COSELA™
trilaciclib for injection 300 mg

CODING AND BILLING GUIDE

POSSIBLE CODING OPTIONS FOR COSELA FOR INJECTION, FOR INTRAVENOUS USE

PERMANENT J CODE
Effective: 10/1/2021

HCPCS Level II code[1]:

J1448 Injection, trilaciclib, 1 mg

CPT® codes[2]:

96365 Intravenous (IV) infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

This guide provides coding and reimbursement information for COSELA™ (trilaciclib)

FIND IN THIS GUIDE

- Overview of codes (NDC, ICD-10-CM, CPT, HCPCS, and NTAP)
- Appendix:
  - Sample annotated physician office billing CMS-1500
  - Sample annotated hospital outpatient billing CMS-1450/UB-04
- G1 to One™ Patient Support Program information

G1 THERAPEUTICS™

New Technology Add-on Payment (NTAP)

NTAP supports access to therapies that represent substantial clinical advances over treatment options available in the hospital inpatient setting

The Centers for Medicare and Medicaid Services (CMS) NTAP designation provides additional reimbursement to address the delay between the introduction of a new technology and the recalculation of Medicare Severity Diagnosis Related Group (MS-DRG) payment rates to reflect the costs of the new technology. The NTAP is a temporary payment, incremental to the MS-DRG payment normally made to the hospital.

NTAP Details

Eligible Facilities and Settings of Care

Acute care inpatient hospitals that are reimbursed under the inpatient prospective payment system (IPPS). Hospitals that are not eligible to receive the add-on payment include hospitals not reimbursed under the IPPS, including but not limited to critical access hospitals, IPPS-exempt cancer hospitals, long-term care hospitals, Veterans Affairs/Department of Defense facilities, and hospitals in the state of Maryland.

Qualified Patients

Traditional (fee-for-service) Medicare beneficiaries where the cost of the case exceeds the MS-DRG payment for the case.

Amount of Additional Payment

Medicare will make an add-on payment **equal to the lesser of:**

65% of the costs of the new medical service or technology

65% of the amount by which the costs of the case exceed the standard MS-DRG payment

Beginning on October 1, 2021, CMS provided an additional maximum payment of $5,526.30 for COSELA when used in the inpatient hospital setting for fiscal year 2022.

Hospitals reimbursed for Medicare inpatient admissions under the IPPS may receive the NTAP for use of COSELA in qualifying cases, based on the cost of the case calculated from the claim. CMS issued COSELA two unique International Classification of Disease Procedure Codes (ICD-10-PCS) to be included on the claim to indicate administration of COSELA in the inpatient setting. Hospitals should include one of the two unique ICD-10-PCS procedure codes to facilitate NTAP when treating eligible patients with ES-SCLC.

XW03377[3] Introduction of Trilaciclib into **Peripheral Vein, Percutaneous Approach, New Technology Group 7**

XW04377[3] Introduction of Trilaciclib into **Central Vein, Percutaneous Approach, New Technology Group 7**

COSELA™
trilaciclib for injection 300 mg

Please see the full Prescribing Information.

Summary of Possible Coding and Billing for COSELA

Once COSELA™ (trilaciclib) has been administered to a patient, you may submit a claim to the patient's health plan. Correct coding is essential for timely claims processing and reimbursement. Important codes include the following:

DISPENSING PACK QUANTITY	1 vial/carton
NDC 10 **NDC 11** **(for billing purposes)**	73462-101-01 73462-0101-01
HCPCS LEVEL II CODE[1]	**J1448** Injection, trilaciclib, 1 mg Effective: 10/1/2021
CPT® CODES[2]	96365 Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
DESCRIPTION[4]	COSELA™ (trilaciclib) 300 mg (equivalent to 349 mg of trilaciclib dihydrochloride)

National Drug Code (NDC)

COSELA NDC numbers are listed below. Please note that converting the 10-digit NDC to an 11-digit NDC requires the use of a leading zero in the product code or middle section of the NDC.

COSELA PACKAGE SIZE	NDC[5]
3 in. x 1.5 in. (carton size)	10-digit: 73462-101-01
	11-digit: 73462-0101-01

International Classification of Disease, 10th Revision, Clinical Modification (ICD-10-CM)

ICD-10-CM codes are used to report a patient's diagnosis on claim submissions. The following ICD-10-CM codes may describe diagnoses for patients treated with COSELA. Be sure to use the correct coding when submitting a claim for the item or service.

