FA progression is different for each person, so mFARS scores won't be the same for everyone. For example, people who are diagnosed at a younger age typically see their mFARS scores rise more quickly than people who are diagnosed when they are older.

Everyday activities will get **harder over time**—but when and how are **different for everyone**

FA progression is unavoidable

Walking, talking, and use of hands are affected over time.

- FA symptoms become apparent: falls, clumsiness, feeling unbalanced, loss of sensation, tiredness
- Lower limb coordination continues to decline
- Mobility aids such as canes or walkers may become helpful
- Speech starts to sound slurred
- Hands and arms become less coordinated
- Many patients require the use of a wheelchair 10 to 15 years after symptoms first appear
- Complications from FA, such as diabetes or cardiomyopathy, become more serious

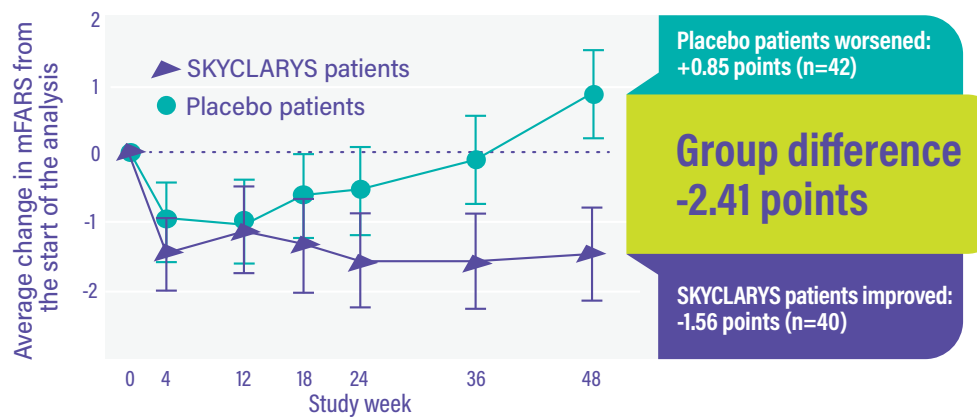
LESS PHYSICAL IMPAIRMENT

SKYCLARYS was shown to slow down FA progression

Results from the clinical trial

Treatment with SKYCLARYS resulted in statistically lower mFARS scores compared with untreated patients at 48 weeks.*

This means that, on average, patients taking SKYCLARYS had less impairment after 48 weeks of treatment compared with untreated patients in the clinical trial.



*In the population of patients without pes cavus (n=82).

Chris: Fisherman, outdoorsman
Taking SKYCLARYS since 2023

SKYCLARYS was shown to improve mFARS scores compared to an untreated population

THREE-YEAR EXPLORATORY ANALYSIS

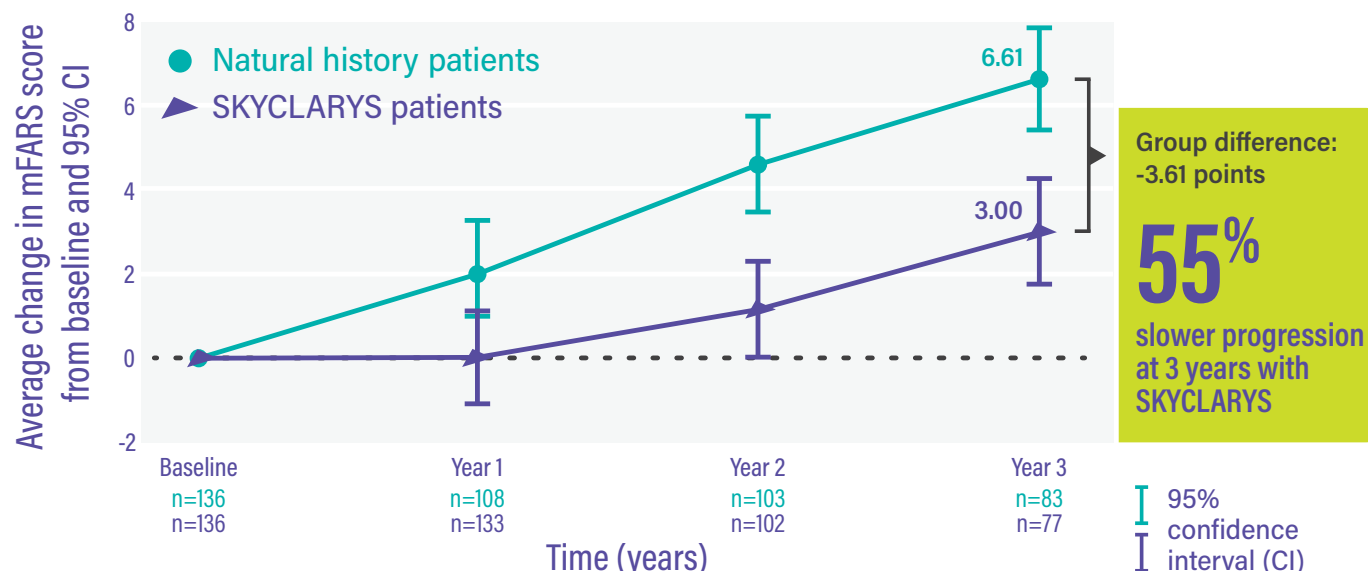
SKYCLARYS showed a sustained benefit by lessening physical impairment

