



# Qalsody (tofersen)

Fax completed form to: (855) 840-1678  
If this is an URGENT request, please call (800) 882-4462  
(800.88.CIGNA)

PHYSICIAN INFORMATION			PATIENT INFORMATION		
* Physician Name:			*Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items on this form are completed.*		
Specialty:	* DEA, NPI or TIN:				
Office Contact Person:			* Patient Name:		
Office Phone:			* Cigna ID:		* Date of Birth:
Office Fax:			* Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient Phone:		
<b>Urgency:</b> <input type="checkbox"/> Standard <span style="margin-left: 200px;"><input type="checkbox"/> Urgent (In checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)</span>					
<b>Medication requested:</b> <input type="checkbox"/> Qalsody 100 mg/15 mL vial <input type="checkbox"/> Other (please specify):  ICD10:  <b>Directions for use:</b> Dose: <span style="margin-left: 150px;">Frequency of therapy:</span> <span style="margin-left: 150px;">Duration of Therapy:</span>					
Is the requested medication for a chronic or long-term condition for which the prescription medication may be necessary for the life of the patient? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>					
<b>Where will this medication be obtained?</b> <input type="checkbox"/> Optum/Frontier Therapies <span style="margin-left: 300px;"><input type="checkbox"/> Home Health / Home Infusion vendor</span> <input type="checkbox"/> Hospital Outpatient <span style="margin-left: 300px;"><input type="checkbox"/> Physician's office stock (billing on a medical claim form)</span> <input type="checkbox"/> Retail pharmacy <input type="checkbox"/> Other (please specify):					
<b>Facility and/or doctor dispensing and administering medication:</b> Facility Name: <span style="margin-left: 150px;">State:</span> <span style="margin-left: 150px;">Tax ID#:</span> Address (City, State, Zip Code):					
Is the patient a candidate for home infusion? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>  Does the physician have an in-office infusion site? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>					
<b>Clinical Information:</b>  <p style="text-align: center;"><b>***This drug requires supportive documentation (i.e. genetic testing, chart notes, lab/test results, etc).***</b></p> Does your patient have a diagnosis of Amyotrophic Lateral Sclerosis (ALS)? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>  (if no) What is the diagnosis related to use?    Is this medication being prescribed by, or in consultation with, a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>  Does the patient have weakness associated with ALS? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>					

Is this initial therapy or is the patient currently receiving Qalsody?

- Initial Therapy  
 Currently Receiving Qalsody

(if initial therapy) Is documentation being provided that the patient have one of the following pathogenic or likely pathogenic variants of the SOD1 gene: p.Ala5Val, p.Ala5Thr, p.Leu39Val, p.Gly42Ser, p.His44Arg, p.Leu85Val, p.Gly94Ala, p.Leu107Val, or p.Val149Gly? Documentation may include, but is not limited to, chart notes, laboratory results, claims records, and/or other information.  Yes  No

(if yes) Is documentation being provided that the patient have a baseline Amyotrophic Lateral Sclerosis Functional Rating Scale - Revised (ALSFRS-R) slope decline of greater than or equal to 0.2 per month. (ALSFRS-R slope decline is calculated as [48 minus baseline ALSFRS-R total score/time since symptom onset])? Documentation may include, but is not limited to, chart notes, laboratory results, claims records, and/or other information.  Yes  No

(if no) Is documentation being provided that the patient has a SOD1 genetic variant WHICH IS NOT LISTED HERE: p.Ala5Val, p.Ala5Thr, p.Leu39Val, p.Gly42Ser, p.His44Arg, p.Leu85Val, p.Gly94Ala, p.Leu107Val, or p.Val149Gly? Documentation may include, but is not limited to, chart notes, laboratory results, claims records, and/or other information.  Yes  No

(if yes) Is documentation being provided that the patient have a baseline Amyotrophic Lateral Sclerosis Functional Rating Scale - Revised (ALSFRS-R) slope decline of greater than or equal to 0.9 per month (ALSFRS-R slope decline is calculated as [48 minus baseline ALSFRS-R total score/time since symptom onset])? Documentation may include, but is not limited to, chart notes, laboratory results, claims records, and/or other information.  Yes  No

(if initial therapy) Is there documentation of elevated plasma (serum) neurofilament light chain levels at baseline?  Yes  No

(if initial therapy) Is there documentation of a slow vital capacity (SVC) of greater than or equal to 65% of predicted value for sex, age, and height (from the sitting position)?  Yes  No

(if initial therapy) Has the patient received, or is currently receiving, riluzole tablets, Tiglutik (riluzole oral suspension), or Exservan (riluzole oral film)?  Yes  No

(if initial therapy) Is the requested dosing three initial loading doses of 100 mg (15 mL), each given every 14 days intrathecally, followed by a maintenance dose of 100 mg (15 mL) intrathecally not more frequently than once every 28 days?  Yes  No

(if no) Please provide clinical support for requesting this DOSE for your patient (examples could include past doses tried, past medications tried, pertinent patient history).

(if currently receiving only) According to the prescriber, does the patient continues to benefit from therapy?  Yes  No

(if no) Please provide support for continued use.

(if currently receiving only) Does the patient have a superoxide dismutase 1 (SOD1) genetic variant?  Yes  No

(if currently receiving only) Does the patient require invasive ventilation?  Yes  No

**Supportive documentation for all answers must be attached with this request. Notes: In subsequent coverage reviews for a patient who has previously met the documentation requirements and related criteria in the Neurology - Qalsody Prior Authorization Policy through the Coverage Review Department, and who is requesting reauthorization, the criteria utilized do NOT require resubmission of documentation for reauthorization, except for the criterion requiring documentation of response or benefit to Qalsody therapy**

**Additional Pertinent Information:** (Please provide clinical support for the use of this drug in your patient (including disease stage, prior therapy, performance status, and names/doses/admin schedule of any agents to be used concurrently):

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

**Prescriber Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

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