



# Prior Authorization Request Administrative Information

## Member information

Last name  First name  MI

Member ID  Date of birth

Sex assigned at birth  Female  Male  "X" or Intersex

Current gender  Female  Male  Transgender male  Transgender female  Other

Place of residence  Home  Nursing facility  Other

Race  Ethnicity

Preferred spoken language  Preferred written language

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

## Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

<p><b>MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan</b></p> <p><input type="checkbox"/> <b>MassHealth Drug Utilization Review Program</b> Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318</p>
<p><b>MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)</b></p> <p><input type="checkbox"/> <b>Fallon Health</b> Online Prior Authorization: <a href="http://go.covermy meds.com/OptumRx">go.covermy meds.com/OptumRx</a> Online Prior Authorization: <a href="http://providerportal.surescripts.net/ProviderPortal/optum">providerportal.surescripts.net/ProviderPortal/optum</a> Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033</p>
<p><input type="checkbox"/> <b>Health New England</b> Online Prior Authorization: <a href="http://go.covermy meds.com/OptumRx">go.covermy meds.com/OptumRx</a> Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545</p>
<p><input type="checkbox"/> <b>Mass General Brigham Health Plan</b> Online Prior Authorization (Non-Specialty Drugs): <a href="http://go.covermy meds.com/OptumRx">go.covermy meds.com/OptumRx</a> Online Prior Authorization (Specialty/Medical Drugs): <a href="http://provider.massgeneralbrighamhealthplan.org">provider.massgeneralbrighamhealthplan.org</a> Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555</p>
<p><input type="checkbox"/> <b>Tufts Health Plan</b> Online Prior Authorization: <a href="http://point32health.promptpa.com">point32health.promptpa.com</a> Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985</p>
<p><input type="checkbox"/> <b>WellSense Health Plan</b> Online Prior Authorization: <a href="http://wellsense.org/providers/ma/pharmacy/prior-authorizations">wellsense.org/providers/ma/pharmacy/prior-authorizations</a> Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822</p>

# Neuromuscular Agents

## Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at [www.mass.gov/druglist](http://www.mass.gov/druglist).

### Medication information

#### Medication requested

- |   |  |
|---|--|
| <input type="checkbox"/> Amondys 45 (casimersen)                                    | <input type="checkbox"/> Spinraza (nusinersen) <sup>MB</sup>                     |
| <input type="checkbox"/> Duvyzat (givinostat)                                       | <input type="checkbox"/> Viltepso (viltolarsen)                                  |
| <input type="checkbox"/> Elevidys (delandistrogene moxeparvovec-rokl) <sup>MB</sup> | <input type="checkbox"/> Vyondys 53 (golodirsen)                                 |
| <input type="checkbox"/> Evrysdi (risdiplam)  | <input type="checkbox"/> Zolgensma (onasemnogene abeparvovec-xioi) <sup>MB</sup> |
| <input type="checkbox"/> Exondys 51 (eteplirsen)                                    |  |

<sup>MB</sup> This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

#### Dose, frequency, and duration of medication requested

**Indication** (Check all that apply or include ICD-10 code, if applicable.)

- |  |   |
|--|---|
| <input type="checkbox"/> Duchenne muscular dystrophy (DMD) | <input type="checkbox"/> Spinal muscular atrophy (SMA)                        |
| <input type="checkbox"/> Other <input type="text"/>        | <input type="checkbox"/> pre-symptomatic <input type="checkbox"/> symptomatic |

Type

Please indicate billing preference.  Pharmacy  Prescriber in-office  Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Member's current weight

Date

Is the member stabilized on the requested medication?  Yes. Please provide start date.   No

### Section I. Please complete for Amondys 45, Duvyzat, Exondys 51, Viltepso, and Vyondys 53 requests.

For initial requests, please complete questions 1 through 12 as applicable. For recertification requests, please complete questions 3, 7, 9, 10, 11, and 12 as applicable.

1. Please attach laboratory testing results of a confirmed out-of-frame deletion in the DMD gene that is amenable to either exon 45 skipping (for Amondys 45 requests), exon 51 skipping (for Exondys 51 requests) or exon 53 skipping (for Viltepso and Vyondys 53 requests). For Duvyzat, attach a copy of genetic test showing mutation in the DMD gene confirming the diagnosis.
2. Is the prescriber a neuromuscular neurologist?  Yes  No. If no, please attach consultation notes from a neuromuscular neurologist addressing the use of the requested agent.

3. Is the member ambulatory as defined by a current six-minute walk test (6MWT-distance walked in six minutes in meters) of  $\geq 200$  meters?

Please note, the test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

Yes. Distance  meters  No  
Date of performance  Treatment at the time of test

4. For Amondys 45, Exondys 51 and Vyondys 53 requests, has the member received a corticosteroid for at least six months prior to use with the requested agent?

Yes. Please list the drug name, dose and frequency, and dates of use below.  
Drug name  Dose and frequency  Dates of use   
 No. Please explain.

