CYTALUX® New Technology Add-On Payment (NTAP) for Ovarian Cancer

cytalux® (pafolacianine) injection

What is NTAP?

NTAP stands for "New Technology Add-On Payment." It's 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.

Why was CYTALUX granted NTAP[1]?

CYTALUX was granted the NTAP by CMS because it meets the 3 criteria for eligibility below. CMS noted that:

- **Newness:** "CYTALUX is the only adjunct for intraoperative identification of malignant lesions in adults with ovarian cancer with a mechanism of action to target the folate receptor to illuminate cancerous lesions.
- **Cost:** The average standardized cost for cases involving CYTALUX "exceeded the average case-weighted threshold amount"
- **Substantial clinical improvement:** CYTALUX represents a substantial clinical improvement over existing technology because:
  - CYTALUX can detect ovarian cancer that is currently undetectable during surgery, which enables the surgeon to diagnose and treat additional cancer earlier and affects the management of the patient.
  - CYTALUX can identify additional ovarian cancer not otherwise planned for resection, leading to revisions in the surgical plan that result in more precise resection of the cancer.

[1]Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates.

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.

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

ICD-10-PCS Codes

8E0U0EN	Fluorescence guided procedure of female reproductive system using pafolacianine, open approach
8E0U3EN	Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous approach
8E0U4EN	Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous endoscopic approac
8E0U7EN	Fluorescence guided procedure of female reproductive system using pafolacianine, via natural or artificial opening

The information described here is intended solely for use as a resource tool to assist hospital inpatient billing staff regarding NTAP. 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. You are ultimately responsible for determining the appropriate reimbursement strategy and reimbursement codes.

CYTALUX Reimbursement Support

Contact Karen Warner, Head of Market Access at
1 (765) 269–4419 • reimbursement@ontargetlabs.com

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.