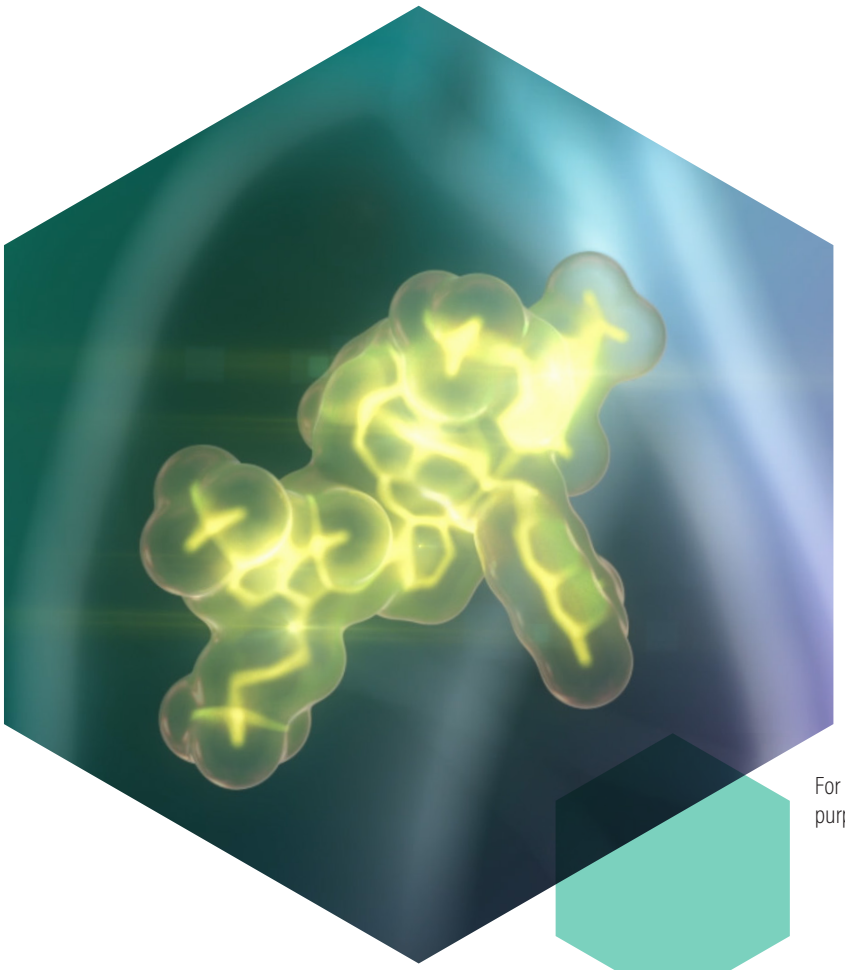
THORACIC



For illustrative purposes only

cytalux®
(pafolacianine) injection

See cancer in real time.

REIMBURSEMENT GUIDE

ON TARGET LABORATORIES

Using the CYTALUX® Reimbursement Guide:

The CYTALUX Reimbursement Guide is intended to provide current and available reimbursement information to hospitals and health care providers so that they may better understand the billing and coding requirements for CYTALUX (pafolaclanine) injection.

DISCLAIMER

Information described in the CYTALUX Reimbursement Guide is intended solely for use as a resource tool to assist hospital inpatient billing staff regarding reimbursement issues. Any determination regarding if and how to seek reimbursement should be made only by the appropriate members of the hospital inpatient staff, and in consideration of the procedure performed or therapy provided to a specific patient. There may be some payers that require specific information for billing imaging agents on inpatient claims. Therefore, please consult the applicable payer organization with regard to local or actual coverage, reimbursement policies, and determination processes and always confirm adherence to specific payer rules and guidelines.

On Target Laboratories does not recommend or endorse the use of any particular diagnosis or procedure code(s) and make no determination if or how reimbursement may be available. Of important note, reimbursement codes and payment, as well as health policy and legislation, are subject to continual change; information contained in this version of the CYTALUX Reimbursement Guide is current as of September 2023.

