



VNSNY CHOICE SelectHealth Plan Medical Benefit Drug Policy

AMONDYS 45® (CASIMERSEN) Injection

COVERAGE RATIONALE

Amondys 45 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 45 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
J1426	Injection, Casimersen, 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

AMONDYS 45 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 45 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with AMONDYS 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.