VNSNY CHOICE SelectHealth Plan
**Medical Benefit Drug Policy**

# VYONDYS 53® (GOLODIRSEN) Injection

## COVERAGE RATIONALE

Vyondys 53 for intravenous use is FDA indicated for:

- Diagnosis of Duchenne muscular dystrophy (DMD)
- Documentation of genetic testing must confirm the DMD gene mutation of the patient is amenable to exon 53 skipping;
- Documentation must confirm a stable dose of corticosteroids prior to starting therapy or a documented reason not to be on corticosteroids; and
- Documentation indicates kidney function testing prior to starting therapy; and
- Patient is not concurrently being treated with another exon skipping therapy for DMD.

## APPLICABLE CODES

**Coverage of this medication is available under the member's medical benefit via the buy-and-bill process for provider-administered drugs.** The following list(s) of procedure codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment.

| HCPCS Code | Description |
|---|---|
| J1429 | Injection, Golodirsen, 10 mg |
| **CPT Administration Codes** | **Description** |
| 96413 | Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug |
| 96415 | Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure) |

## BACKGROUND

VYONDYS 53 is an antisense oligonucleotide 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.

Vyondys 53®[package insert]. Cambridge, MA: Sarepta Therapeutics, Inc. February 2021