ICD-10-CM[6]	DESCRIPTION
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
C34.20	Malignant neoplasm of middle lobe, bronchus or lung

COSELA™
trilaciclib for injection 300 mg

Please see the full Prescribing Information.

International Classification of Disease, 10th Revision, Clinical Modification (ICD-10-CM)

ICD-10-CM	DESCRIPTION
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

Current Procedural Terminology (CPT®)

Most health plans cover IV therapies under their medical benefit. CPT codes are used to identify services and procedures provided by healthcare practitioners. The chart below lists the potential CPT code for your reference when submitting claims for COSELA.

CPT CODES[2]	DESCRIPTION
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

Healthcare Common Procedure Coding System (HCPCS)

HCPCS codes, like the permanent J Code for COSELA below, are used by commercial insurers and government payers to standardize claims submissions and medication reimbursement. Please contact the insurer or G1 to One at 1-833-G1toOne (1-833-418-6663) for additional info.

HCPCS CODES[1]	DESCRIPTION
J1448	Injection, trilaciclib, 1 mg

PAYER SPECIFICS To find your Medicare Part B DME MAC jurisdiction, visit the CMS website.

References: 1. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions: Second Quarter, 2021 Coding Cycle for Drug and Biological Products. https://www.cms.gov/files/document/2021-hcpcs-application-summary-quarter-2-2021-drugs-and-biologics-updated-08062021.pdf. Accessed August 24, 2021. **2.** American Academy of Professional Coders website. 2021 CPT Code 96365. https://www.aapc.com/codes/cpt-codes/96365. Accessed August 24, 2021. **3.** Centers for Medicare & Medicaid Services. 2022 ICD-10-PCS Code Tables And Index. https://www.cms.gov/medicare/icd-10/2022-icd-10-pcs. Accessed August 24, 2021. **4.** COSELA (trilaciclib). Prescribing Information. G1 Therapeutics, Inc; 2/2021. **5.** Data on File. G1 Therapeutics, Inc. 2022. **6.** Centers for Medicare & Medicaid Services. 2022 ICD-10-CM Code Tables, Tabular and Index. https://www.cms.gov/medicare/icd-10/2022-icd-10-cm. Accessed August 26, 2021.

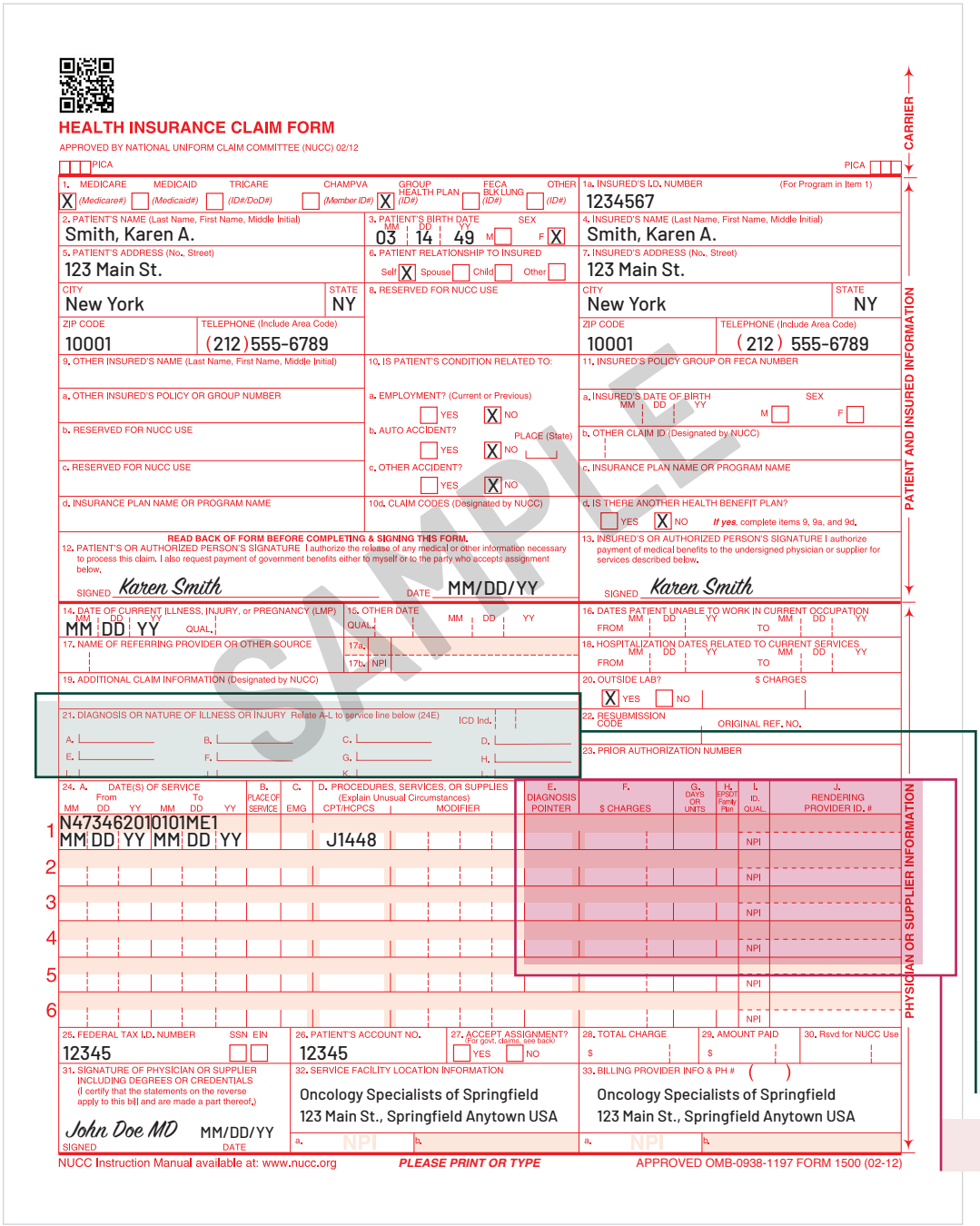
CPT codes, descriptions, and other data only are copyright 2021 American Medical Association. All Rights Reserved. Applicable FARS/HHSAR apply.

