Medical Policy

Cosela™ (trilaciclib)	
MEDICAL POLICY NUMBER	Med_Clin_Ops_079
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare 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 Medical 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.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Cosela™ (trilaciclib) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Cosela will be provided for 6 months and may be renewed.

1. Patient is 18 years of age or older; AND
2. Cosela is prescribed by or in consultation with an oncologist; AND
3. Patient has a documented diagnosis of extensive-stage small cell lung cancer (ES-SCLC); AND
4. Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression; AND
5. Patient will be receiving one of the following:
    a. Platinum (carboplatin or cisplatin) OR etoposide-containing chemotherapy

regimen
   b. Topotecan-containing chemotherapy regimen
6. Cosela will be given within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered; AND
7. Cosela will **not** be given with granulocyte colony-stimulating factor (G-CSF) and/or erythropoiesis-stimulating agents (ESAs) as primary prophylaxis during cycle.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Concomitant use with granulocyte colony-stimulating factor (G-CSF) and/or erythropoiesis-stimulating agents (ESAs) as primary prophylaxis during cycle

BACKGROUND

Cosela is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).

DEFINITIONS

1. COSELA™ (trilaciclib) for injection, for intravenous use. Initial U.S. Approval: 2021
   a. COSELA (trilaciclib) for injection is a yellow lyophilized cake supplied in a single-dose vial.
   b. Each carton (NDC 73462-101-01) contains one 300 mg strength single-dose vial.

CODING

Applicable NDC Codes	
73462-0101-01	COSELA™ (trilaciclib) 300 mg (equivalent to 349 mg of trilaciclib dihydrochloride)

Applicable Procedure Code	
C9399	Unclassified drugs or biologics (When utilized for Cosela [trilaciclib])
J3490	Unclassified drugs (When utilized for Cosela [trilaciclib])

Applicable ICD-10 Codes	
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung

C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

EVIDENCE BASED REFERENCES

1. Cosela [package insert]. Durham, NC; G1 Therapeutics, Inc; February 2021. Accessed June 2021.

POLICY HISTORY

Approved by the Pharmacy and Therapeutics Committee

Original Effective Date	July 19, 2021
Revised Date	November 1, 2021 November 8, 2022 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UMC (no changes) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 11/8/2022