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Policy Number: C17926-A

Vyondys 53 (golodirsen) NC

PRODUCTS AFFECTED

Vyondys 53 (golodirsen)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Duchenne muscular dystrophy (DMD)

REQUIRED MEDICAL INFORMATION:
Vyondys 53 (golodirsen) is considered not medically necessary for all indications, including but not limited to Duchenne muscular dystrophy (DMD), due to insufficient evidence of therapeutic value since clinical benefit has not been established. Data from clinical studies of golodirsen in a small number of people with DMD have demonstrated a consistent safety and tolerability profile. However, the pivotal trials were not designed to evaluate long-term safety and a clinical benefit of Vyondys 53 has not been established.
Molina Healthcare will continue to evaluate and update this policy as relevant clinical evidence becomes available to determine whether Vyondys 53 (golodirsen) provides clear clinical benefit or slows progression of the disease. Coverage of Vyondys 53 (golodirsen) may be contingent upon verification of a clinical benefit in confirmatory trials.
Vyondys 53 (golodirsen) was granted †accelerated approval by the FDA four months after rejecting approval of the drug over safety concerns in the Complete Response Letter in August of 2019. The letter stated concerns of possible infection at the injection sites and renal toxicity that was seen in preclinical (animal) studies. The toxicity in those studies was observed at dosage levels ten-times what is being used in clinical trials. No toxicity was observed in the clinical trial used for the drug application. Sarepta

Therapeutics filed an appeal and after meeting with the FDA, the FDA reversed its decision and gave Vyondys 53 accelerated approval in December of 2019.

†*While the accelerated approval pathway makes Vyondys 53 available to DMD patients based on initial data, the drug's clinical benefit must be established from the ongoing confirmatory clinical trial.*

Confirmatory Trial

The clinical benefit of treatment for DMD with Vyondys 53 (golodirsen), including improved motor function, has not been demonstrated. The manufacturer is required by the FDA to conduct ongoing clinical trials to establish the drug's clinical benefit. Continued approval of Vyondys 53 (golodirsen) may be contingent upon verification of a clinical benefit in these confirmatory trials. [Prescribing Information 2021]

ESSENCE (4045-301): Phase 3 placebo-controlled, post-marketing confirmatory trial to support the Vyondys 53 accelerated approval. The study is ongoing and posted as 'active'. The estimated primary completion date is October 2025. (NCT02500381).

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
NA

PRESCRIBER REQUIREMENTS:
NA

AGE RESTRICTIONS:
NA

QUANTITY:
NA

PLACE OF ADMINISTRATION:
NA

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Muscular Dystrophy – Gene Therapy Agents

FDA-APPROVED USES:
Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Vyondys 53. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Muscular dystrophy includes a group of genetic disorders that cause muscle weakness and progressive disability. Duchenne muscular dystrophy (DMD) is the most common and progresses most rapidly.
Duchenne muscular dystrophy (DMD)

- A rare genetic disorder characterized by progressive muscle deterioration and weakness
- An X-chromosome-linked disease recessive disorder caused by mutations (mainly deletions) in the dystrophin gene that lead to an absence or defect in the dystrophin protein, dystrophin is essential for maintenance of myocyte integrity and helps keep muscle cells intact
- As males have only one X chromosome, and therefore one single copy of the dystrophin gene, they have a much higher probability of developing DMD. A small number of females are also affected but remain asymptomatic and only rarely present with a mild form of the disease.
- The most common type of muscular dystrophy; DMD is caused by an absence of dystrophin, a protein that helps keep muscle cells intact
- Based on population studies, the prevalence of DMD in the US is estimated to be 0.4 per 10,000 males, resulting in approximately 6,000 affected people in the US (Romitti, 2015)
- Associated with complete inability to produce functional dystrophin protein
- Affected children with DMD typically develop symptoms in early childhood around 3-5 years old, experiencing progressive muscle weakness and deterioration. Patients with DMD progressively lose the ability to perform activities independently and usually become non-ambulatory by their early teenage years and require the use of a wheelchair.
- As the disease progresses, life-threatening heart and respiratory conditions can occur. Patients typically succumb to the disease in their 20s or 30s; however, disease severity and life expectancy vary.
- In absence of treatment, the patient experiences:
    - wheelchair dependence before age 13 years
    - death occurs by, or around, age 20 years