5. For Viltepso requests, has the member received a corticosteroid for at least three months prior to use with the requested agent?

Yes. Please list the drug name, dose and frequency, and dates of use below.  
Drug name  Dose and frequency  Dates of use   
 No. Please explain.

6. For Duvyzat requests, is the member on a stable dose of corticosteroid?

Yes. Please list the drug name, dose and frequency, and dates of use below.  
Drug name  Dose and frequency  Dates of use   
 No

7. Will the member be taking the requested agent concurrently with a corticosteroid?

Yes. Please document drug name with dose and frequency below.  
Drug name  Dose and frequency   
 No. Please explain.

8. Please provide dates and measurements and attach medical records of baseline measurements for each of the following five timed function tests: timed 10-meter walk/run, timed floor (supine) to stand, timed four-step descend, timed four-step climb, timed sit to stand. Medical records must include the times in seconds, dates of performances, and treatment at the time of tests. Please note, the test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

Timed 10-meter walk/run (time in seconds)   
Date of performance  Treatment at the time of test

Timed floor (supine) to stand (time in seconds)   
Date of performance  Treatment at the time of test

Timed four-step descend (time in seconds)   
Date of performance  Treatment at the time of test

Timed four-step climb (time in seconds)   
Date of performance  Treatment at the time of test

Timed sit to stand (time in seconds)   
Date of performance  Treatment at the time of test

9. Please provide dates and measurements and attach medical records of all previous and current six-minute walk tests (6MWTs). Please note, the current test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

Baseline 6MWT

Distance  meters

Date of performance  Treatment at the time of test

Current 6MWT

Distance  meters

Date of performance  Treatment at the time of test

Additional 6MWT(s)

Date(s) of performance

10. Please provide dates and measurements and attach medical records of current measurements for each of the following five timed function tests: timed 10-meter walk/run, timed floor (supine) to stand, timed four-step descend, timed four-step climb, timed sit to stand. Medical records must include the times in seconds, dates of performances, and treatment at the time of tests. Please note, the test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

Timed 10-meter walk/run (time in seconds)

Date of performance  Treatment at the time of test

Timed floor (supine) to stand (time in seconds)

Date of performance  Treatment at the time of test

Timed four-step descend (time in seconds)

Date of performance  Treatment at the time of test

Timed four-step climb (time in seconds)

Date of performance  Treatment at the time of test

Timed sit to stand (time in seconds)

Date of performance  Treatment at the time of test

11. Has the member previously received treatment with a gene therapy for DMD?  Yes  No

12. For Duvyzat requests, will the requested agent be used in combination with other disease-modifying therapies for DMD (e.g., exon-skipping therapies)?  Yes  No

**Section II. Please complete for Evrysdi and Spinraza requests.**

- 1. Please attach a copy of genetic test(s) confirming the diagnosis of SMA and SMN2 copy number.
- 2. Is the member symptomatic?  Yes  No
- 3. Is the member a pre-symptomatic infant diagnosed via newborn screening?  Yes  No
- 4. Is the prescriber a neurologist?  Yes  No. If no, please attach consultation notes from a neurologist addressing the use of the requested agent.
- 5. Please attach documentation of current motor function test.
- 6. Will the requested agent be used in combination with other agents for SMA?

Yes. Please provide drug name(s).

No

7. For initial and recertification requests, does the member have evidence of permanent ventilator, defined as any of the following?
- Member has an endotracheal tube  Yes  No  
 Member has a tracheotomy tube  Yes  No  
 Member has at least 14 days of continuous respiratory assistance for at least 16 hours per day  
 Yes  No
8. Has the member been previously treated with any other SMA agent?  Yes  No  
 If yes, please list the drug names and outcomes below.
- Drug name   Adverse reaction  Inadequate response  Other  
 Briefly describe details of adverse reaction, inadequate response, or other.
9. For members previously treated with another SMA agent, please attach documentation of pre-treatment baseline motor function tests and post-treatment motor function tests.
10. For members previously treated with Zolgensma, please attach pre-Zolgensma baseline motor function test (if different than the pre-treatment tests) and post-treatment motor function tests.
11. For recertification requests, please attach medical records documenting positive response to therapy (e.g., follow up information on motor function tests and/or member's improvement or stability of function).

**Section III. Please complete for Zolgensma requests.**

Please note, questions 7, 8, and 9 will not impact the outcome of review for approval of Zolgensma.

