



# Vyondys 53<sup>®</sup> (golodirsen) Injectable Medication Precertification Request

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(All fields must be completed and legible for Precertification Review.)

Aetna Precertification Notification

Phone: 1-866-752-7021

FAX: 1-888-267-3277

For Medicare Advantage Part B:

Phone: 1-866-503-0857

FAX: 1-844-268-7263

Please indicate:  Start of treatment: Start date \_\_\_\_/\_\_\_\_/\_\_\_\_  
 Continuation of therapy: Date of last treatment \_\_\_\_/\_\_\_\_/\_\_\_\_

Precertification Requested By: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

### A. PATIENT INFORMATION

First Name:		Last Name:	
Address:		City:	State: ZIP:
Home Phone:	Work Phone:	Cell Phone:	
DOB:	Allergies:	E-mail:	
Current Weight: _____ lbs or _____ kgs		Height: _____ inches or _____ cms	

### B. INSURANCE INFORMATION

Aetna Member ID #: _____	Does patient have other coverage? <input type="checkbox"/> Yes <input type="checkbox"/> No
Group #: _____	If yes, provide ID#: _____ Carrier Name: _____
Insured: _____	Insured: _____
Medicare: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide ID #: _____	Medicaid: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide ID #: _____

### C. PRESCRIBER INFORMATION

First Name:	Last Name:	(Check One): <input type="checkbox"/> M.D. <input type="checkbox"/> D.O. <input type="checkbox"/> N.P. <input type="checkbox"/> P.A.		
Address:		City:	State:	ZIP:
Phone:	Fax:	St Lic #:	NPI #:	DEA #: UPIN:
Provider E-mail:		Office Contact Name:		Phone:
Specialty (Check one): <input type="checkbox"/> Neurologist <input type="checkbox"/> Other: _____				

### D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

<b>Place of Administration:</b> <input type="checkbox"/> Self-administered <input type="checkbox"/> Physician's Office <input type="checkbox"/> Outpatient Infusion Center Phone: _____ Center Name: _____ <input type="checkbox"/> Home Infusion Center Phone: _____ Agency Name: _____ <input type="checkbox"/> Administration code(s) (CPT): _____ Address: _____	<b>Dispensing Provider/Pharmacy: (Patient selected choice)</b> <input type="checkbox"/> Physician's Office <input type="checkbox"/> Retail Pharmacy <input type="checkbox"/> Specialty Pharmacy <input type="checkbox"/> Other: _____ Name: _____ Address: _____ Phone: _____ Fax: _____ TIN: _____ PIN: _____
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### E. PRODUCT INFORMATION

Request is for Vyondys 53 (golodirsen): Dose: \_\_\_\_\_ Frequency: \_\_\_\_\_

### F. DIAGNOSIS INFORMATION – Please indicate primary ICD Code and specify any other where applicable.

Primary ICD Code: \_\_\_\_\_ Secondary ICD Code: \_\_\_\_\_ Other ICD Code: \_\_\_\_\_

### G. CLINICAL INFORMATION – Required clinical information must be completed in its entirety for all precertification requests.

**For All Requests (clinical documentation required):**

Yes  No Is this infusion request in an outpatient hospital setting?

Yes  No Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion?

Yes  No Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting?

Yes  No Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?  
Please provide a description of the behavioral issue or impairment: \_\_\_\_\_

Yes  No Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?  
Please provide a description of the condition:  Cardiopulmonary: \_\_\_\_\_  
 Respiratory: \_\_\_\_\_  
 Renal: \_\_\_\_\_  
 Other: \_\_\_\_\_

Yes  No Does the patient have a documented diagnosis of Duchenne muscular dystrophy (DMD)?

Yes  No Is the requested drug prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy?

Yes  No Will the requested medication be used concomitantly with viltolarsen (Viltepso)?

Yes  No Does the patient's dose exceed 30 mg/kg once weekly?

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB
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**G. CLINICAL INFORMATION (continued)** – Required clinical information must be completed in its entirety for all precertification requests.

**For Initial Requests (clinical documentation required):**

Yes  No Was genetic testing conducted to confirm the diagnosis of Duchenne muscular dystrophy?

Yes  No Was genetic testing conducted to identify the specific type of DMD gene mutation?

→ Please indicate the DMD gene mutation: \_\_\_\_\_

Yes  No Is the DMD gene mutation amenable to exon 53 skipping?

Yes  No Is the patient able to achieve an average distance of at least 250 meters while walking independently over 6 minutes?

Yes  No Will treatment with the requested drug be initiated prior to 16 years of age?

**For Continuation Requests (clinical documentation required):**

Yes  No Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program?

Yes  No Is the patient able to achieve an average distance of at least 250 meters while walking independently over 6 minutes?

Yes  No Has the patient demonstrated a response to therapy as evidenced by remaining ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent)?

**H. ACKNOWLEDGEMENT**

Request Completed 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.

The plan may request additional information or clarification, if needed, to evaluate requests.