

Letter of Medical Necessity

[Date]

[Payer Name]

[Payer Street Address]

[Payer City, State, and Zip Code]

Patient Name: [Patient Name]

Date of Birth: [Patient Birth Date]

Member ID: [Patient Member ID Number]

Policy or Group Number: [Patient Policy or Group Number] Case ID Number: [Case ID Number (if available)]

To Whom It May Concern:

I am writing on behalf of my patient, [patient name], to provide information supporting medical necessity for MODEYSO™ (dordaviprone) treatment. In this letter, I am providing my patient's medical history, diagnosis, and a summary of their treatment plan. I have also provided a brief description of [patient name]'s previous treatments and a clinically based treatment rationale supporting the medical necessity for MODEYSO.

MODEYSO received FDA approval under accelerated approval on August 6, 2025. MODEYSO is medically appropriate and necessary for this patient, who has been diagnosed with [insert diagnosis] ([ICD-10 code(s)]). Therefore, I am requesting that [Health Plan Name] approve coverage for MODEYSO as a preferred medication for my patient.

Clinical History, Considerations For, and Treatment Plan

[Patient Name] is a [age]-year-old patient who was diagnosed with [insert diagnosis] ([ICD-10-code(s)]) on [date of diagnosis]. [He/She/They] has/have been in my care since [date]. Please find below a summary of [Patient Name]'s clinical course, including: []. Key considerations for this patient's treatment include: []. My plan of treatment includes []. This treatment aligns with [relevant clinical practice guidelines, professional society recommendations, or expert consensus that support MODEYSO's use for this specific type of glioma].

Why MODEYSO is Medically Necessary

Clearly articulate why MODEYSO is the most appropriate and necessary treatment for this patient.

Summary

Based on [Patient Name]'s condition, confirmed diagnosis of [insert diagnosis], and my extensive experience treating patients with this challenging diagnosis, I have concluded that MODEYSO is medically appropriate and essential in this case. I expect [physician expectation regarding clinical outcomes for patient].

I request an immediate and expedited review of this request by a board-certified and specialty-matched physician who can render a decision based upon the standards of care outlined above. If you have any questions or require a peer-to-peer discussion, please contact me at [Physician Phone Number]. I would be pleased to provide further details on why coverage for MODEYSO is necessary for [Patient Name]'s treatment of [insert diagnosis].

Should the information provided not establish medical necessity to your satisfaction, please provide me with a detailed rationale based upon current standards of care, including the specialty and board certification status of the reviewing physician.

I look forward to your timely response and approval of MODEYSO.

Sincerely,

[Physician Name]

[Physician Signature] [Physician Contact Information]

Appeal Letter

[Date]

[Payer Name]

[Payer Street Address]

[Payer City, State, and Zip Code]

Patient Name: [Patient Name]

Date of Birth: [Patient Birth Date]

Member ID: [Patient Member ID Number]

Policy or Group Number: [Patient Policy or Group Number] Case ID Number: [Case ID Number (if available)]

To Whom It May Concern:

My name is [Physician Name], and I am a [board-certified medical specialty] (NPI: [Your NPI]). This letter serves as the [1st/2nd] appeal for approval of MODEYSO™ (dordaviprone), which was originally denied for [Patient Name] on [date of denial]. I am writing to provide additional information to support my request to treat [Patient Name], who has been diagnosed with [insert diagnosis] ([ICD-10 code(s)]), with MODEYSO.

In brief, treating [Patient Name] with MODEYSO is medically appropriate and necessary and should be covered and reimbursed. [Health Plan Name] determined MODEYSO was not covered for [Patient Name] because [clearly state the specific reason(s) for denial provided in the EOB]. This letter provides my clinical rationale and relevant information about the patient's medical history and treatment plan to address the denial.

Clinical History, Considerations For, and Treatment Plan

[Patient Name] is a [age]-year-old patient who was diagnosed with [insert diagnosis] ([ICD-10-code(s)]) on [date of diagnosis]. [He/She/They] has/have been in my care since [date]. Please find below a summary of [Patient Name]'s clinical course, including: []. Key considerations for this patient's treatment include: []. My plan of treatment includes []. This treatment aligns with [relevant clinical practice guidelines, professional society recommendations, or expert consensus that support MODEYSO's use for this specific type of glioma].

Why MODEYSO is Medically Necessary

Clearly articulate why MODEYSO is the most appropriate and necessary treatment for this patient.

Summary

Based on the patient's condition, confirmed diagnosis of [insert diagnosis], prior therapies for [insert indication], and my experience treating patients with this challenging diagnosis, I believe treatment with MODEYSO is warranted, appropriate, and medically necessary in this case. The accompanying package insert provides the approved clinical information for MODEYSO. I have attached relevant lab test analyses, imaging reports, and medical records to support my decision and refute the grounds for the previous denial.

I am requesting an immediate and expedited review of this appeal, along with the enclosed documents and supporting evidence, by my office and by a board-certified and specialty-matched physician who can render a decision based upon the standards of care outlined above. If you have any further questions about this matter, please contact me at [Physician Phone Number], via e-mail at [Physician Email], or by fax at [Provider Fax Number]. I look forward to receiving your timely response and approval of this claim.

Once approved for MODEYSO, I will discontinue the treatment/prescription of [alternate BRAND (generic) name], if applicable.

If you do not feel that the information provided has established medical necessity, please provide me with your detailed rationale based upon current standards of care, the specialty of the physician who reviewed this case, and whether they are board-certified in an applicable medical specialty.

Sincerely,

[Physician Name]

[Physician Signature] [Physician Contact Information]

Formulary Exception Letter

[Date]

[Payer Name]

[Payer Street Address]

[Payer City, State, and Zip Code]

Patient Name: [Patient Name]

Date of Birth: [Patient Birth Date]

Member ID: [Patient Member ID Number]

Policy or Group Number: [Patient Policy or Group Number] Case ID Number: [Case ID Number (if available)]

Dear [PBM/Insurance Company Name] Prior Authorization Department,

I am writing on behalf of my patient, [Patient's Full Name], to request a formulary exception for the medication MODEYSO™ (dordaviprone) [125 mg capsules]. This medication is medically necessary for [Patient's Full Name]'s treatment due to [insert diagnosis].

[Patient's Full Name]'s clinical history clearly supports the need for MODEYSO. [Provide detailed clinical justification here. This is the most crucial part. Include information such as:]

- **Diagnosis and relevant medical history** [Briefly explain [Patient's Full Name]'s condition]
- **Previous treatments and their outcomes** [List preferred formulary alternatives (if any) that have been tried and failed, were contraindicated, or caused intolerable side effects. Be specific about dates, dosages, and reasons for failure]
- **Rationale for MODEYSO** [Explain why this particular medication is superior or necessary for [Patient's Full Name] compared to other options. Highlight specific patient characteristics or disease aspects that make MODEYSO the most appropriate choice]
- **Potential risks of not receiving the requested medication** [Briefly explain the negative consequences if [Patient's Full Name] does not receive this specific treatment We have carefully considered all available formulary alternatives, and based on [Patient's Full Name]'s individual medical needs and treatment response to previous therapies, MODEYSO is the most appropriate and medically necessary option at this time to achieve optimal therapeutic outcomes and prevent further complications]

I am available to discuss [Patient's Full Name]'s case further and provide any additional information you may require to facilitate this approval. Please contact me at [Your Phone Number] or [Your Email Address].

Thank you for your prompt attention to this urgent matter.

Sincerely,

[Physician Name]

[Physician Signature] [Physician Contact Information]