

**11/20/2025**

## **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. MCOs may update clinical criteria and do not need to wait for publication in the TMPPM before implementation.

### **Resources:**

<b>Links:</b>	<ul style="list-style-type: none"><li>· <a href="https://investorrelations.sarepta.com/news-releases/news-release-details/sarepta-announces-fdas-approval-updated-elevidys-prescribing">investorrelations.sarepta.com/news-releases/news-release-details/sarepta-announces-fdas-approval-updated-elevidys-prescribing</a></li><li>· <a href="https://elevidys.com/pi">elevidys.com/pi</a></li></ul>
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