CYTALUX Reimbursement Support

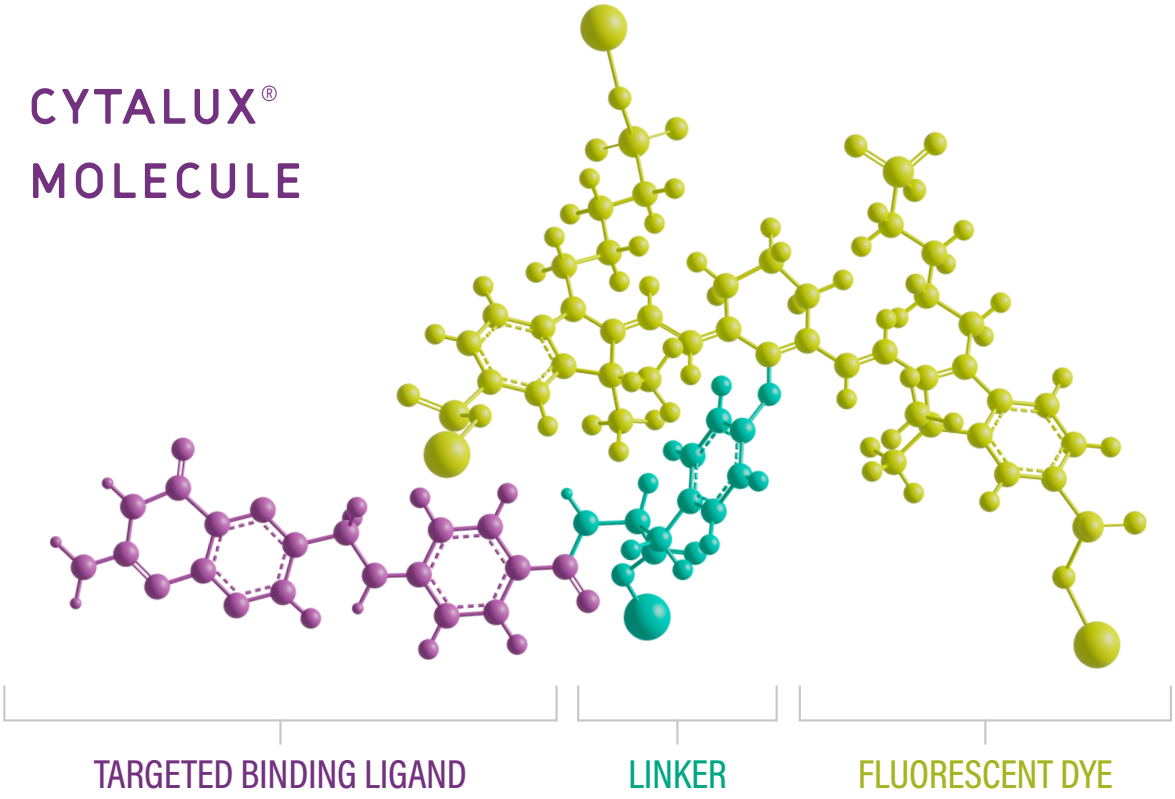
1 (765) 269–4419
reimbursement@ontargetlabs.com

The CYTALUX Reimbursement Support Line assists hospitals, healthcare providers and patients and is composed of a comprehensive reimbursement support program that is available to provide support for CYTALUX reimbursement and access issues.

The CYTALUX Reimbursement Support Program does not file claims or appeal claims for callers, nor can it guarantee that you will be successful in obtaining reimbursement. Third-party payment for medical products and services is affected by numerous factors, not all of which can be anticipated or resolved by the Reimbursement Support Line.

Table of Contents

CYTALUX® Overview



What is CYTALUX?

