02/20/2024

Coverage of Elevidys Begins Jan. 2024; Prior Authorization Effective Feb. 2024

Background:

On Jan. 1, 2024, Elevidys became a benefit of Medicaid and CHIP. On Feb. 1, 2024, prior authorization began for Elevidys (procedure code J1413) for Medicaid and CHIP. HHSC will further refine prior authorization for Elevidys (procedure code J1413) for Medicaid and CHIP, effective April 1, 2024.

Key Details:

Elevidys (delandistrogene moxeparvovec-rokl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory pediatric clients ages 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.

Additional Information:

Prior Authorization Requirements:

Prior authorization is required for Elevidys (delandistrogene moxeparvovec-rokl). The request for this single-dose therapy must include all the following documentation to support the client meets all approval criteria:

- Client is age 4 through 5 years old.
- Client has a confirmed mutation in the DMD gene (ICD 10 – 71.01).
- Clients with a mutation in exons 1-17 and/or 59-71 of the DMD gene, should be monitored for immune-mediated myositis.
- Client does not have any deletion in exon 8 or exon 9 in the DMD gene.
- Documentation that client is ambulatory and not wheelchair bound (able to walk with or without assistance).
- Client is not on concomitant DMD antisense oligonucleotide therapy (e.g., golodirsen, casimersen, viltolarsen, eteplirsen, etc).
- Documentation of client's baseline testing for presence of anti-AAVrh74 total binding antibody titers of less than 1:400.
- Client has no current infection. If there are signs of infection prior to infusion, treatment with Elevidys should be postponed until infection clears.
- Due to the possibility of acute serious liver injury, client's baseline liver function must be documented and monitored prior and post Elevidys therapy.
- Documentation of client's platelet count and troponin-I level should be obtained prior to infusion.
- Client does not have a history of previously receiving treatment with Elevidys infusion.

- Elevidys (delandistrogene moxeparvovec-rokl), J1413 is limited to one transfusion treatment per lifetime.

Monitoring Requirements:

Monitoring parameters after Elevidys infusion:

- Liver function should be monitored upon initiation of therapy and continued on a weekly schedule for the first 3 months after Elevidys infusion.

- Troponin–I level should be monitored weekly for the first month after treatment with Elevidys.

Refer to the Outpatient Drug Services Handbook Chapter of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

Additional:

HHSC approved this updated clinical prior authorization for MCO use and will implement the criteria for fee-for-service on April 1, 2024. MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but shall not make them more restrictive.

Contact:

vdp_cad@hhsc.state.tx.us

Type: Informational

To: CHIP; STAR; STAR+PLUS; STARHEALTH; STAR_KIDS

From: VDP