Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Vyondys 53® (golodirsen) PA Criteria

- ☐ Diagnosis of Duchenne Muscular Dystrophy (DMD) with mutation amenable to Vyondys 53® skipping; ICD-10 code: _____

For both the initial and the reauthorization requests, providers must submit documentation of a recent clinical progress note including patient's current age and weight with the date the weight was obtained; the weight must be dated no more than 30 days before the request date, a copy of the prescription, and the Vyondys 53® (golodirsen) prior authorization form.

INITIAL AUTHORIZATION requests shall also include documentation of*:*

- The genetic laboratory test result with specific mutation, and
- Physical function with age-appropriate testing tools used to measure physical function.

REAUTHORIZATION requests shall also include documentation of either:

- An increase in the physical function from baseline, or
- That baseline physical function has been maintained.

Providers should use the same testing instrument as used in the baseline evaluation for physical function. If re-use of the initial testing instrument is not appropriate, for example, due to change in client status or restricted age range of the testing tool, the provider must explain the reason for the change.

Prior authorization requests for Vyondys 53® (golodirsen) may be approved if all the following criteria are met: (Yes should be checked for each statement):

INITIAL AUTHORIZATION: (prior authorization will be issued for, no more than, a six-month duration):

☐ Yes ☐ No	Patient must be at least six (6) years of age,
☐ Yes ☐ No	Patient must have the diagnosis of Duchenne Muscular Dystrophy (DMD),
☐ Yes ☐ No	Submission of medical records including the following: ○ Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 53 skipping. ○ Baseline renal function tests (i.e., glomerular filtration rate GFR).
☐ Yes ☐ No	Medication is prescribed by or in consultation with a neurologist or a physician who specializes in treatment of DMD (i.e., pediatric neurologist, cardiologist, or pulmonary specialist).
☐ Yes ☐ No	The patient must be on corticosteroids at baseline.

☐ Yes ☐ No If the patient is ambulatory, functional level determination of baseline assessment of ambulatory function (six-minute walk test) is required.

☐ Yes ☐ No If not ambulatory, patient must have a Brooke Upper Extremity Function Scale of five or less documented and a Forced Vital Capacity of 30% or more.

☐ Yes ☐ No Request is for FDA approved dosing,

☐ Yes ☐ No Copy of prescription is provided,

☐ Yes ☐ No Patient's weight in kilograms and the date weight recorded.
Dates of Weight/Visit: _____
Weight (in kg) _____

REATHORIZATION: (prior authorization will be issued for no more than a six-month duration):

☐ Yes ☐ No Patient initial authorization criteria for initial treatment are still met,

☐ Yes ☐ No Patient has not had significant decline in neuromotor function or forced vital capacity while on Vyondys 53® (golodirsen),

☐ Yes ☐ No Statement from prescribing physician that the patient has been compliant with treatment.

☐ Yes ☐ No Copy of prescription is provided.

☐ Yes ☐ No Documentation of improvement from baseline or maintenance:

- For ambulatory patients- Submission of six-minute walk test.
- For non-ambulatory patients- Submission of Brooke Upper Extremity Function Scale (five or less) documented and a Forced Vital Capacity documented (30% or more).

☐ Yes ☐ No Submission of renal function tests (i.e., GFR),

☐ Yes ☐ No Patient's weight in kilograms and the date weight recorded.
Dates of Weight/Visit: _____
Weight (in kg) _____

Maximum dose of 30mg/kg once weekly. Each prescription may be written for 6 months; however, the prescription must specify that medication is to be dispensed at no more than four (4) weeks supply at a time. Mississippi Division of Medicaid will only allow a 28-day supply to be dispensed at a time to ensure that the patient tolerates the medication prior to subsequent medication doses being dispensed to the physician clinic/hospital for administration.

*NOTE: Mississippi Division of Medicaid's coverage of Vyondys 53® (golodirsen) is contingent upon continued FDA approval. Update Effective 1/22/2021.