***Cover Letter of Medical Necessity/Appeal Template
for QALSODY® (tofersen)***

**The following pages may be customized to use as a letter of medical necessity/appeal in support of a patient receiving QALSODY for treatment of amyotrophic lateral sclerosis (ALS) who has a mutation in the superoxide dismutase 1 (*SOD1*) gene. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional. Please note that the Important Safety Information does not need to be included as part of your letter.**

The following sample letter is intended to be used as a guide; therefore, it is important to tailor the letter to the specific needs of your patients and address the reason(s) why QALSODY is the appropriate treatment option. You should always include pertinent clinical information that supports your decision to prescribe QALSODY.

Please see below for considerations when writing a letter of medical necessity/appeal:

* Review the health plan’s medical policy criteria and point out the criteria that your patient meets. Explain why your patient should be excluded from any criteria that he/she/they do(es) not meet
* Provide background on your patient’s condition and clearly state your patient’s individual circumstances to justify why the prescribed therapy is the appropriate choice
* Provide clinical justification and include copies of relevant clinical data to support your decision
(eg, chart notes, genetic testing results)
* Submit the letter as required by the health plan and state guidelines. It is important that you understand the process for each health plan, including how to submit the request (eg, fax, phone, email, the company’s website) as well as how and when the decision will be communicated
* Track the status of your request and follow up with the health plan as needed

**INDICATION**

QALSODY® (tofersen) is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (*SOD1*) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

**IMPORTANT SAFETY INFORMATION**

**Warnings and Precautions**

**Myelitis and/or Radiculitis**

Serious adverse reactions of myelitis and radiculitis have been reported in patients treated with QALSODY. Six patients treated with QALSODY experienced myelitis or radiculitis in the clinical studies. Two patients discontinued treatment with QALSODY and required symptomatic management with full resolution of symptoms. In the remaining 4 patients, symptoms resolved without discontinuation of QALSODY. If symptoms consistent with myelitis or radiculitis develop, diagnostic workup and treatment should be initiated according to the standard of care. Management may require interruption or discontinuation of QALSODY.

**Please see additional Important Safety Information continued on next page and click for full** [**Prescribing Information**](https://www.biogencdn.com/us/pdfs/qalsody-prescribing-information.pdf)**.**

**IMPORTANT SAFETY INFORMATION (CONT’D)**

**Warnings and Precautions (cont’d)**

**Papilledema and Elevated Intracranial Pressure**

Serious adverse reactions of papilledema and elevated intracranial pressure have been reported in patients treated with QALSODY. Four patients developed elevated intracranial pressure and/or papilledema. All patients received treatment with standard of care with resolution of symptoms, and no events led to discontinuation of QALSODY. If symptoms consistent with papilledema or elevated intracranial pressure develop, diagnostic workup and treatment should be initiated according to the standard of care.

**Aseptic Meningitis**

Serious adverse reactions of aseptic meningitis (also called chemical meningitis or drug-induced aseptic meningitis) have been reported in patients treated with QALSODY. One patient experienced a serious adverse reaction of chemical meningitis, which led to discontinuation of QALSODY. One patient experienced a serious adverse reaction of aseptic meningitis, which did not lead to discontinuation of QALSODY. In addition, nonserious adverse drug reactions of CSF white blood cell increased, and CSF protein increased have also been reported with QALSODY. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

**Adverse Reactions**

The most common adverse reactions (≥10% of patients treated with QALSODY and greater than placebo) were pain, fatigue, arthralgia, cerebrospinal fluid white blood cell increased, and myalgia.

**Please click for full** [**Prescribing Information**](https://www.biogencdn.com/us/pdfs/qalsody-prescribing-information.pdf)**.**

This sample letter is for informational purposes only, providing an example of language that may be required or helpful when responding to a request from a patient’s health plan. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional.

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[*Note: When preparing the actual letter, use professional/personal letterhead.*]

[Date] Patient: [First and last name]

[Health plan contact name] Patient date of birth: [Patient date of birth]

[Health plan name] Policy number: [Number]

[Address] Group number: [Number]

[City, State, ZIP code] [Claim number: Number if relevant to request]

RE: [Reason for letter]

Dear [Health plan contact name]:

I am writing this letter of [medical necessity/appeal] in support of my request to [initiate treatment/continue treatment] for [patient name] with QALSODY® (tofersen), a US Food and Drug Administration (FDA)–approved therapy for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (*SOD1*) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

[If appealing a denial:] The reason[s] for denial of QALSODY [is/are] stated as [reason(s) for denial]. I disagree with this decision because [reason(s) you disagree with the denial].

I am a board-certified [field of certification] ([National Provider Identifier]) with [#] years of experience caring for patients with ALS. I believe that treatment with QALSODY is warranted, appropriate, and medically necessary for this patient based on my clinical judgment and expertise. [I have been treating [patient name] for [#] [months/years].] Below, this letter outlines [patient name]’s medical history and prognosis and the rationale for treatment with QALSODY.

1. **Summary of Patient’s Medical History *[You may want to include]*:**
* [Patient’s diagnosis, current condition/ICD-10 code(s), and date of diagnosis
* Relevant medical history
* Information pertaining to the mutation of the *SOD1* gene, baseline testing, and genetic testing
* Previous treatments/therapies (if any) and patient’s response to these treatments/therapies, including reasons for failure, discontinuation, or contraindication (if applicable)
* Overview of the patient’s current abilities and level of mobility, if applicable
	+ Consider including relevant functional assessment scores prior to treatment and, if applicable, during]
1. **Patient-Specific Rationale for Treatment**

**[Note: Exercise your medical judgement and discretion when providing a diagnosis and characterization of the patient’s medical conditions. Provide your clinical rationale for treatment while considering the health plan’s medical policy criteria for QALSODY.]**

[HCP to insert the reason(s) for recommendation to use QALSODY, which may include:]

* [Reason(s) QALSODY is most appropriate for this patient, such as efficacy profile of this product, safety and tolerability profile of this product, pharmacokinetic profile, dosage, and/or route of administration]
* [Relevant information about QALSODY (Note: You may wish to include relevant background information about QALSODY in the letter. For additional information, please refer to the QALSODY Prescribing Information)]
* [Additional reason(s) why QALSODY is the most appropriate treatment for this patient based on relevant medical history, genetic testing, previous treatments/therapies and patient’s response to these treatments/therapies (if applicable), or patient’s current abilities and level of mobility, if applicable]

In brief, based on the clinical data available to date, it is my medical opinion that [initiating/continuing/
re-initiating] treatment with QALSODY for [patient name] is warranted, appropriate, and medically necessary, and the procedures required for its administration are services that should be covered and reimbursed.

1. **Concluding Remarks**

[HCP to insert information relevant to the particular case (eg, Given the patient’s history, his/her/their current condition, and the emerging data of the effects of QALSODY in patients with ALS, I believe that treatment of [patient name] with this product is warranted, appropriate, and medically necessary. The totality of the data available to date supports the potential benefit of [treatment/continuing treatment] with QALSODY).]

Please call my office at [telephone number] for any additional information. I look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician Name, National Provider Identifier]

Attachments: [Copy of patient’s health plan card(s); QALSODY Prescribing Information; additional relevant information such as chart notes, laboratory results, and functional assessment results; original claim form; and previous communications with the health plan/denial letters (if relevant).]

**Reference:** QALSODY Prescribing Information. Cambridge, MA: Biogen.