Mass General Brigham
Health Plan

Duvyzat (givinostat)
Effective 11/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Duvyzat (givinostat) is a histone deacetylase inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

Coverage Guidelines
Authorization may be reviewed for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Member has a genetically confirmed diagnosis of Duchenne muscular dystrophy (DMD). Laboratory confirmation of genetic testing is required.
2. Member is 6 years of age or older
3. Duvyzat is prescribed by or in consultation with a specialist with experience treating DMD
4. Member is ambulatory at the time of initiation
5. Member has been stable on corticosteroids for at least 6 months
6. Documentation of a baseline evaluation, including a standardized assessment of motor function. Examples include: 4 Standard Stairs Climb (4SC); North Star Ambulatory Assessment (NSAA); 6- Minute Walk Test

<u>Continuation of Therapy</u>
Requests for reauthorization will be approved when the following criteria are met:

1. Member continues to administer corticosteroids concurrently with Duvyzat

2. Documentation the member continues to benefit from Duvyzat based on the prescriber's assessment. Examples include improved strength, pulmonary function test, or functional assessments (e.g., 6- minute walk test).

Limitations

1. Initial requests will be approved for 6 months
2. Reauthorizations will be approved for 12 months.

References

1. Birnkrant DJ, Bushby K, Bann CM, et al for the DMD Care Considerations Working Group. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. *Lancet Neurol*. 2018[a]; 17(3):251-267. doi: 10.1016/S1474-4422(18)30025-3.
2. Birnkrant DJ, Bushby K, Bann CM, et al for the DMD Care Considerations Working Group. Diagnosis and management of Duchenne muscular dystrophy, part 2: respiratory, cardiac, bone health, and orthopaedic management. *Lancet Neurol*. 2018[b]; 17(4):347-361. doi: 10.1016/S1474-4422(18)30025-5.
3. Birnkrant DJ, Bushby K, Bann CM, et al for the DMD Care Considerations Working Group. Diagnosis and management of Duchenne muscular dystrophy, part 3: primary care, emergency management, psychosocial care, and transitions of care across the lifespan. *Lancet Neurol*. 2018[c]; 17(5):251-267. doi: 10.1016/S1474-4422(18)30026-7.
4. Duvyzat [package insert]. Madrid, Spain: Italfarmaco S.A.; March 2024.
5. Efficacy, safety, and tolerability of givinostat in non-ambulant patients with Duchenne muscular dystrophy (ULYSSES) (NCT05933057). ClinicalTrials.gov. https://clinicaltrials.gov/. Accessed April 8, 2024.
6. Food and Drug Administration. FDA news release: FDA approves nonsteroidal treatment for Duchenne muscular dystrophy. March 21, 2024. FDA Web site. https://www.fda.gov/news-events/press-announcements/fda-approves-nonsteroidal-treatment-duchenne-muscular-dystrophy. Accessed April 5, 2024.
7. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86(5):465-72.
8. Gronseth GS, Cox J, Gloss D, et al. American Academy of Neurology clinical practice guideline process manual, 2017 edition. AAN Web Site. https://www.aan.com/practice/what-are-clinical-practice-guidelines. Accessed February 8, 2024.
9. North Star Clinical Network. North Star Ambulatory Assessment. Updated September 30, 2020. https://www.musculardystrophyuk.org/static/s3fs-public/2021-08/NSAA%20_Manual_%2015102020.pdf?VersionId=BaPGDWk5TxA3rtF2DDipAVYlOJ5Eoumo. Accessed February 21, 2024.
10. Quinlivan R, Messer B, Murphy P, et al on behalf of the ANSN. Adult North Star Network (ANSN): consensus guideline for the standard of care of adults with Duchenne muscular dystrophy. *J Neuromuscul Dis*. 2021;8(6):899-926. doi: 10.3233/JND-200609.
11. Mercuri E, Vilchez JJ, Boespflug-Tanguy O, et al. Safety and efficacy of givinostat in boys with Duchenne muscular dystrophy (EPIDYS): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2024;23:393-403. doi: 10.1016/S1474-4422(24)00036-X.

12. Ricci G, Bello L, Torri F, et al. Therapeutic opportunities and clinical outcome measures in Duchenne muscular dystrophy. Neurol Sci. 2022;43(Suppl 2):625-633. doi: 10.1007/s10072-022-06085-w.
13. Sandonà M, Caioli G, Renzini A, et al. Histone deacetylases: molecular mechanisms and therapeutic implications for muscular dystrophies. *Int J Mol Sci*. 2023;24(5):4306. doi:10.3390/ijms24054306.

Review History
09/11/2024 – Reviewed at September P&T. Effective 11/1/2024.