CYTALUX is the only IV-delivered molecular imaging agent that illuminates lung cancer intraoperatively for real-time localization of pulmonary lesions.

CYTALUX Indications

CYTALUX is an FDA approved optical imaging agent indicated as an adjunct for intraoperative identification of:

- Malignant lesions in adult patients with ovarian cancer.
- Malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung.

Please consult the full **Prescribing Information** for additional preparation and storage instructions.

Coding for Lung Cancer

NATIONAL DRUG CODE (NDC)

The NDC, or National Drug Code, is a unique 10-digit (drug packaging) or 11-digit (claim filing), 3-segment number, and a universal product identifier for drugs in the United States. The 3 segments of the NDC identify: the labeler, the product, and the commercial package size.

There may be times when a payer may require our NDC number to be on the inpatient claim therefore it is important that you confirm the NDC billing instructions with each payer, as their requirements may vary. Proper billing of an NDC requires the 11-digit number in a 5-4-2 format.

CYTALUX NDC NUMBER

10 DIGIT NUMBER	81052-138-10
11 DIGIT NUMBER	81052-0138-10

HCPCS Code

Healthcare Common Procedure Coding System (HCPCS) is a standardized code system necessary for medical providers to submit healthcare claims to Medicare and other health insurances in a consistent and orderly manner.

HCPCS Level II Code

A9603	Injection, pafolacianine, 0.1 mg

New Technology Add-On Payment (NTAP)

NTAP a term used in the U.S. healthcare system to refer to a payment mechanism that provides additional reimbursement to hospitals for the use of certain new and innovative medical technologies that are deemed to be of significant clinical benefit. NTAP, which is part of the CMS Inpatient Prospective Payment System (IPPS), was set up to support the adoption of cutting-edge technologies that have demonstrated substantial clinical improvement and ensure early availability to Medicare patients. This incremental payment seeks to mitigate financial disincentives for use on Medicare and Tricare patients by providing hospitals with an add-on payment to help offset the technology's cost.

CYTALUX was 1 of only 8 new technologies to be granted the NTAP, effective Oct 1, 2023.

Details of NTAP

Eligible Facilities	• Acute care hospitals participating in the inpatient prospective payment system. • Military hospitals and clinics under the TRICARE program
Qualified Patients	Traditional Medicare and dual-eligible (Medicare-Medicaid) fee-for-service patients or TRICARE patients whose case totals exceed the MS-DRG rate payment
Add-on Payment	• The NTAP is limited to the lesser of 65% of the cost of the new technology or 65% of the amount by which the cost of the case exceeds the MS-DRG payment. • The maximum add-on payment for CYTALUX is $2,762.50 for fiscal year (FY) 2024 (reassessed annually)
Effective Date	October 1, 2023
Duration	NTAP is approved for up to 3 years; the maximum add-on payment amount is reassessed annually

HOW TO CODE FOR ADD-ON PAYMENT

Hospitals must report the ICD-10-PCS code on claim forms for procedures related to CYTALUX to receive the add-on payment for eligible inpatient cases.

ICD-10- PCS Procedure Coding System

Effective 10/01/2023, the Centers for Medicare & Medicaid Services (CMS) created 5 new PCS codes that captures the PCS method value Fluorescence Guided Procedure and the PCS qualifier value Pafolacianine and applies them to the fourth character body region values and applicable approaches. These changes enable the capture of additional detail for fluorescence-guided procedures that use Pafolacianine.

ICD-10 CODE: 8E0

- **Section** 8 Other Procedures
- **Body System** E Physiological Systems and Anatomical Regions
- **Operation** 0 Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease

Body Region	Approach	Method	Qualifier
W Trunk Region	0 Open 3 Percutaneous 4 Percutaneous Endoscopic 7 Via Natural or Artificial Opening 8 Via Natural or Artificial Opening Endoscopic	E Fluorescence Guided Procedure	N Pafolacianine Z No Qualifier

ICD-10-PCS Code

Our new ICD-10-PCS code can be used for discharges effective October 1, 2023.