COSELA™
trilaciclib for injection 300 mg

Please see the full Prescribing Information.

Coding Resource
CMS-1500 Annotated Claim Form

It's important to include the drug name, NDC, and dose given in Item 19 when filling out the CMS-1500 form. Confirm with each patient's health plan, as the information required may vary.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE [X] (Medicare#) MEDICAID [ ] (Medicaid#) TRICARE [ ] (ID#/DoD#) CHAMPVA [ ] (Member ID#) GROUP HEALTH PLAN [X] (ID#) FECA BLK LUNG [ ] (ID#) OTHER [ ] (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 1234567

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Smith, Karen A.

3. PATIENT'S BIRTH DATE: 03 14 49 SEX: M [ ] F [X]

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Smith, Karen A.

5. PATIENT'S ADDRESS (No., Street): 123 Main St.

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): 123 Main St.

CITY: New York STATE: NY

8. RESERVED FOR NUCC USE

CITY: New York STATE: NY

ZIP CODE: 10001 TELEPHONE (Include Area Code): (212)555-6789

ZIP CODE: 10001 TELEPHONE (Include Area Code): (212) 555-6789

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES [ ] NO [X]

a. INSURED'S DATE OF BIRTH SEX

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES [ ] NO [X] PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES [ ] NO [X]

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [X] If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED Karen Smith DATE MM/DD/YY

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED Karen Smith

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES [X] NO [ ] $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 N473462010101ME1 MM DD YY	MM DD YY			J1448						NPI	
2										NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN: 12345

26. PATIENT'S ACCOUNT NO.: 12345

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES [ ] NO [ ]

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

John Doe MD SIGNED MM/DD/YY DATE

32. SERVICE FACILITY LOCATION INFORMATION

Oncology Specialists of Springfield
123 Main St., Springfield Anytown USA

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

Oncology Specialists of Springfield
123 Main St., Springfield Anytown USA

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

Prescribers use this form when billing insurers for medication administered in the physician's office and for their professional services.

The suggestions contained on this form are for example only and G1 Therapeutics makes no representation that the information is accurate or that it will comply with the requirements of any particular payer/insurer. Providers are solely responsible for determining the billing and coding requirements applicable to any payer/insurer. The information provided here is not intended to be conclusive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. G1 Therapeutics makes no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use. The use of this information does not guarantee payment or that any payment received will cover your costs.

