



## VNSNY CHOICE SelectHealth Plan Medical Benefit Drug Policy

### EXONDYS 51® (ETEPLIRSEN) Injection

#### COVERAGE RATIONALE

Exondys 51 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 51 skipping;
- Documentation must confirm a stable dose of corticosteroids prior to starting therapy or a documented reason not to be on corticosteroids; 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
J1428	Injection, Eteplirsen, 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

EXONDYS 51 is an exon skipping phosphorodiamidate morpholino oligomer (PMO) which restores the mRNA reading frame to induce dystrophin protein production and is 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 51 skipping. This indication is approved on a surrogate endpoint demonstrating an increase in dystrophin production. Clinical benefit will be evaluated through confirmatory trials.

Exondys 51®[package insert]. Cambridge, MA: Sarepta Therapeutics, Inc.  
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