Sample Letter of Medical Necessity for SKYCLARYS™ (omaveloxolone)

TO PRESCRIBER:

Please refer to the Important Safety Information in the full Prescribing Information when making a determination as to whether therapy is medically appropriate for the individual patient.

This sample **Letter of Medical Necessity** is provided for informational purposes only for patients who have been prescribed SKYCLARYS™ (omaveloxolone) capsules and is not based on legal advice or official guidance from payers. Reata Pharmaceuticals does not warrant, promise, guarantee, or make any statement that the use of this information will result in payer coverage or reimbursement for SKYCLARYS. There is no requirement that any patient or healthcare provider use any Reata product in exchange for this information, and this template letter is not meant to substitute for a prescriber's independent medical decision-making.

Payers may request a letter of medical necessity to support coverage of SKYCLARYS. The letter should explain why the drug is medically necessary for the specific patient and may include supporting documentation (eg, medical records, peer-reviewed literature, Prescribing Information, clinical treatment history, etc).

The letter may be submitted as part of a prior authorization (PA) request, in response to a payer's request for additional documentation to support approval of a PA, or to support an appeal of a PA denial. The letter must include patient-specific information, be written on the prescriber's letterhead, and be signed by the prescriber.

BELOW IS A TEMPLATE YOU CAN USE TO DRAFT YOUR LETTER OF MEDICAL NECESSITY

QUESTIONS?

Visit www.ReataREACH.com or call 1-844-98-REACH

REACH Care Navigators are available

8 AM to 8 PM, Monday–Friday (except holidays)

The information provided is for reference only and is not advice. Coding information provided does not provide a guarantee of reimbursement and should be considered together with all applicable coding guidance and standards. The healthcare provider is solely responsible for determining the appropriate codes. Reata assumes no liability for and its agents make no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information. Code information is subject to change.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Elevation of Aminotransferases: Treatment with SKYCLARYS can cause an elevation in hepatic transaminases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]). Monitor ALT, AST, and total bilirubin prior to initiation of SKYCLARYS, every month for the first 3 months of treatment, and periodically thereafter.

Please see additional Important Safety Information on page 3 and the full Prescribing Information for SKYCLARYS™ (omaveloxolone).

SAMPLE ONLY
Use your practice's letterhead

Prescriber's Name, Credentials
Prescriber's Practice Address
(###) ###-####

Date
Name of Healthcare Insurance Company
Address

Insured: Patient's Name; Policy Number: Policy number; Group Number: Group number
Date(s) of service: Date(s)

To Whom It May Concern,

I am writing on behalf of my patient, Patient's Name, to request coverage approval of SKYCLARYS™ for the treatment of Friedreich's ataxia (FA) in patients aged 16 years or older.

Patient's Name is Patient's age years of age and has been diagnosed with FA, ICD-10-CM diagnosis G11.11. The patient was diagnosed as of MM/DD/YYYY and has been in my care for FA since MM/DD/YYYY. I have prescribed SKYCLARYS (three 50-mg capsules orally, once daily) based on the dosing regimen for FA as recommended in the full Prescribing Information.

Below, please find a brief summary of rationale for treatment with SKYCLARYS:

- Genetic test results
- Blood test results (alanine aminotransferase, aspartate aminotransferase, bilirubin, b-type natriuretic peptide, and lipid parameters)
- Physical symptoms
- Any symptomatic treatment or ancillary therapy

In my medical opinion, SKYCLARYS is medically necessary for Patient's Name for treatment of FA based on the Prescribing Information. **If you have any further questions, please feel free to call me at (###) ###-#### to discuss.**

Thank you in advance for your immediate attention to this request,

Prescriber's Name, Credentials
Prescriber's Practice Name
(###) ###-####

Enclosures: Payer's prior authorization form, medical records, chart notes, copy of patient's insurance card, Prescribing Information for SKYCLARYS™, FDA approval letter for SKYCLARYS™ in Friedreich's ataxia

WARNINGS AND PRECAUTIONS (cont'd)

Elevation of B-Type Natriuretic Peptide: Treatment with SKYCLARYS can cause an increase in B-type natriuretic peptide (BNP), a marker of cardiac function. Elevations in BNP may indicate cardiac failure and should prompt an evaluation of cardiac function. Check BNP prior to initiation of SKYCLARYS. Monitor patients for the signs and symptoms of fluid overload.

Lipid Abnormalities: Treatment with SKYCLARYS can cause changes in cholesterol. Assess lipid parameters prior to initiation of SKYCLARYS and monitor periodically during treatment.

ADVERSE REACTIONS

Adverse reactions reported in 10% or more of patients and greater than placebo were elevated liver enzymes (AST/ALT) (37%), headache (37%), nausea (33%), abdominal pain (29%), fatigue (24%), diarrhea (20%), musculoskeletal pain (20%), oropharyngeal pain (18%), influenza (16%), vomiting (16%), muscle spasms (14%), back pain (13%), decreased appetite (12%), rash (10%).

To report SUSPECTED ADVERSE REACTIONS, contact Reata Pharmaceuticals, Inc. at 1-800-314-3934 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATION

SKYCLARYS is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

For more information about SKYCLARYS, please see the full Prescribing Information.

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Please see additional Important Safety Information on page 1 and the full Prescribing Information for SKYCLARYS™ (omaveloxolone).