MADISON NEUROLOGY LLC

608 403 0000

*Neurology Care 7 days a Week. Because Your Brain Matters.*

# Amondys 45®

## Casimersen

COMPLETE CLINICAL PROTOCOL: PRE-TREATMENT CHECKLIST • ORDER SET • FOLLOW-UP • HOLD/DISCONTINUE CRITERIA

| | |
|---|---|
| **GENERIC NAME** | casimersen |
| **BRAND** | AMONDYS 45® |
| **MEDICATION CLASS** | Antisense oligonucleotide (phosphorodiamidate morpholino oligomer, exon 45 skipping) |
| **PRESENTATION** | 100 mg/2 mL (50 mg/mL) single-dose vial — dilute in 0.9% NaCl |
| **ROUTE** | IV infusion over 35–60 minutes, once weekly |
| **US INDICATION (FDA)** | Duchenne muscular dystrophy in patients with a CONFIRMED mutation amenable to exon 45 skipping (accelerated approval based on dystrophin increase). |

**Class context.**
Exon 45 — not 53 — amenability defines this product's population; confirm the exon on the genetic report before the first dose.

## Section 1 — Pre-Treatment Checklist

### A. Required screening labs

☐ Genetic confirmation of an exon 45–amenable DMD mutation — REQUIRED.

☐ Renal baseline: creatinine, cystatin C (preferred in DMD), BUN, urine dipstick.

☐ Baseline motor function and steroid-regimen documentation.

### B. Vaccinations

☐ No label restrictions.

### C. Clinical assessments & counseling

☐ Baseline motor assessment; sustainable weekly-access plan.

☐ Hypersensitivity counseling.

### D. Exclusion / hold criteria — do not start

| CRITERION | RATIONALE / REQUIRED ACTION |
|---|---|
| Mutation not amenable to exon 45 skipping | Not the labeled population. |
| Serious hypersensitivity to casimersen | Do not administer. |

## Section 2 — Order Set

### Premedication

☐ None required; premedicate after prior hypersensitivity per institutional practice.

### Dosing schedule

| | |
|---|---|
| **Standard dose** | 30 mg/kg IV once weekly over 35–60 minutes. |

### Standing orders — every infusion

☐ Hypersensitivity monitoring each infusion; periodic weight checks.

### Missed or delayed dose

Give a missed dose as soon as possible; resume the weekly schedule.

## Section 3 — Follow-Up Protocol

| ITEM | FREQUENCY / TIMING | ACTION / THRESHOLD |
|---|---|---|
| Renal function — cystatin C, creatinine, BUN, urine dipstick | Baseline, then periodically | Deterioration → hold and evaluate. |
| Motor function | Every 6–12 months | Continuation documentation. |
| Hypersensitivity review | Every infusion | Anaphylaxis → discontinue. |

## Section 4 — Pause vs. Stop Criteria

### A. Pause or delay (resume when resolved)

| CRITERION | REQUIRED ACTION |
|---|---|
| Renal signal | Hold and evaluate. |

### B. Discontinue permanently

| CRITERION | REQUIRED ACTION |
|---|---|
| Anaphylaxis or serious hypersensitivity | Discontinue. |
| Progressive renal toxicity attributed to therapy | Discontinue; specialist review. |

## Section 5 — Notes & Practical Points

☐ Accelerated approval on dystrophin surrogate; confirmatory trials ongoing.

**Prepared November 2026 by Madison Neurology LLC.**

This document is an educational compilation and does not reproduce the complete prescribing information. Verify every element against the current FDA label and applicable REMS requirements before clinical use.

- Current U.S. prescribing information via NIH DailyMed — https://dailymed.nlm.nih.gov/dailymed/
- FDA Drugs@FDA database — https://www.accessdata.fda.gov/scripts/cder/daf/
- FDA drug safety and availability updates — https://www.fda.gov/drugs/drug-safety-and-availability

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Questions about infusion referrals: call 608 403 0000. Neurology Care 7 days a Week. Because Your Brain Matters.