At the end of the clinical trial, all patients who participated were given the option to continue in a longer-term study called an open-label extension.

Before participating in the open-label extension study, patients were asked to temporarily stop taking their treatment. Then, all patients were given SKYCLARYS, including those who had not been on treatment in the clinical trial.

After 3 years of treatment, people taking SKYCLARYS experienced less functional loss compared to those who were untreated

Researchers took the results from the 3-year open-label extension study and compared them with a matched set of untreated patients in the Friedreich Ataxia Clinical Outcome Measures Study (FA-COMS). FA-COMS is an ongoing natural history study that measures the progression of more than a thousand FA patients to determine just how the condition progresses.



This kind of study is called an exploratory analysis and is not the same as a clinical trial. Because of that, there are some limitations to the study and the results should be interpreted cautiously.

95% confidence interval (CI) means that if the study were repeated with a similar patient population and the same study design, the results would likely fall in this range 95% of the time.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of SKYCLARYS? (cont'd)

SKYCLARYS may cause serious side effects, including (cont'd):

- **Increase in a blood protein called B-Type Natriuretic Peptide (BNP).** BNP tells how well your heart is working. Your healthcare provider will check your BNP levels before your treatment with SKYCLARYS. Tell your healthcare provider if you have signs and symptoms of your heart not working well such as too much fluid in your body (fluid overload). Signs and symptoms may include:
 - sudden weight gain (3 pounds or more of weight gain in 1 day, or 5 pounds or more of weight gain in 1 week)

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Safety and side effects

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- ▶ sudden weight gain (3 pounds or more of weight gain in 1 day, or 5 pounds or more of weight gain in 1 week)
- ▶ swelling in your arms, hands, legs, or feet (peripheral edema)
- ▶ fast heartbeat (palpitations)
- ▶ shortness of breath

If you have symptoms of fluid overload that is considered a side effect of SKYCLARYS, your healthcare provider may stop treatment with SKYCLARYS.

Changes in cholesterol levels. Increases in low density lipoprotein cholesterol (LDL-C) or bad cholesterol and decreases in high density lipoprotein cholesterol (HDL-C) or good cholesterol have happened during treatment with SKYCLARYS. Your healthcare provider will check your cholesterol levels before and during your treatment with SKYCLARYS

IMPORTANT SAFETY INFORMATION (cont'd)

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Know how long side effects may last, if they occur

It's important to talk to your doctor about how long side effects may last. This helps you set appropriate expectations for treatment. However, everyone's experience may be different.

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**Jacob: Youth mentor,
motivational speaker**

**Taking SKYCLARYS
since 2023**



What are the most common side effects?

In the clinical trial, the most common side effects were elevated liver enzymes, along with headache, nausea, stomach pain, and tiredness. Some people also experienced diarrhea and muscle aches and pain. These are not all the possible side effects of SKYCLARYS. Call your doctor for medical advice about side effects.

Most common side effects*

Side effects	SKYCLARYS patients	Untreated patients
Elevated liver enzymes (AST/ALT)	37%	2%
Headache	37%	25%
Nausea	33%	13%
Stomach pain	29%	6%
Tiredness	24%	14%
Diarrhea	20%	10%
Muscle aches and pain	20%	15%

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

*Defined as affecting 20% or more of patients and more SKYCLARYS patients than untreated patients.



SKYCLARYS was studied in a diverse group of individuals with FA, aged 16 to 40, with a range of disease severity

**Libby: Yoga enthusiast,
interior designer
Taking SKYCLARYS since 2023**

What should I do before I start taking SKYCLARYS?