Prognosis of DMD

- Death occurs around age 20 in absence of treatment and is usually due to cardiac or respiratory failure
- Disease progression in patients with DMD
    - Scoliosis is frequent after loss of ambulation
    - Risk for cardiomyopathy increases with age in absence of ventilatory intervention

Treatment Overview: Pharmacologic Agents/Conventional Therapy
There is no curative therapy, but management of disease manifestations can prolong survival and improve quality of life. A multidisciplinary team is required for management of patient with DMD and treatment options for DMD predominantly focus on management of symptoms and secondary complications.
Goals of management for DMD

- Preserve strength, ambulation, and ventilatory and cardiac function
- Minimize of steroid complications where applicable
- Prevent and treat complications including contractures, scoliosis, ventilatory function impairment or failure, and cardiomyopathy
- Determine and arrange appropriate school environment and manage family stressors

Other pharmacologic therapies for DMD are primarily aimed at the management of comorbidities such as cardiomyopathy, osteoporosis, pain management, and respiratory failure. These treatment options include: angiotensin-converting-enzyme (ACE) inhibitors, beta-blockers, calcium and vitamin D supplements, muscle relaxants, and non-steroidal anti-inflammatory drugs.

- Corticosteroids
  - DMD Care Considerations Working Group consensus guidelines urge consideration of glucocorticoid therapy (prednisone or deflazacort) for all patients with DMD (optimal dose ranges not established)
    - Goal in the ambulatory child is to preserve ambulation and minimize later respiratory, cardiac, and orthopedic complications
    - Goal of continuing glucocorticoid therapy after loss of ambulation is to preserve upper limb strength, reduce scoliosis progression, and delay declines in respiratory and cardiac function
  - Generally used to preserve ambulation and minimize complications in patients with DMD
  - In ambulatory patients, recommended if motor skills have plateaued or begun to decline
  - In non-ambulatory patients, glucocorticoids often continued if already started while ambulatory, but limited evidence regarding starting glucocorticoids
  - Daily dosing preferred over alternative regimens (alternate day, high-dose weekend, or 10-day cycles)
  - Monitor and manage side effects associated with chronic steroid therapy

- Vitamin D and calcium supplementation suggested to manage bone health in patients with DMD
- Respiratory care including airway clearance techniques, nocturnal ventilatory support, daytime non-invasive ventilation, and tracheostomy may be indicated/desired as disease progresses
- For management of cardiac dysfunction, consider:
  - Diuretics, angiotensin-converting enzyme (ACE) inhibitors, and/or beta blockers to treat manifestations of cardiac dysfunction
- Anticoagulation therapy in patients with severe cardiac dysfunction to prevent systemic thromboembolic events

Vyondys 53 (golodirsen) was granted †accelerated approval by the FDA four months after rejecting approval of the drug over safety concerns in the Complete Response Letter in August of 2019. The letter stated concerns of possible infection at the injection sites and renal toxicity that was seen in preclinical (animal) studies. The toxicity in those studies was observed at dosage levels ten-times what is being used in clinical trials. No toxicity was observed in the clinical trial used for the drug application. Sarepta Therapeutics filed an appeal and after meeting with the FDA, the FDA reversed its decision and gave Vyondys 53 accelerated approval in December of 2019.
†*While the accelerated approval pathway makes Vyondys 53 available to DMD patients based on initial data, the drug's clinical benefit must be established from the ongoing confirmatory clinical trial.*

Confirmatory Trial
The clinical benefit of treatment for DMD with Vyondys 53 (golodirsen), including improved motor function, has not been demonstrated. The manufacturer is required by the FDA to conduct ongoing clinical trials to establish the drug's clinical benefit. Continued approval of Vyondys 53 (golodirsen) may be contingent upon verification of a clinical benefit in these confirmatory trials. [Prescribing Information 2021]

ESSENCE (4045-301): Phase 3 placebo-controlled, post-marketing confirmatory trial to support the Vyondys 53 accelerated approval. **The study is ongoing and posted as 'active'. The estimated primary completion date is October 2025**. (NCT02500381)
*****Additional information in the following section on the ESSENCE confirmatory trial

The FDA based its decision to grant accelerated approval to Vyondys 53 on the positive results of a pivotal phase ½ clinical trial (4053-101 study) conducted in Europe to assess the safety, tolerability, pharmacokinetics (how the drug is absorbed, distributed, and metabolized in the body), and efficacy (dystrophin expression) of Vyondys 53 in 25 boys with DMD with confirmed deletions in the dystrophin gene amenable to exon 53 skipping. The results showed an observed statistically significant increase in dystrophin production in skeletal muscle of patients treated with Vyondys 53, which is reasonably likely to predict clinical benefit for those patients. Consistent with the FDA's accelerated approval pathway, the continued approval of Vyondys 53 may be contingent on confirmation of a clinical benefit in a post-marketing confirmatory trial

(ESSENCE), which is currently active and expected to conclude by 2025.