8E0W0EN	Fluorescence guided procedure of trunk region using pafolacianine, open approach
8E0W3EN	Fluorescence guided procedure of trunk region using pafolacianine, percutaneous approach
8E0W4EN	Fluorescence guided procedure of trunk region using pafolacianine, percutaneous endoscopic approach
8E0W7EN	Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening
8E0W8EN	Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening endoscopic

For additional information, please consult the current ICD-10-PCS manual. Some individual payers may require specific accommodations for billing imaging agents on inpatient claims. Always conform to specific payer rules and guidelines.

ICD-10-CM Clinical Modification Diagnosis Codes

The ICD-10-CM is used to classify diagnoses and reasons for visits in all health care settings. Always check with the payers guidelines to verify ICD-10-CM requirements, for individual rules may vary. Below is a range of potential ICD-10-CM diagnosis codes that may be related to a diagnosis within CYTALUX approved label.

Potential ICD-10-CM Clinical Modification Diagnosis Codes

C3411	Malignant neoplasm of upper lobe, right bronchus, or lung
C3412	Malignant neoplasm of upper lobe, left bronchus or lung
C342	Malignant neoplasm of middle lobe, bronchus, or lung
C3430	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C3431	Malignant neoplasm of lower lobe, right bronchus or lung
C3432	Malignant neoplasm of lower lobe, left bronchus or lung
C3481	Malignant neoplasm of overlapping sites of right bronchus and lung
C3490	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C3491	Malignant neoplasm of unspecified part of right bronchus or lung
C3492	Malignant neoplasm of unspecified part of left bronchus or lung
C7800	Secondary malignant neoplasm of unspecified lung
C7801	Secondary malignant neoplasm of right lung
C7802	Secondary malignant neoplasm of left lung
C7A090	Malignant carcinoid tumor of the bronchus and lung
D0221	Carcinoma in situ of right bronchus and lung
D0222	Carcinoma in situ of left bronchus and lung
D381	Neoplasm of uncertain behavior of trachea, bronchus and lung

Medicare Severity Diagnosis Related Group (MS-DRG)

MS-DRG means Medicare severity-diagnosis-related group. It's a system of classifying patient hospital stays. Within the system, Medicare classifies groups to facilitate service payments. CYTALUX is an inpatient drug and will be bundled by payers into hospital payment rates (MS-DRGs), all patient refined (APR DRGs), or other DRGs specific to the individual payer's internal methodology. The DRG assignment depends on the diagnosis and the procedure with which CYTALUX will be bundled. There are 3 MS-DRGs that represent the procedures involving CYTALUX and are shown in the table below. This table may not be inclusive of all MS-DRGs or other non–MS-DRGs that may be used for CYTALUX. Only 1 MS-DRG should be assigned to a patient for a particular hospital admission.

Potential MS-DRG Codes

163	MAJOR CHEST PROCEDURES WITH MCC
164	MAJOR CHEST PROCEDURES WITH CC
165	MAJOR CHEST PROCEDURES WITHOUT CC MCC

Revenue Codes

Revenue codes may also be used to report services and supplies that are utilized during treatment.

Suggested Revenue Codes

0360	Operating Room Services General
0250	Pharmacy General

Professional Current Procedural Terminology (CPT) Codes

In addition to facility inpatient reimbursement, some hospitals also bill out professional physician fees separate from the inpatient procedure. Below is a list meant to serve as a guide of commonly used professional fees; it is not exhaustive, and individual circumstances and payer rules will determine coding.

