

## **POLICY Document for AVGEMSI**

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

### **Section 1: Clinical Criteria**

- Policy information specific to the clinical appropriateness for the medication

### **Section 2: Oncology Clinical Policy**

- Policy information specific to regimen review per NCCN Guidelines.

### **Section 1: Clinical Criteria**

# Medical Prior Authorization gemcitabine

## **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

<b>Brand Name</b>	<b>Generic Name</b>
Avgemsi	gemcitabine
gemcitabine (all other brands)	gemcitabine

## **Indications**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### **FDA-approved Indications<sup>1,2</sup>**

#### **Ovarian Cancer**

In combination with carboplatin for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy

## Breast Cancer

In combination with paclitaxel for the first-line treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated

## Non-Small Cell Lung Cancer

In combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) non-small cell lung cancer (NSCLC)

## Pancreatic Cancer

As first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas. Gemcitabine is indicated for patients previously treated with fluorouracil.

## Compendial Uses<sup>3-7</sup>

Ampullary adenocarcinoma

Bladder cancer, primary carcinoma of the urethra, upper genitourinary tract tumors, transitional cell carcinoma of the urinary tract, urothelial carcinoma of the prostate, non-urothelial and urothelial cancer with subtype histology

Bone cancer

Ewing sarcoma

Osteosarcoma

Breast cancer

Cervical cancer

Head and neck cancers (including very advanced head and neck cancer, cancer of the nasopharynx, occult primary and salivary gland tumors)

Biliary tract cancer

Extrahepatic cholangiocarcinoma

Intrahepatic cholangiocarcinoma

Gallbladder cancer

Hodgkin lymphoma

Classic Hodgkin lymphoma

Nodular lymphocyte-predominant Hodgkin lymphoma

Kidney cancer

Pleural or peritoneal mesothelioma

Non-small cell lung cancer (NSCLC)

Occult primary tumors (cancer of unknown primary)

Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer

Pancreatic adenocarcinoma

Small cell lung cancer (SCLC)

Soft tissue sarcoma

Testicular cancer

Thymomas and thymic carcinomas



Uterine neoplasms (including endometrial carcinoma, uterine sarcoma and uterine leiomyosarcoma)

Kaposi sarcoma

Primary cutaneous lymphomas

    Mycosis fungoides/Sezary syndrome

    Primary cutaneous CD30+ T-Cell lymphoproliferative disorders

T-Cell lymphomas

    Peripheral T-Cell lymphomas

    Adult T-Cell leukemia/lymphoma

    Breast implant-associated anaplastic large cell lymphoma

    Extranodal natural killer (NK)/T-Cell lymphoma

    Hepatosplenic T-Cell lymphoma

Gestational trophoblastic neoplasia

B-Cell lymphomas

    Histologic transformation of indolent lymphomas to diffuse large B-Cell lymphoma

    Mantle cell lymphoma

    Diffuse large B-Cell lymphoma

    High-Grade B-Cell lymphomas

    Burkitt lymphoma

    Human immunodeficiency virus (HIV)-Related B-Cell lymphomas

    Post-Transplant lymphoproliferative disorders

Small bowel adenocarcinoma

Malignant germ cell tumor

Vaginal cancer

Vulvar cancer

All other indications are considered experimental/investigational and not medically necessary.

## Coverage Criteria

### Pancreatic Adenocarcinoma<sup>1-4</sup>

Authorization of 6 months may be granted for treatment of pancreatic adenocarcinoma.

### Breast Cancer<sup>1-3</sup>

Authorization of 6 months may be granted for treatment of members with no response to preoperative systemic therapy, recurrent, or metastatic breast cancer.

### Biliary Tract Cancer<sup>3,4</sup>

Authorization of 6 months may be granted for treatment of biliary tract cancer (including intrahepatic and extrahepatic cholangiocarcinoma, and gallbladder cancer).

## Ampullary Adenocarcinoma<sup>4</sup>

Authorization of 6 months may be granted for treatment of ampullary adenocarcinoma.

## Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer<sup>1-3,5</sup>

Authorization of 6 months may be granted for treatment of advanced, persistent, or recurrent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential), mucinous carcinoma of the ovary, or malignant germ cell tumor.

## Non-Small Cell Lung Cancer (NSCLC)<sup>1-3</sup>

Authorization of 6 months may be granted for treatment of NSCLC.

## Cervical Cancer<sup>3,4,6</sup>

Authorization of 6 months may be granted for treatment of cervical cancer.

## Bladder Cancer, Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumors, Transitional Cell Carcinoma of the Urinary Tract, Urothelial Carcinoma of the Prostate, and Non-Urothelial and Urothelial Cancer with Variant Histology<sup>3,4,6</sup>

Authorization of 6 months may be granted for treatment of bladder cancer, primary carcinoma of the urethra, upper genitourinary tract tumors, transitional cell carcinoma of the urinary tract, urothelial carcinoma of the prostate, and non-urothelial and urothelial cancer with subtype histology.

