Vyondys 53® (golodirsen) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021 (TTY: 711)
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

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 #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

Medicare: ☐ Yes ☐ No If yes, provide ID #: _____ **Medicaid**: ☐ Yes ☐ No If yes, provide ID #: _____

C. PRESCRIBER INFORMATION

First Name:	Last Name:		*(Check One)*: ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.		
Address:		City:	State:	ZIP:	
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider E-mail:	Office Contact Name:		Phone:		

Specialty *(Check one)*: ☐ **Neurologist** ☐ **Other**: _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy: *(Patient selected choice)*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other: _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

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 patient's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in and 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 Will the requested medication be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD)?
☐ Yes ☐ No Will the requested medication be used concomitantly with viltolarsen?
☐ 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

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 medication be initiated prior to 16 years of age?
☐ Yes ☐ No Has the patient previously received gene replacement therapy for DMD (e.g., Elevidys)?
→ ☐ Yes ☐ No Has the patient experienced a worsening in clinical status (e.g., decline in ambulatory function) since receiving gene replacement therapy for DMD (e.g., Elevidys)?

For patients re-starting therapy with the requested medication after administration of gene replacement therapy (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 medication be initiated prior to 16 years of age?
☐ Yes ☐ No Has the patient experienced a worsening in clinical status (e.g., decline in ambulatory function) since receiving gene replacement therapy for DMD (e.g., Elevidys)?

For Continuation Requests (clinical documentation required):

☐ 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.