Potential CPT Codes

32096	Thoracotomy, with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, inc.isional), unilateral
32097	Thoracotomy, with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral
32480	Removal of lung, other than pneumonectomy; single lobe (lobectomy)
32482	Removal of lung, other than pneumonectomy; 2 lobes {bilobectomy)
32484	Removal of lung, other than pneumonectomy; single segment (segmentectomy)
32486	Removal of lung, other than pneumonectomy; with circumferential resection of segment of bronchus followed by broncho-bronchial anastomosis (sleeve lobectomy)
+32501	Resection and repair of portion of bronchus (bronchoplasty) when performed at time of lobectomy or segmentectomy (List separately in addition to code for primary procedure)
32505	Thoracotomy; with therapeutic wedge resection (eg, mass, nodule), initial
+32506	Thoracotomy; with therapeutic wedge resection (eg, mass, nodule), each additional resection, ipsilateral (List separately in addition to code for primary procedure)
*32507	Thoracotomy; with diagnostic wedge resection followed by anatomic lung resection (List separately in addition to code for primary procedure)
32663	Thoracoscopy, surgical; with lobectomy (single lobe)
32666	Thoracoscopy, surgical; with therapeutic wedge resection (eg, mass, nodule), initial unilateral
+32667	Thoracoscopy, surgical; with therapeutic wedge resection (eg, mass, nodule), each additional resection, ipsilateral surgical; (List with separately
+32668	Thoracoscopy, surgical; with diagnostic wedge resection followed by anatomic lung resection (List separately in addition to code for primary procedure)
32669	Thoracoscopy, surgical; with removal of a single lung segment (segmentectomy)
32670	Thoracoscopy, surgical; with removal of two lobes (bilobectomy)

Coverage

CYTALUX® PUBLIC AND PRIVATE PAYER COVERAGE INFORMATION COVERAGE

Medicare

Medicare is a federally funded health insurance program that was established as part of the Social Security Act of 1965, which provides coverage to 49 million beneficiaries, and is administered through the following 4 benefit categories:

Part A Hospital Insurance	Covers inpatient hospital, skilled nursing facility, hospice and certain home healthcare services. Reimbursement is a prospective payment with a single payment inclusive of all service, supplies, and drugs.
Part B Medical Insurance	Covers outpatient services, physician services and physician-administered drugs in the office and hospital outpatient settings.
Part C Medicare Advantage	Administered by managed care plans which are accountable for providing traditional Medicare services/benefits; however, they have flexibility to offer additional benefits
Part D Medicare Prescription Drug Coverage	Covers self-administered drugs through Part C or standalone Prescription Drug Plans administered by private organizations.

BECAUSE CYTALUX IS A HOSPITAL-ADMINISTERED PRODUCT, IT IS COVERED UNDER MEDICARE PART A.

