Medical Policy

ELAHERE® (mirvetuximab soravtansine)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-137
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

*Policy applies to all markets where IFP, SG, or MA plans are offered

Brand New Day/Central Medicare Health Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan `Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Elahere, mirvetuximab soravtansine therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Elahere will be provided for 6 months and may be renewed unless otherwise specified.

- Max Units (per dose and over time):
  - 600mg every 21 days

Initial

A. Patient is 18 years of age or older; **AND**

B. Patient will use therapy in combination with artificial tears and ophthalmic topical steroids; **AND**
C. Patient has a baseline ophthalmological test (i.e., visual acuity, slit lamp exam) obtained prior to initiation of therapy and will continue to have follow-up ophthalmological examinations periodically thereafter (i.e., every other cycle for the first 8 cycles, and as clinically indicated); **AND**
D. Patient does not have moderate to severe hepatic impairment (Child-Pugh Class B or C); **AND**
E. Patient does not have any of the following;
    a. Non-infectious interstitial lung disease or pneumonitis (Grade 3 or 4); **AND**
    b. Peripheral neuropathy greater than Grade 1; **AND**
    c. Patients with active or chronic corneal disorders, history of corneal transplantation, or active ocular conditions requiring ongoing treatment/ monitoring (e.g., uncontrolled glaucoma, wet age-related macular degeneration requiring intravitreal injections, active diabetic retinopathy with macular edema, macular degeneration, presence of papilledema, and/or monocular vision); **AND**

Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

A. Used as single agent therapy; **AND**
B. Patient has folate receptor alpha (FRα)-positive expression as determined by an FDA-approved or CLIA-compliant test†; **AND**
C. Patient has platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; **AND**
D. Patient has received up to three prior lines of systemic therapy which must have included therapy containing bevacizumab.

†If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics

Renewal

Coverage can be renewed based upon the following criteria:

A. Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial criteria; **AND**
B. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: persistent or recurrent pneumonitis, severe peripheral neuropathy, severe ocular toxicities (i.e., visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis), etc.

LIMITATIONS/EXCLUSIONS

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

DEFINITIONS

A. Elahere (mirvetuximab soravtansine) injection, for intravenous use. Initial U.S. Approval: 2022
    a. ELAHERE (mirvetuximab soravtansine-gynx) for injection is a clear to slightly opalescent, colorless solution for intravenous infusion after dilution in 5% Dextrose Injection. It is supplied as an individually packaged, single-dose vial.

CODING

Applicable NDC Codes	
72903-0853-01	Elahere 5mg/1ml-20ml solution in a single dose vial

Applicable Procedure Code	
J9999	Not otherwise classified, antineoplastic drug

Applicable ICD-10 Codes	
C48.1	Malignant neoplasm of specified part of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
Z85.43	Personal history of malignant neoplasm of ovary

EVIDENCE BASED REFERENCES

1. Elahere [package insert]. Waltham, MA; ImmunoGen, Inc; November 2022. Accessed January 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) mirvetuximab soravtansine. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2023.

3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer - Fallopian Tube Cancer and Primary Peritoneal Cancer 1.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2023.

POLICY HISTORY

Original Effective Date	2/28/2023
Revised Date	
P&T Committee Endorsement	02/28/2023
Updated to Brand New Day/Central Health Medicare Plan	01/01/2024