MEDICAID POLICY CHANGE

IMMINENT PERIL JUSTIFICATION

June 23, 2025

ELEVIDYS™ AMBULATORY FUNCTION REQUIREMENT

POLICY CHANGE:

Reinstatement of ambulatory function requirement criterion for delandistrogene moxeparvovec-rokl (Elevidys™).

JUSTIFICATION:

On June 15, 2025, Sarepta Therapeutics, Inc. provided a safety update for Elevidys™ following a second reported case of acute liver failure (ALF) resulting in death. The cases of ALF to date have both occurred in non-ambulatory individuals with Duchenne. In response, Sarepta Therapeutics, Inc. is suspending shipments of Elevidys™ for infusions in non-ambulatory patients in commercial setting and pausing the ENVISION study (which serves as the confirmatory trial required under the FDA's accelerated approval pathway for non-ambulatory patients). There is an imminent peril to the welfare of Louisiana Medicaid recipients to ensure the safe utilization of Elevidys™.

EFFECTIVE DATE:

July 1, 2025