Phase ½ Clinical Trial (4053-101 study)
This first-in-human study assessed the safety, tolerability, pharmacokinetics, and efficacy of weekly intravenous Vyondys 53 versus placebo in 25 boys with confirmed deletions of the DMD gene amenable to skipping exon 53. All patients were on a stable dose of corticosteroids for at least 6 months before entering the trials. (NCT02310906)

- Part 1: A randomized 12-week dose-escalation period to assess pharmacokinetics of 4 doses of golodirsen
  Part 1 primarily assessed safety and tolerability in a 12-week dose-escalation period. A double-blind, placebo-controlled, dose-titration study in 12 DMD patients age 6 to 15 years (n=12) (golodirsen n=8; placebo n=4). Vyondys 53-treated patients received 4 escalating dose levels, ranging from 4 mg/kg/week (less than the recommended dosage) to 30 mg/kg/week by intravenous infusion for 2 weeks at each dose level). Secondary endpoints include drug pharmacokinetics, change from baseline in FVC percent predicted, and change from baseline in dystrophin intensity at 144 weeks.

- **A clinical benefit of golodirsen has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.** The FDA label includes the following statement, "A clinical benefit of Exondys 51 has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials."

  Similar to Exondys 51, Vyondys 53 was approved under the †accelerated approval pathway based only on dystrophin production "*that is reasonably likely to predict clinical benefit*" in DMD patients, according to the FDA—not on proven clinical improvements.

  Accelerated approval based on a ‡surrogate endpoint rather than measured clinical benefit. The surrogate endpoint is the improvement in production of the dystrophin protein in skeletal muscle; however, no correlation has been established between dystrophin levels and clinical outcomes in golodirsen-treated patients with DMD.

  ‡*A "surrogate marker" can be defined as "…a laboratory measurement or physical sign that is used in therapeutic trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions, or survives and is expected to predict the effect of the therapy."*
  †*Accelerated approval pathway provides for the approval of drugs that treat serious or life-threatening diseases and generally provide a meaningful advantage over existing treatments. Approval under this pathway can be based on adequate and well-controlled studies showing the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit to patients. This pathway provides earlier patient access to promising new drugs while the company conducts clinical trials to verify the predicted clinical benefit. Under the accelerated approval provisions, the FDA is requiring Sarepta Therapeutics to conduct a clinical trial to confirm the drug's clinical benefit. The required ongoing study is designed to assess whether Vyondys 53 improves motor function of DMD patients with a confirmed mutation of the dystrophin gene amenable to exon 53 skipping. If the trial fails to verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug.*

  As part of the accelerated approval process, the FDA is requiring the manufacturer to conduct a trial to determine whether golodirsen improves motor function of DMD patients with a confirmed mutation of the dystrophin gene amenable to exon 53 skipping. If the trial fails to verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug. The FDA may withdraw approval of the drug if the trial fails to show clinical benefit.

- The FDA has concluded that the data submitted demonstrated an increase in dystrophin production that is **reasonably likely to predict clinical benefit in patients with DMD** who have a confirmed mutation of the dystrophin gene amenable to exon 53 skipping. **However, a clinical benefit of Vyondys 53, including improved motor function, has not been established.** In making this decision, the FDA considered the potential risks associated with the drug, the life-threatening and debilitating nature of the disease for these

children and the lack of available therapy.