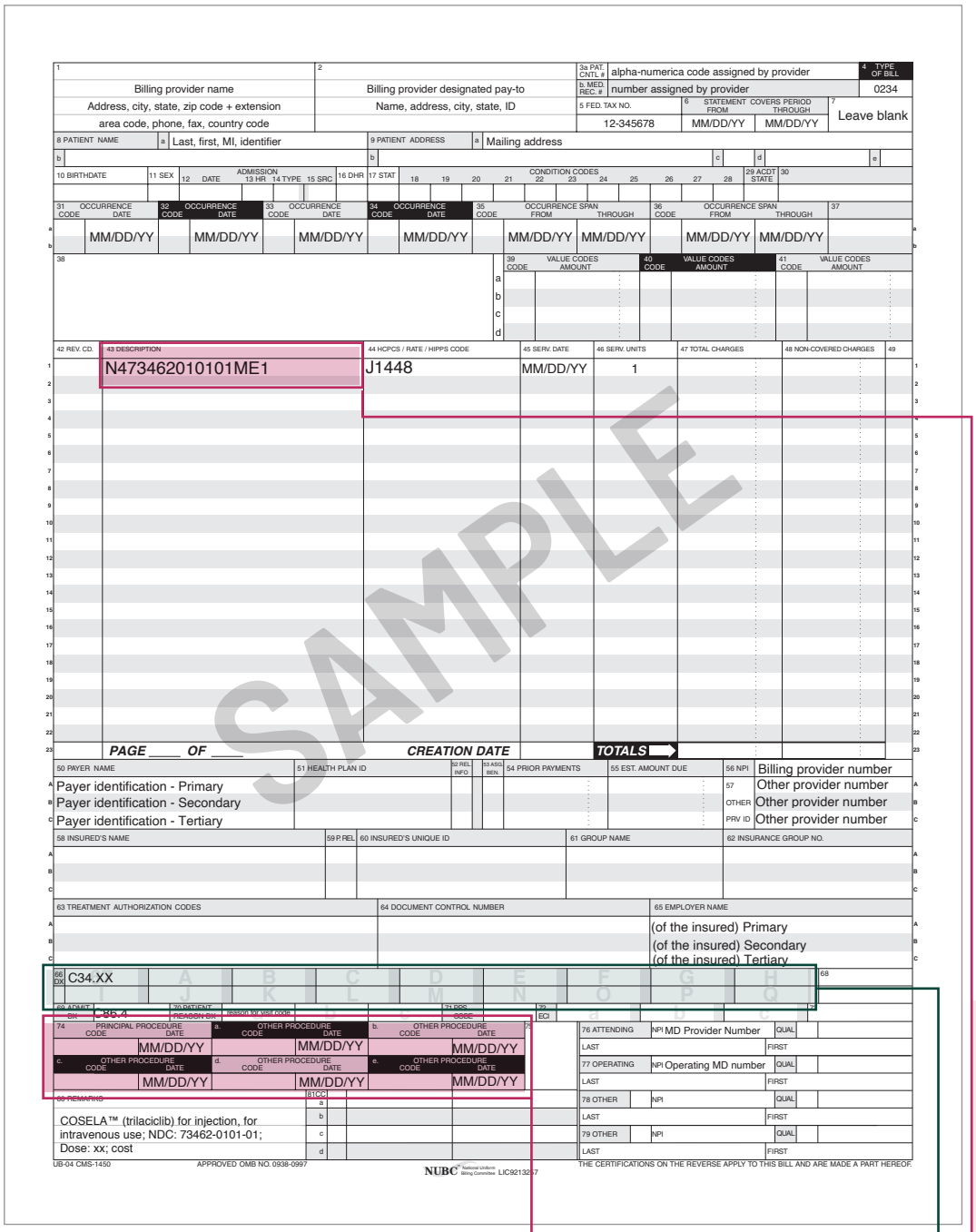
Input Diagnosis Code(s) here

Complete Sections E-J

COSELA™
trilaciclib for injection 300 mg

Please see the full Prescribing Information.

Coding Resource
UB-04 Annotated Claim Form



Hospitals use this form when billing insurers for medication administered in the inpatient or outpatient setting. Outpatient hospitals should bill with the appropriate revenue code.

The suggestions contained on this form are for example only and G1 Therapeutics makes no representation that the information is accurate or that it will comply with the requirements of any particular payer/insurer. Providers are solely responsible for determining the billing and coding requirements applicable to any payer/insurer. The information provided here is not intended to be conclusive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. G1 Therapeutics makes no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use. The use of this information does not guarantee payment or that any payment received will cover your costs.

Enter detailed drug description: the N4 indicator, the 11-digit National Drug National Code (NDC), a code describing the unit of measurement qualifier (eg, ME for milligrams), and the unit quantity. Example: N473462010101ME1

Input NTAP Code(s) here

Input Diagnosis Code(s) here

COSELA™
trilaciclib for injection 300 mg

Please see the full Prescribing Information.