Private Payers

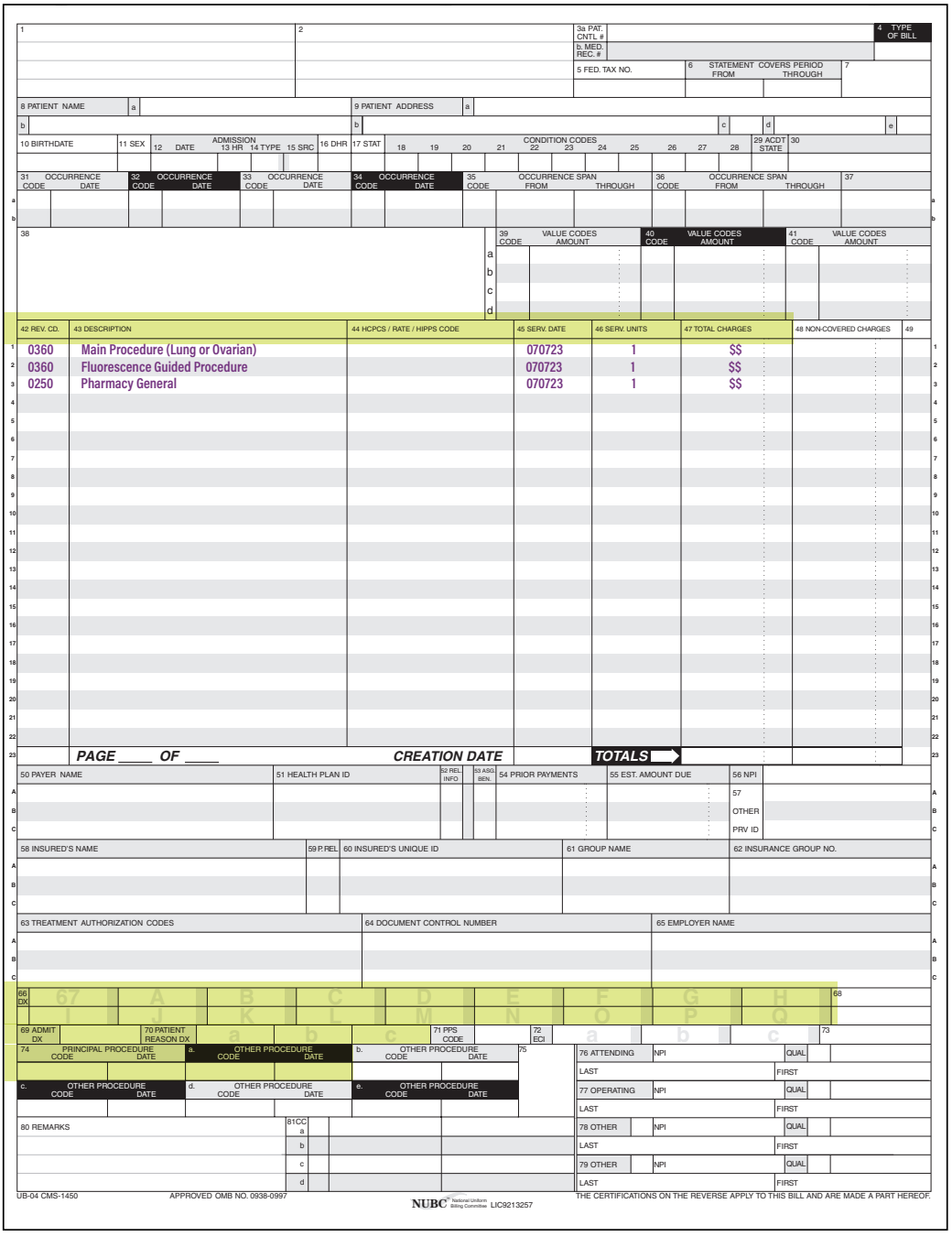
Each private payer plan administers its own benefits and determines specific coverage and payment policies. Some private payers may follow Medicare's coverage policies, while other private payers may have more restrictive or less restrictive benefits. Private payers will consider covering CYTALUX when used for its FDA-approved indication. They may implement restrictions, such as requiring prior authorization and/or other utilization controls. Reimbursement may also vary significantly by the specific contracts that are negotiated between the hospitals and private payers.

Medicaid

Most states have direct administration of the program and also contract with managed care organizations to administer the program. Medicaid programs and their MCOs may follow Medicare's coverage policies, while others may create their own coverage guidelines. Typically, Medicaid will consider covering CYTALUX when used for its FDA-approved indication. Some programs may implement restrictions, such as requiring prior authorization and/or other utilization controls.

Sample Claim Form: CMS-1450/UB-04

Form CMS-1450, also known as the UB-04, is the standard claim form to bill Medicare Administrative Contractors (MACs).



