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VYONDYS 53 PRIOR AUTHORIZATION REQUEST FORM

This form **MUST BE** submitted with medical records to support services

| | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------------------------|
| Date: | | |
| RECEIPIENT INFORMATION | | |
| Medicaid ID: | Date of Birth: | Sex: M F |
| Last Name: | | First Name: |
| GENERAL INFORMATION | | |
| First Date of Service: | | Last Date of Service: |
| Primary Diagnosis Code: | | HCPC Code: |
| Drug Name: | | Dose & Frequency: |
| Hospitalizations/Treatments/Medications Used in the last 6 months: | | |
| POINT OF CONTACT | | |
| Name and Title: | | |
| Email: | Phone: | Fax: |
| <i>Note: The point of contact is the individual completing the PA and would be the contact for questions SD Medicaid may have regarding the PA. The determination notice will be sent to the listed point of contact.</i> | | |
| REFERRING PROVIDER INFORMATION | | |
| Name: | | |
| NPI #: | | Taxonomy: |
| Phone: | | Fax: |
| SERVICING PROVIDER INFORMATION | | |
| Name: | | |
| Address: | | |
| NPI #: | | Taxonomy: |
| Phone: | | Fax: |

| CRITERIA | | |
|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Medical records to support use of product are submitted | | |
| Initial Therapy (check one) | Yes | No |
| | Therapy is prescribed by a neurologist with expertise in neuromuscular disorders | |
| | Individual must have a diagnosis of DMD with documentation of confirmed mutation that DMD gene is amenable to exon 53 skipping (submission of medical records, genetic testing, etc.) | |
| | If ambulatory, documentation of baseline values for one of the following is provided no longer than one month prior to beginning Vyondys 53 <ul style="list-style-type: none"> • North Star Ambulatory Assessment (NSAA) • 6 Minute Walk Test (6MWT) | |
| | If non-ambulatory, documentation is submitted indicating Brooke upper extremity scale is ≤ 5 | |
| | Documentation is submitted indicating forced vital capacity of $\geq 30\%$ and stable cardiac function with left ventricular ejection fraction (LVEF) of $>40\%$ | |
| | Individual is not ventilator dependent | |
| | Therapy is not being used in conjunction with other exon skipping therapies for DMD (ie Exondys 51, Amondys 45, Viltepso) | |
| | Therapy is initiated before the age of 14 | |
| | Individual has been on a stable dose of corticosteroids for 6 months unless contraindicated or adverse effects were previously experienced | |
| | Individual has not received previous gene therapy for the treatment of DMD | |
| Continuation of Therapy (check one) | Yes | No |
| | Individual continues to meet all initial criteria | |
| | Individual will continue to have follow-up with neurology provider and/or neuromuscular clinic | |
| | Documentation of response to therapy is recorded every 6 months and shows stability or improvement in both of the following: <ul style="list-style-type: none"> • 6-minute walk or NorthStar Ambulatory Assessment (or Brooke Upper Extremity if non-ambulatory) • Forced Vital Capacity | |
| PHYSICIAN SIGNATURE – PROVIDER ONLY | | |
| This form <u>must be</u> signed by a physician | | |
| | I certify that the information given in this form is a true and accurate medical indication for the required product | |
| Name & Title (Printed): | | Specialty: |
| Signature: | | |