The G1 to One™ Patient Support Program

Your single source for access and affordability solutions

G1 to One offers a suite of solutions to common access and reimbursement hurdles, such as:

- Benefits verifications for patient coverage and out-of-pocket responsibilities
- Providing payer-specific guidance for prior authorizations and appeals to address patient needs
- Offering solutions for insurance-related delays
- Connecting patients, regardless of insurance type, to resources that address high deductibles, co-pays/coinsurance, or even a lack of coverage*

Complete and submit the form to enroll patients in G1 to One.
Download the enrollment form at www.G1toOne.com.
Fax the completed form to 1-833-FAX-G121 (1-833-329-4121).

Call us with questions at
1-833-G1toOne (1-833-418-6663),
Monday–Friday
or email us at **Enroll@G1toOne.com**.
Visit **www.G1toOne.com**
for additional information.

*Patients must express need and meet certain eligibility requirements.

COSELA™
trilaciclib for injection 300 mg

Please see the full Prescribing Information.

INDICATION

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).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

- COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

WARNINGS AND PRECAUTIONS

Injection-Site Reactions, Including Phlebitis and Thrombophlebitis

- COSELA administration can cause injection-site reactions, including phlebitis and thrombophlebitis, which occurred in 56 (21%) of 272 patients receiving COSELA in clinical trials, including Grade 2 (10%) and Grade 3 (0.4%) adverse reactions. Monitor patients for signs and symptoms of injection-site reactions, including infusion-site pain and erythema during infusion. For mild (Grade 1) to moderate (Grade 2) injection-site reactions, flush line/cannula with at least 20 mL of sterile 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP after end of infusion. For severe (Grade 3) or life-threatening (Grade 4) injection-site reactions, stop infusion and permanently discontinue COSELA. Injection-site reactions led to discontinuation of treatment in 3 (1%) of the 272 patients.

Acute Drug Hypersensitivity Reactions

- COSELA administration can cause acute drug hypersensitivity reactions, which occurred in 16 (6%) of 272 patients receiving COSELA in clinical trials, including Grade 2 reactions (2%). Monitor patients for signs and symptoms of acute drug hypersensitivity reactions. For moderate (Grade 2) acute drug hypersensitivity reactions, stop infusion and hold COSELA until the adverse reaction recovers to Grade ≤1. For severe (Grade 3) or life-threatening (Grade 4) acute drug hypersensitivity reactions, stop infusion and permanently discontinue COSELA.

Interstitial Lung Disease/Pneumonitis

- Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with cyclin-dependent kinases (CDK)4/6 inhibitors, including COSELA, with which it occurred in 1 (0.4%) of 272 patients receiving COSELA in clinical trials. Monitor patients for pulmonary symptoms of ILD/pneumonitis. For recurrent moderate (Grade 2) ILD/pneumonitis, and severe (Grade 3) or life-threatening (Grade 4) ILD/pneumonitis, permanently discontinue COSELA.

Embryo-Fetal Toxicity

- Based on its mechanism of action, COSELA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with COSELA and for at least 3 weeks after the final dose.

ADVERSE REACTIONS

- Serious adverse reactions occurred in 30% of patients receiving COSELA. Serious adverse reactions reported in >3% of patients who received COSELA included respiratory failure, hemorrhage, and thrombosis.
- Fatal adverse reactions were observed in 5% of patients receiving COSELA. Fatal adverse reactions for patients receiving COSELA included pneumonia (2%), respiratory failure (2%), acute respiratory failure (<1%), hemoptysis (<1%), and cerebrovascular accident (<1%).
- Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received COSELA. Adverse reactions leading to permanent discontinuation of any study treatment for patients receiving COSELA included pneumonia (2%), asthenia (2%), injection-site reaction, thrombocytopenia, cerebrovascular accident, ischemic stroke, infusion-related reaction, respiratory failure, and myositis (<1% each).
- Infusion interruptions due to an adverse reaction occurred in 4.1% of patients who received COSELA.
- The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

DRUG INTERACTIONS

- COSELA is an inhibitor of OCT2, MATE1, and MATE-2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATE1, and MATE-2K substrates in the kidney (e.g., dofetilide, dalfampridine, and cisplatin).

To report suspected adverse reactions, contact G1 Therapeutics at 1-800-790-G1TX or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This information is not comprehensive. Please see the full Prescribing Information.

G1 THERAPEUTICS™

COSELA™
trilaciclib for injection 300 mg