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0360	Main Procedure (Lung or Ovarian)		070723	1	$$	
0360	Fluorescence Guided Procedure		070723	1	$$	
0250	Pharmacy General		070723	1	$$	

FIELD 42
Enter the appropriate revenue code: 0360

FIELD 43
Enter the appropriate procedure description and Fluorescence Guided Procedure

Box 44
Enter appropriate CPT code and modifier

BOX 45
Date of Procedure

BOX 46
Enter number of units administered

BOX 47
Total Charges

FIELD 66
Identify the type of ICD diagnosis code used. Enter a "0" for ICD-10-CM

FIELD 67 AND 67A-67Q
Enter appropriate ICD-10-CM diagnosis
Note: Other diagnoses codes may apply

FIELDS 69-70
Admitting and reason diagnosis code

BOX 74
Main Procedure ICD 10 -PCS code and date

BOX 74A
Other Procedure Code & Date
Enter CYTALUX unique ICD-10-PCS procedure code and date

DISCLAIMER: CYTALUX Sample Claim Form CMS-1450/UB-04 is intended solely for use as a resource tool to assist hospital inpatient billing staff regarding reimbursement issues. Any determination about it and how to seek reimbursement should be made only by the inpatient staff and in consideration of the procedure performed or therapy provided to a specific patient. On Target Laboratories does not recommend or endorse the use of any particular diagnosis or procedure code(s) and makes no determination if or how reimbursement may be available. Of important note, reimbursement codes and payment as well as health policy/legislation are subject to continual change; information contained in this version of the CYTALUX Reimbursement Guide is current as of July 2023.

Important Safety Information

INDICATION AND USAGE

CYTALUX® is an FDA approved optical imaging agent indicated as an adjunct for intraoperative identification of:

- Malignant lesions in adult patients with ovarian cancer.
- Malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Adverse reactions including nausea, vomiting, abdominal pain, flushing, hypersensitivity, elevation in blood pressure, dyspepsia, and chest discomfort were reported in patients receiving CYTALUX in clinical studies. A total of 17% of patients experienced reactions during administration of CYTALUX. Reactions typically occurred within 15 minutes of the start of infusion. CYTALUX infusion interruption or discontinuation due to adverse reactions occurred in 11% of all patients. Treatment with antihistamines and/or anti-nausea medication may be used. If an adverse reaction occurs during administration, the infusion can be interrupted and resumed after treatment of the reaction.

Risk of Misinterpretation

Errors may occur with the use of CYTALUX during intraoperative fluorescence imaging to detect ovarian cancer and lesions in the lung, including false negatives and false positives. Non-fluorescing tissue in the surgical field does not rule out the presence of ovarian cancer or lesions in the lung. Fluorescence may be seen in normal tissues including bowel, kidneys, lymph nodes, lungs, and inflamed tissue.

Embryo-Fetal Toxicity

Based on its mechanism of action, CYTALUX may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the potential risk to a fetus. Verify pregnancy status of females of reproductive potential prior to initiating CYTALUX treatment.

Risk of Pafolacianine Aggregation and Infusion Reactions

Use of the incorrect diluent to prepare the CYTALUX infusion solution can cause the aggregation of pafolacianine; aggregation may induce infusion reactions such as nausea, vomiting, abdominal pain or rash. Use only 5% Dextrose Injection to prepare the CYTALUX infusion solution. Do not use other diluents.

DRUG INTERACTIONS

Use of folate, folic acid, or folate-containing supplements may reduce binding of pafolacianine to folate receptors and could reduce the detection of lesions with CYTALUX. Avoid administration of folate, folic acid, or folate-containing supplements within 48 hours before administration of CYTALUX.

ADVERSE REACTIONS

The safety of CYTALUX was evaluated in four open label clinical studies, two studies (N = 44 and N = 150) in patients with ovarian cancer and two studies (N = 100 and N = 112) in patients with known or suspected cancer in the lung. A total of 406 patients received 0.025 mg/kg of CYTALUX via intravenous administration. Adverse reactions that occurred in ≥ 1% of patients were: nausea (13%), vomiting (5%), abdominal pain (2%), flushing (2%), other infusion-related reactions (2%), hypersensitivity (2%), elevation in blood pressure (1%), dyspepsia (1%), and chest discomfort (1%). Adverse reactions occurred during the administration of CYTALUX in 17% of patients.

See full Prescribing Information to learn more.

cytalux®
(pafolacianine) injection

ONTARGET
LABORATORIES®