Medical Policy

Zepzelca™ (lurbinectedin)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-116
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Zepzelca™ (lurbinectedin) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Zepzelca will be provided for six months and may be renewed.

- Max Units (per dose and over time): 80 billable units every 21 days

Initial

A. Patient is 18 years of age or older; **AND**
B. Zepzelca is being used as single agent therapy; **AND**

Generalized Myasthenia Gravis (gMG)

A. Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease*; **AND**
B. Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **AND**
C. Patient has had a thymectomy (Note: Applicable only to patients with thymomas OR non-thymomatous patients who are 50 years of age or younger); **AND**
D. Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); **AND**
E. Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score of at least 5; **AND**
F. Patient had an inadequate response after a minimum one-year trial with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); **OR**
    a. Patient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant

* Myasthenia Gravis Foundation of America (MGFA) Disease Clinical Classification
Class I: Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
Class II: Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
- IIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
- IIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.

Class III: Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
- IIIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
- IIIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.

Class IV: Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
- IVa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
- IVb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.

Class V: Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the patient in class IVb.

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: infection, severe hypersensitivity reactions, etc.; **AND**

C. Patient has had an improvement (i.e., reduction) of at least 2-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score sustained for at least 4-weeks**; **AND**
D. Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline; **AND**
E. Patient requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity (Note: a minimum of 50 days must have elapsed from the start of the previous treatment cycle)

*(** May substitute an improvement of at least 3-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4-weeks, if available)*

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. VYVGART™ (efgartigimod alfa-fcab) injection, for intravenous use. Initial U.S. Approval: 2021
   a. VYVGART (efgartigimod alfa-fcab) injection is a preservative free, sterile, colorless to slightly yellow, clear to slightly opalescent solution supplied as 400 mg/20 mL (20 mg/mL) in one single-dose vial per carton.

CODING

Applicable NDC Codes	
73475-3041-xx	Vyvgart 400 mg/20 mL single-dose vial

Applicable Procedure Code	
J3590	Unclassified biologics

Applicable ICD-10 Codes	
G70.0	Myasthenia gravis
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

EVIDENCE BASED REFERENCES

1. Vyvgart [package insert]. Boston, MA; Argenx, Inc., December 2021. Accessed December 2021.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	March 1, 2023 - Adopted by MA UM Committee (no policy revisions made)
P&T Committee Endorsement	5/24/2022
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024