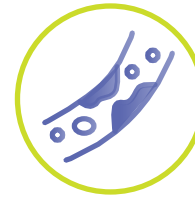
Keep your healthcare provider in the loop! Make sure to inform them about all your medical conditions, including:



**Liver
problems**



**History of heart problems,
including heart failure**



**High
cholesterol**

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements such as St John's Wort

- ▶ Taking SKYCLARYS with other medicines can cause serious side effects
- ▶ SKYCLARYS may affect the way other medicines work, and other medicines may affect how SKYCLARYS works
- ▶ Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine

Family planning with SKYCLARYS

Pregnancy: Tell your healthcare provider if you are pregnant or plan to become pregnant. It is not known if SKYCLARYS will harm your unborn baby. There is a pregnancy registry for women who are pregnant and are taking SKYCLARYS. The purpose of this registry is to collect information about the health of you and your baby. Your healthcare provider can enroll you or you may enroll yourself by calling [1-866-609-1785](tel:1-866-609-1785) or by sending an email to SkyclarysPregnancySurveillance@ppd.com.

Birth control: Women who use hormonal birth control should use another form of birth control such as a non-hormonal intrauterine system or an extra non-hormonal birth control such as condoms while using SKYCLARYS and for 28 days after stopping SKYCLARYS.

Breastfeeding: Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known if SKYCLARYS passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take SKYCLARYS.

Talk to your doctor about any side effects you may experience

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DOSING AND ADMINISTRATION

SKYCLARYS is the only once-daily oral treatment for FA

How do I take SKYCLARYS?

ONCE DAILY

The recommended dose is 150 mg



Each SKYCLARYS capsule is 50 mg



Standard administration

- ▶ Take SKYCLARYS on an empty stomach, at least 1 hour before or 2 hours after eating
- ▶ Swallow SKYCLARYS capsules whole. Do not crush or chew



Sprinkle administration

If you are not able to swallow whole capsules:

- ▶ Take SKYCLARYS on an empty stomach, at least 1 hour before or 2 hours after eating
- ▶ If SKYCLARYS capsules cannot be swallowed whole, the capsules may be opened and the entire contents of both halves sprinkled onto 2 tablespoons (30 mL) of applesauce
- ▶ Stir the mixture
- ▶ Swallow all the mixture of medicine and applesauce right away. Do not store the mixture of medicine and applesauce to use at a later time
- ▶ The contents of the SKYCLARYS capsules should not be mixed with milk or orange juice
- ▶ Do not administer SKYCLARYS by an enteral feeding tube

If you miss a dose, then you should skip the missed dose and take the next dose at the regular time the next day. Do not double your next dose or take more than the prescribed dose.

What should I avoid while taking SKYCLARYS?

- ▶ Do not drink grapefruit juice or eat grapefruit. These may change the amount of SKYCLARYS in your blood

For the best chance to slow your FA, take SKYCLARYS as your doctor prescribes

Consistent treatment may help support long-term goals

According to the World Health Organization, not keeping up with medications can lessen the benefits of treatment

Here are some suggestions that can help you follow your doctor's directions:



Set up phone reminders to take your medicine every day



Mark your calendar for follow-up appointments



Document your experience so you are ready for a conversation with your doctor



Ask your doctor for advice about managing side effects

Scheduled check-ins aren't just about lab results—they're about how you're doing, what's changed, and what matters to you

IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of SKYCLARYS include: increased liver enzymes (ALT/AST), headache, nausea, stomach pain, tiredness, diarrhea, and muscle pain.

Before taking SKYCLARYS, tell your healthcare provider about all of your medical conditions, including if you:

- ▶ have liver problems
- ▶ have a history of heart problems, including heart failure
- ▶ have a high level of fat in your blood (high blood cholesterol)
- ▶ are pregnant or plan to become pregnant. It is not known if SKYCLARYS will harm your unborn baby. Women who use hormonal birth control should use another form of birth control such as a non-hormonal intrauterine system or an extra non-hormonal birth control such as condoms while using SKYCLARYS and for 28 days after stopping SKYCLARYS
- ▶ Pregnancy exposure registry: There is a pregnancy registry for women who are pregnant and are taking SKYCLARYS. The purpose of this registry is to collect information about the health of you and your baby. Your healthcare provider can enroll you or you may enroll yourself by calling [1-866-609-1785](tel:1-866-609-1785) or by sending an email to SkyclarysPregnancySurveillance@ppd.com
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ACCESS AND RESOURCES

Get support for accessing your SKYCLARYS prescription with Biogen REACH

REACH is an access resource committed to helping people with FA receive SKYCLARYS quickly, easily, and affordably.