- **Confirmatory Study: ONGOING**

Post-marketing Confirmatory Trial to Accelerated Approval

The clinical benefit of treatment for DMD with Vyondys 53 (golodirsen), including improved motor function, has not been demonstrated. The manufacturer is required by the FDA to conduct ongoing clinical trials to establish the drug's clinical benefit. Continued approval of Vyondys 53 (golodirsen) may be contingent upon verification of a clinical benefit in these confirmatory trials. [Prescribing Information 2021]

Phase 3 placebo-controlled, post-marketing confirmatory trial to support the Vyondys 53 accelerated approval:

ESSENCE (4045-301): Study of SRP -4045 and SRP-4053 in DMD Patients (Phase III study) NCT02500381

A Double-Blind, Placebo-Controlled, Multi-Center Study with an Open-Label Extension to Evaluate the Efficacy and Safety of SRP-4045 (Casimersen) and SRP-4053 (Vyondys 53) in Patients with DMD

This 96-week double-blind, placebo-controlled, multi-center, Phase 3 study trial is currently ongoing and recruiting. The trial is evaluating the efficacy of SRP-4045 and SRP-4053 for up to 96 weeks and will be followed by an open label extension (OLE) period. In the OLE period, all patients will receive open-label active treatment for 48 weeks in patients with DMD amenable to skipping exon 45and exon 53. Twice as many patients will receive active treatment as will receive placebo (2:1). Target estimated enrollment of 222 subjects, males aged 7-13 years. Clinical efficacy will be assessed via six-minute walk test. All patients will undergo a muscle biopsy at baseline and a second muscle biopsy either at Week 48 or Week 96. **The study is ongoing and posted as 'active'. The estimated primary completion date is October 2025.**

- The safety and tolerability profile of golodirsen does not include significant adverse events. No serious hypersensitivity events were reported. Rash was the most frequently non-serious hypersensitivity event. All patients reported at least 1 adverse event after beginning treatment, however the majority of these events were non-serious, mild, and unrelated to study drug. No patients discontinued due to an adverse event.
- There is a lack of long-term data for exon-skipping therapies and thus the potential long-term benefits and harms of these drugs is unknown, particularly in comparison to supportive care and corticosteroids.

- Additional considerations

  - 100% of study participants were male, thus the safety and efficacy in female patients is unknown
  - The potential impact of race is not known because 92% of the patients in studies were Caucasians
  - Vyondys 53 has not been studied in patients with hepatic impairment
  - All patients in clinical trials were on a stable dose of corticosteroids for at least 6 months prior to initiating therapy with Vyondys 53; therefore, there is insufficient evidence to judge the net health benefit of adding golodirsen compared with using corticosteroids and supportive care alone.

- The **Institute for Clinical and Economic Review (ICER)**, published an **Evidence Report** assessing the comparative clinical benefit and value of the corticosteroid deflazacort (Emflaza), and two exon-skipping therapies eteplirsen (Exondys 51™) and golodirsen for the treatment DMD. ICER noted:
  - The exon-skipping therapies, eteplirsen and golodirsen, cannot be assessed for cost-effectiveness because "*no persuasive evidence yet exists to demonstrate the clinical effectiveness of either drug*."
  - Data for exon-skipping therapies consist primarily of surrogate outcomes (e.g., dystrophin levels)from very small trials that have no validated threshold that defines meaningful clinical improvement. The small increases in dystrophin levels seen in the RCTs are of uncertain clinical significance.
  - Both eteplirsen and golodirsen have been shown to increase production of dystrophin, which is deficient in DMD, although dystrophin levels remained very low. The best results were for golodirsen, according to the report; at 48 weeks, the mean level of dystrophin had increased to 1.019 percent of normal. There is no validated threshold in dystrophin levels associated with

meaningful clinical improvement.

- There is found no evidence demonstrating improvements in muscle strength, motor function, ambulation, or pulmonary function.
- No functional outcome results have been reported for golodirsen.
- There was insufficient evidence to judge the net health benefit of adding golodirsen compared with using corticosteroids and supportive care alone.

- **No published guidelines were identified that recommend the use of Vyondys 53 for the treatment of DMD**

Phase 3 Extension Study (NCT03532542)

A Phase 3 open-label interventional extension study to evaluate the safety and tolerability of long-term treatment with casimersen or golodirsen in patients with DMD who have been treated previously with these exon-skipping treatments in a clinical trial setting. Target estimated enrollment, by invitation, of 260 subjects (males between the ages of 7 to 23 years).

- Boys with mutations amenable to exon 53 skipping will be included in the Vyondys 53 treatment group, while those with mutations that can benefit from exon 45 skipping will be treated with Casimersen
- Patients will receive weekly intravenous infusions of treatment for up to 144 weeks, and the number of severe adverse events will be assessed.

The estimated primary completion date is August 2026

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Vyondys 53 (golodirsen) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Vyondys 53 (golodirsen) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Vyondys 53 SOLN 100MG/2ML single-dose vial

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Background	Q2 2024
REVISION- Notable revisions: FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation References	Q2 2023
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file