December 1, 2025

SAREPTA THERAPEUTICS PROVIDES CLINICAL UPDATES FOR ELEVIDYS

BACKGROUND

ELEVIDYS (Delandistrogene moxeparvovec-rokl) (HCPCS code J1413) is an adeno-associated virus vector-based gene therapy indicated for the treatment of individuals aged four years or older with Duchenne muscular dystrophy (DMD) who have a confirmed mutation in the DMD gene.

KEY DETAILS

HHSC has been made aware of several key updates for the drug:

- A boxed warning for the risk of acute serious liver injury and acute liver failure
- Removal of the non-ambulatory indication from the "Indication and Usage" section of the Prescribing Information
- Expanded guidance for prescribers, including a modified pre- and post-infusion oral corticosteroids regimen, and enhanced monitoring recommendations every week for 3 months post-infusion
- A new Warnings & Precaution regarding increased susceptibility to serious infections due to immunosuppression

ADDITIONAL INFORMATION

HHSC is updating the clinical policy and prior authorization criteria for the clients based on guidance from regulatory bodies. Clinical criteria may be updated and does not need to wait for publication in the TMPPM before implementation.

RESOURCES

Links:	· investorrelations.sarepta.com/news-releases/news-release-details/sarepta-announces-fdas-approval-updated-elevidys-prescribing · elevidys.com/pi

COMMUNITY HEALTH CHOICE

QUESTIONS

For any questions regarding this notice, please contact your Community Provider Performance Manager (provider representative). E-mail: ProviderRelationsInquiries@CommunityHealthChoice.org