Enroll in REACH to explore your eligibility for affordability options

Your doctor must complete and submit a Start Form before you can access REACH support offerings.* Once enrolled in REACH, you will be assigned a Family Access Manager (FAM) and a Lead Case Manager (LCM).



FAM: Your point person

Your FAM will be your main point of contact for questions or concerns about the logistics surrounding treatment. Your FAM can assist with things such as:

- ▶ Access to medication
- ▶ REACH services
- ▶ Information about other eligible programs



LCM: Helping you understand access

Your FAM will connect you with your LCM if you have questions about access. Your LCM can help you:

- ▶ Understand your insurance status and SKYCLARYS treatment plan
- ▶ Navigate copay assistance as well as other financial services
- ▶ Facilitate communication with Biologics



Biologics: Getting your prescription

Biologics is the Biogen REACH exclusive specialty pharmacy and will collect any copayments or coinsurance needed for your SKYCLARYS prescription. They may also contact you about your:

- ▶ SKYCLARYS prescription
- ▶ Insurance benefits and copays
- ▶ Eligibility for copay assistance

SKYCLARYS is handled by a specialty pharmacy and delivered right to your door

Ongoing REACH support

REACH support does not end after you get access to SKYCLARYS. Registered pharmacists are here to support you throughout your SKYCLARYS treatment journey. Customized ongoing support services will be offered through the specialty pharmacy based on your individual needs and applicable program requirements.

Learn more by calling **1-844-987-3224**, 8:30 am-8:00 pm ET, Monday through Friday (except holidays).

*You are not required to enroll in Biogen REACH to receive a prescription for SKYCLARYS.

Whether or not you are insured, if SKYCLARYS is right for you, there are financial assistance programs that may help*

97%

of commercially insured patients have **\$0 in out-of-pocket costs** per month[†]

96%

of Medicare patients have **\$15 or less in out-of-pocket costs** per month[†]



If you are uninsured, the REACH program can help you determine financial assistance options.

If you have limited income or resources, you may qualify for Medicare Part D Extra Help. Extra Help is a subsidy program for Medicare prescription drug plan premiums, deductibles, and prescription copays. Patients enrolled in the Extra Help program may pay as little as \$0 to \$12.15[‡] for SKYCLARYS.

Apply online at ssa.gov/medicare/part-d-extra-help or by calling **1-800-772-1213**.

*Subject to eligibility and program terms and conditions. REACH affordability options are not healthcare insurance. Federal and state laws and other factors may prevent or otherwise restrict eligibility. People covered by Medicare, Medicaid, Veterans Affairs (VA), the Department of Defense (DoD), or any other federal plans are not eligible to enroll.

[†]As of August 2025.

[‡]In 2025.

Think of REACH as your personal support team for SKYCLARYS—here to help with access, treatment costs, insurance, and delivery



Get started today by finding your local FAM



You're not stepping into the unknown

No matter your age, it's not too late to take action. Over 3000 people with FA—from 16 to 83 years of age—have chosen SKYCLARYS worldwide.*

Hear real stories from people taking SKYCLARYS since 2023



JACOB *Diagnosed with FA at age 24*
"I can't control being born with FA, but I can control my daily choices."



CHRIS *Diagnosed with FA at age 17*
"Make the best of everything you have."



LIBBY *Diagnosed with FA at age 22*
"I think knowing that I have a lot of support makes it easier for me."



MATT *Diagnosed with FA at age 9*
"My philosophy in life is very much rooted in finding a sense of purpose."

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Call your doctor for medical advice about side effects. You may report side effects to FDA at [1-800-FDA-1088](tel:1-800-FDA-1088).

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REASONS TO CHOOSE SKYCLARYS FOR YOUR FA JOURNEY

IMPROVEMENT VS AN UNTREATED POPULATION

At Week 48 of the clinical trial, SKYCLARYS was shown to improve scores for mFARS, which measures mouth and throat function, upper and lower limb coordination, and upright stability

PRESCRIBED ACROSS AGE GROUPS

Over 3000 people globally—from 16 to 83 years of age—have chosen SKYCLARYS*

PAY AS LITTLE AS \$0 PER MONTH

97% of commercially insured patients have \$0 in out-of-pocket costs per month†

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Register for events near you!

Scan the QR code to learn more about FA and SKYCLARYS Spotlight, a series of free events hosted by Biogen.



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Intended for a US audience.

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