



**Nulibry**  
**Nulibry (fosdenopterin) J1809**  
**Prior Authorization Request**  
**Medicare Part B Form**

Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	<b>Standard Request– (72 Hours)</b>	<input type="checkbox"/>	<b>Urgent Request</b> (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

**MEMBER INFORMATION**

\*Name: \_\_\_\_\_ \*ID#: \_\_\_\_\_ \*DOB: \_\_\_\_\_

**PRESCRIBER INFORMATION**

\*Name: \_\_\_\_\_  MD  FNP  DO  NP  PA \*Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ \*Fax: \_\_\_\_\_

**DISPENSING PROVIDER / ADMINISTRATION INFORMATION**

\*Name: \_\_\_\_\_ Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ Fax: \_\_\_\_\_

**PROCEDURE / PRODUCT INFORMATION**

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

Self-administered       Provider-administered       Home Infusion

Chart notes attached. **Other important information:** \_\_\_\_\_

**Diagnosis: ICD10:** \_\_\_\_\_ **Description:** \_\_\_\_\_

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

**CLINICAL INFORMATION**

**New Start or Initial Request: (Clinical documentation required for all requests)**

**Molybdenum Cofactor Deficiency (MoCD) Type A**

- Patient has confirmed diagnosis of Molybdenum Cofactor Deficiency Type A via genetic testing (biallelic pathogenic variants in MOCS1 gene)
- Patient is pediatric (initiation of therapy recommended as early as possible after diagnosis)
- Prescribed by or in consultation with metabolic disease specialist or geneticist

If not, please provide **clinical rationale** for formulary exception: \_\_\_\_\_

**Continuation Requests: (Clinical documentation required for all requests)**

- Patient had an **adequate response** or **significant improvement** while on this medication.
- Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: \_\_\_\_\_

**ACKNOWLEDGEMENT**

**Request By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

## Prior Authorization Group – Nulibry Prior Authorization

### Drug Name(s):

**NULIBRY**

**FOSDENOPTERIN**

### Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
  - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
  - Quantity limits and Tiering will be determined by the Plan, in accordance with the Label.
  - Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

### Exclusion Criteria:

**N/A**

### Prescriber Restrictions:

**Metabolic Disease specialist, Geneticist or other related specialist**

### Coverage Duration:

**Approval will be for 6 months**

### FDA Indications:

**Nulibry**

- Combined molybdoflavoprotein enzyme deficiency, Type A

### Off-Label Uses:

**N/A**

### Age Restrictions:

**N/A**

### Other Clinical Consideration:

**N/A**

### Resources:

[https://www.google.com/search?q=is+a+nulibry+rems+program+still+required&rlz=1C1GCEA\\_enUS996US996&oq=is+a+nulibry+rems+program+still+required&gs\\_lcrp=EgZjaHJvbWUyBggAEEUYOTIKCAEQABiBBiJBTIKCAIQABiABBiBDIKCAMQABiBBiJBTIHCAQQABjvBTIKCAUQABiBBiJBdIBCTExNTU5ajBqN6gCALACAA&sourceid=chrome&ie=UTF-8](https://www.google.com/search?q=is+a+nulibry+rems+program+still+required&rlz=1C1GCEA_enUS996US996&oq=is+a+nulibry+rems+program+still+required&gs_lcrp=EgZjaHJvbWUyBggAEEUYOTIKCAEQABiBBiJBTIKCAIQABiABBiBDIKCAMQABiBBiJBTIHCAQQABjvBTIKCAUQABiBBiJBdIBCTExNTU5ajBqN6gCALACAA&sourceid=chrome&ie=UTF-8)