Medical Policy:

Elevidys (delandistrogene moxeparvovec-rokl) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.393	March 18, 2024	October 3, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Elevidys is indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene. Elevidys is comprised of three components: 1. The adeno-associated virus (AAV) vector (AAVrh74), which delivers the micro-dystrophin and promoter to muscle cells; 2. The promoter (MHCK7), which promotes and drives selective gene expression; and 3. The transgene or micro-dystrophin-encoding gene that produces the micro-dystrophin protein, a shortened version of dystrophin that is expressed in normal muscle cells. Elevidys micro-dystrophin has been demonstrated to localize to the sarcolemma.

Policy Statement

EmblemHealth will not cover Elevidys due to lack of conclusive evidence confirming clinical efficacy.

Applicable Procedure Codes

Code	Description
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose

Applicable NDCs

Code	Description
60923-0501-10	ELEVIDYS 10-10.4 KG (10ML X10)
60923-0502-11	ELEVIDYS 10.5-11.4 KG (10MLX11)
60923-0503-12	ELEVIDYS 11.5-12.4 KG (10MLX12)
60923-0504-13	ELEVIDYS 12.5-13.4 KG (10MLX13)
60923-0505-14	ELEVIDYS 13.5-14.4 KG (10MLX14)
60923-0506-15	ELEVIDYS 14.5-15.4 KG (10MLX15)
60923-0507-16	ELEVIDYS 15.5-16.4 KG (10MLX16)
60923-0508-17	ELEVIDYS 16.5-17.4 KG (10MLX17)
60923-0509-18	ELEVIDYS 17.5-18.4 KG (10MLX18
60923-0510-19	ELEVIDYS 18.5-19.4 KG (10MLX19)
0923-0511-20	ELEVIDYS 19.5-20.4 KG (10MLX20)
60923-0512-21	ELEVIDYS 20.5-21.4 KG (10MLX21)
60923-0513-22	ELEVIDYS 21.5-22.4 KG (10MLX22)
60923-0514-23	ELEVIDYS 22.5-23.4 KG (10MLX23)
60923-0515-24	ELEVIDYS 23.5-24.4 KG (10MLX24)
60923-0516-25	ELEVIDYS 24.5-25.4 KG (10MLX25)
60923-0517-26	ELEVIDYS 25.5-26.4 KG (10MLX26)
60923-0518-27	ELEVIDYS 26.5-27.4 KG (10MLX27)
60923-0519-28	ELEVIDYS 27.5-28.4 KG (10MLX28)
60923-0520-29	ELEVIDYS 28.5-29.4 KG (10MLX29)
60923-0521-30	ELEVIDYS 29.5-30.4 KG (10MLX30)
60923-0522-31	ELEVIDYS 30.5-31.4 KG (10MLX31)
60923-0523-32	ELEVIDYS 31.5-32.4 KG (10MLX32)
60923-0524-33	ELEVIDYS 32.5-33.4 KG (10MLX33)
60923-0525-34	ELEVIDYS 33.5-34.4 KG (10MLX34)
60923-0526-35	ELEVIDYS 34.5-35.4 KG (10MLX35)
60923-0527-36	ELEVIDYS 35.5-36.4 KG (10MLX36)
60923-0528-37	ELEVIDYS 36.5-37.4 KG (10MLX37)
60923-0529-38	ELEVIDYS 37.5-38.4 KG (10MLX38)
60923-0530-39	ELEVIDYS 38.5-39.4 KG (10MLX39)
60923-0531-40	ELEVIDYS 39.5-40.4 KG (10MLX40)
60923-0532-41	ELEVIDYS 40.5-41.4 KG (10MLX41)
60923-0533-42	ELEVIDYS 41.5-42.4 KG (10MLX42)
60923-0534-43	ELEVIDYS 42.5-43.4 KG (10MLX43)

60923-0535-44	ELEVIDYS 43.5-44.4 KG (10MLX44)
60923-0536-45	ELEVIDYS 44.5-45.4 KG (10MLX45)
60923-0537-46	ELEVIDYS 45.5-46.4 KG (10MLX46)
60923-0538-47	ELEVIDYS 45.5-46.4 KG (10MLX46)
60923-0539-48	ELEVIDYS 47.5-48.4 KG (10MLX48)
60923-0540-49	ELEVIDYS 48.5-49.4 KG (10MLX49)
60923-0541-50	ELEVIDYS 49.5-50.4 KG (10MLX50)
60923-0542-51	ELEVIDYS 50.5-51.4 KG (10MLX51)
60923-0543-52	ELEVIDYS 51.5-52.4 KG (10MLX52)
60923-0544-53	ELEVIDYS 52.5-53.4 KG (10MLX53)
60923-0545-54	ELEVIDYS 53.5-54.4 KG (10MLX54)
60923-0546-55	ELEVIDYS 54.5-55.4 KG (10MLX55)
60923-0547-56	ELEVIDYS 55.5-56.4 KG (10MLX56)
60923-0548-57	ELEVIDYS 56.5-57.4 KG (10MLX57)
60923-0549-58	ELEVIDYS 57.5-58.4 KG (10MLX58)
60923-0550-59	ELEVIDYS 58.5-59.4 KG (10MLX59)
60923-0551-60	ELEVIDYS 59.5-60.4 KG (10MLX60)
60923-0552-61	ELEVIDYS 60.5-61.4 KG (10MLX61)
60923-0553-62	ELEVIDYS 61.5-62.4 KG (10MLX62)
60923-0554-63	ELEVIDYS 62.5-63.4 KG (10MLX63)
60923-0555-64	ELEVIDYS 63.5-64.4 KG (10MLX64)
60923-0556-65	ELEVIDYS 64.5-65.4 KG (10MLX65)
60923-0557-66	ELEVIDYS 65.5-66.4 KG (10MLX66)
60923-0558-67	ELEVIDYS 66.5-67.4 KG (10MLX67)
60923-0559-68	ELEVIDYS 67.5-68.4 KG (10MLX68)
60923-0560-69	ELEVIDYS 68.5-69.4 KG (10MLX69)
60293-0561-70	ELEVIDYS 69.5KG-ABOVE (10MLX70)

ICD-10 Diagnoses

Code	Description
G71.01	Duchenne or Becker muscular dystrophy

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/18/2024	Annual Review: Removed J3590 and C9399, added J1413. No criteria changes.
EmblemHealth & ConnectiCare	10/3/2023	New Policy

References

1. Elevidys® intravenous infusion [prescribing information]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2023.