1. Please attach a copy of the genetic test confirming diagnosis of SMA and number of copies of SMN2 gene.
2. Is the prescriber a neuromuscular specialist?  Yes  No. If no, please attach the consultation notes from a neuromuscular specialist addressing the use of the requested agent.
3. Please attach a copy of baseline AAV9 antibody test.
4. Pre-treatment baseline Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) score.
5. Does the member have evidence of complete paralysis of limbs?  Yes  No
6. Does the member have evidence of permanent ventilator dependence at the time Zolgensma is to be administered, defined as any of the following?
- Member has an endotracheal tube  Yes  No  
 Member has a tracheotomy tube  Yes  No  
 Member has at least 14 days of continuous respiratory assistance for at least 16 hours per day  
 Yes  No
7. Has the member had a trial with Spinraza?  Yes  No  
 If yes, please list the dose and frequency, dates of use, outcome, and treatment plan below.
- Dose and frequency  Dates of use   
 Did member experience any of the following?  Adverse reaction  Inadequate response  Other  
 Briefly describe details of adverse reaction, inadequate response, or other.
- Will the member continue Spinraza after Zolgensma?  Yes  No
8. Has the member had a trial with Evrysdi?  Yes  No  
 If yes, please list the dose and frequency, dates of use, outcome, and treatment plan below.
- Dose and frequency  Dates of use   
 Did member experience any of the following?  Adverse reaction  Inadequate response  Other  
 Briefly describe details of adverse reaction, inadequate response, or other.

Will the member continue Evrysdi after Zolgensma?  Yes  No

9. Please describe the functional tests that will be used to monitor this member and attach medical records with baseline functional test scores.

10. Has the member previously received treatment with a gene therapy for DMD?  Yes  No

11. Does the member have an active viral infection, including human immunodeficiency virus (HIV) or positive serology for hepatitis B or C, or Zika virus?  Yes  No

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**Section IV. Please complete for Elevidys requests.**

1. Please attach a copy of genetic test with a confirmed mutation in the DMD gene.

2. Please attach a copy of baseline anti-AAVrh74 total binding antibody titers < 1:400.

3. Will the infusion take place in a qualified treatment center?  Yes   No

4. Please provide anticipated date of administration.

5. Is the prescriber a neuromuscular specialist?  Yes  No

6. Does the member have any deletion in exon 8 or exon 9 of the DMD gene?  Yes  No

7. Is the member on a stable dose of corticosteroid?  Yes  No

8. Will the member continue to utilize chronic corticosteroids after Elevidys infusion?  Yes  No

9. Does the member have a contraindication to corticosteroids?  Yes  No

If yes, briefly describe details of contraindication.

10. Has the member been previously treated with a gene therapy for DMD?  Yes  No

11. Is the member currently utilizing antisense oligonucleotides?  Yes  No

12. Has the member had a baseline measurement for the North Star Ambulatory Assessment (NSAA)?  
 Yes. Please attach medical records of NSAA, including scores and times on individual items.  No

13. Is the member ambulatory as defined by a current 6MWT of  $\geq 200$  meters?  
Please note, the test must have been observed or completed by the treating provider or ordered by the treating provider and completed by a qualified medical practitioner.

Yes. Distance  meters  No  
Date of performance  Treatment at the time of test

14. Please provide dates and measurements and attach medical records of all previous and current six-minute walk tests (6MWTs). Please note, the current test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

Baseline 6MWT  
Distance  meters  
Date of performance  Treatment at the time of test

Current 6MWT  
Distance  meters  
Date of performance  Treatment at the time of test

Additional 6MWT(s)  
Date(s) of performance

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**Section V. Please complete and provide documentation for exceptions to step therapy.**

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member?  Yes  No

If yes, briefly describe details of contraindication, adverse reaction, or harm.

  

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

Yes  No

If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

  

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

Yes  No

If yes, please provide details for the previous trial.

Drug name

Dates/duration of use

Did the member experience any of the following?  Adverse reaction  Inadequate response

Briefly describe details of adverse reaction or inadequate response.

  

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

Yes. Please provide details.

No

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**Please continue to next page and complete Prescriber and Provider Information section.**

# Prior Authorization Request Prescriber and Provider Information

## Prescriber information

Last name*	<input type="text"/>	First name*	<input type="text"/>	MI	<input type="text"/>
NPI*	<input type="text"/>	Individual MH Provider ID	<input type="text"/>		
DEA No.	<input type="text"/>	Office Contact Name	<input type="text"/>		
Address	<input type="text"/>	City	<input type="text"/>	State	<input type="text"/>
		Zip	<input type="text"/>		
E-mail address	<input type="text"/>				
Telephone No.*	<input type="text"/>				
Fax No.* (Please provide fax number for PA response notification.)	<input type="text"/>				

\* Required

## Please also complete for professionally administered medications, if applicable.

Start date	<input type="text"/>	End date	<input type="text"/>		
Servicing prescriber/facility name	<input type="text"/>	<input type="checkbox"/>	Same as prescribing provider		
Servicing provider/facility address	<input type="text"/>				
Servicing provider NPI/tax ID No.	<input type="text"/>				
Name of billing provider	<input type="text"/>				
Billing provider NPI No.	<input type="text"/>				
Is this a request for recertification?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	
CPT code	<input type="text"/>	No. of visits	<input type="text"/>	J code	<input type="text"/>
				No. of units	<input type="text"/>

## Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

### Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

<input type="text"/>	Date	<input type="text"/>
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(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)