



Subject: Community Statement: Medicaid Update Related to SKYCLARYS

Dear FA Community,

We are pleased to recognize the three-year anniversary of the approval of SKYCLARYS® (omaveloxolone), and to inform the community of potential Medicaid updates related to recent federal policy changes.

As you may have heard in the news, the “One, Big, Beautiful Bill Act” may bring changes to how often Medicaid eligibility is reviewed and the responsibility of the individual to reverify eligibility. This means individuals on Medicaid may need to provide updated information more frequently to ensure they remain eligible. It’s very important to carefully read and respond to any letters or notices you receive from your Medicaid plan. Ignoring these could lead to a gap in your coverage. For individuals prescribed SKYCLARYS who need help understanding Medicaid coverage, completing paperwork, or even looking into other coverage options, your Biogen Family Access Manager (FAM) is here to support you or you can contact our Biogen REACH Patient Support program at 1-844-987-3224.

While we do not expect these policy changes to affect SKYCLARYS coverage directly, some individuals, particularly those in expanded Medicaid programs, may face paperwork or administrative hurdles as states conduct eligibility reviews. In some cases, patients who miss or overlook important notices from their Medicaid provider may unintentionally experience gaps in their coverage.

Biogen remains vigilant in monitoring any impact and is committed to supporting people with FA through our Biogen REACH Patient Support Program, which is available to help navigate insurance questions. For individuals prescribed SKYCLARYS or exploring treatment who have questions about coverage, financial assistance, or access, you or your healthcare provider can contact Biogen REACH at 1-844-987-3224 or visit [Biogen REACH -- SKYCLARYS.com](https://www.biogen.com/reach-skyclarys).

Sincerely,

Biogen Team

## 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?

#### SKYCLARYS may cause serious side effects, including:

- **Increase in blood liver enzymes:** Some people taking SKYCLARYS have had an increase in the level of liver enzymes in their blood. Your healthcare provider will do liver function tests
  - before you start taking SKYCLARYS
  - every month for the first 3 months after starting your treatment with SKYCLARYS
  - during certain times as needed while taking SKYCLARYS

If your liver enzymes increase, your healthcare provider may change your dose, stop treatment for some time, or completely stop treatment with SKYCLARYS.

- **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)
  - 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

**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 or by sending an email to [SkyclarysPregnancySurveillance@ppd.com](mailto:SkyclarysPregnancySurveillance@ppd.com)
- are breastfeeding or plan to breastfeed. It is not known if SKYCLARYS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take SKYCLARYS

**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

#### **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

These are not all the possible side effects of SKYCLARYS. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Please see full [Prescribing Information](#), including [Patient Information](#).**

Link click directs to  
<https://www.biogen.com/us/sky/prescribing-information.pdf>

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<https://www.skyclarys.com/content/dam/commercial/fa/sky/pat/en-us/pdf/skyclarys-us-patient-information.pdf>