## Small Cell Lung Cancer (SCLC)<sup>3,4</sup>

Authorization of 6 months may be granted for treatment of SCLC.

## Soft Tissue Sarcoma<sup>3,4</sup>

Authorization of 6 months may be granted for treatment of soft tissue sarcoma (including angiosarcoma, extremity/body wall, head/neck, retroperitoneal/intra-abdominal, rhabdomyosarcoma, solitary fibrous tumor, dedifferentiated chordoma, dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma, epithelioid hemangioendothelioma, and dermatofibrosarcoma protuberans (DFSP) with fibrosarcomatous transformation).

## **Bone Cancer<sup>3</sup>**

### **Ewing Sarcoma**

Authorization of 6 months may be granted for treatment of relapsed, progressive, or metastatic Ewing sarcoma.

### **Osteosarcoma**

Authorization of 6 months may be granted for treatment of relapsed/refractory or metastatic osteosarcoma.

## **Head and Neck Cancer<sup>3,4,6</sup>**

Authorization of 6 months may be granted for treatment of head and neck cancer (including very advanced head and neck cancer, cancer of the nasopharynx, occult primary, and salivary gland tumors).

## **Hodgkin Lymphoma<sup>3,4</sup>**

### **Hodgkin Lymphoma**

Authorization of 6 months may be granted for treatment of Hodgkin lymphoma including classic Hodgkin lymphoma and pediatric Hodgkin lymphoma.

### **Nodular Lymphocyte-Predominant Hodgkin Lymphoma**

Authorization of 6 months may be granted for treatment of progressive, relapsed, or refractory nodular lymphocyte-predominant Hodgkin lymphoma.

## **Kidney Cancer<sup>3,4</sup>**

Authorization of 6 months may be granted for treatment of relapsed or metastatic kidney cancer.

## **Pleural or Peritoneal Mesothelioma<sup>3,4</sup>**

Authorization of 6 months may be granted for treatment of pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma.

## **Occult Primary Tumors (cancer of unknown primary)<sup>3</sup>**

Authorization of 6 months may be granted for treatment of occult primary tumors.

## **Testicular Cancer<sup>3,4</sup>**

Authorization of 6 months may be granted for treatment of testicular cancer.

## **Thymomas and Thymic Carcinomas<sup>3</sup>**

Authorization of 6 months may be granted for treatment of thymomas and thymic carcinomas.

## Uterine Neoplasms<sup>3,4</sup>

Authorization of 6 months may be granted for treatment of uterine neoplasms (including endometrial carcinoma, uterine sarcoma and uterine leiomyosarcoma).

## Kaposi Sarcoma<sup>3</sup>

Authorization of 6 months may be granted for treatment of Kaposi sarcoma.

## Primary Cutaneous Lymphomas<sup>3</sup>

Authorization of 6 months may be granted for treatment of primary cutaneous lymphomas (including mycosis fungoides/Sezary syndrome and primary cutaneous CD30+ T-Cell lymphoproliferative disorders).

## T-Cell Lymphomas<sup>3,6</sup>

Authorization of 6 months may be granted for treatment of T-Cell lymphomas (including peripheral T-Cell lymphomas, adult T-Cell leukemia/lymphoma, hepatosplenic T-Cell lymphoma, breast implant-associated anaplastic large cell lymphoma, and extranodal NK/T-Cell lymphoma).

## Gestational Trophoblastic Neoplasia<sup>3</sup>

Authorization of 6 months may be granted for treatment of gestational trophoblastic neoplasia.

## B-Cell Lymphomas<sup>3-5</sup>

Authorization of 6 months may be granted for treatment of B-Cell lymphomas (including histologic transformation of indolent lymphomas to diffuse large B-Cell lymphoma, mantle cell lymphoma, diffuse large B-Cell lymphoma, high-grade B-Cell lymphomas, Burkitt lymphoma, HIV-Related B-Cell lymphomas, and post-transplant lymphoproliferative disorders).

## Small Bowel Adenocarcinoma<sup>3</sup>

Authorization of 6 months may be granted for treatment of small bowel adenocarcinoma.

## Malignant Germ Cell Tumor<sup>3,6,7</sup>

Authorization of 6 months may be granted for treatment of malignant germ cell tumor.

## Vaginal Cancer<sup>3</sup>

Authorization of 6 months may be granted for treatment of vaginal cancer when used as a single agent.

## Vulvar Cancer<sup>3</sup>

Authorization of 6 months may be granted for treatment of vulvar cancer as concurrent chemoradiation as a single agent or in combination with cisplatin.

# Continuation of Therapy

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## Section 2: Oncology Clinical Policy

### **PURPOSE**

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

### **SCOPE**

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

### Program Description

The National Comprehensive Care Network® (NCCN®) is a not-for profit alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness and efficiency of cancer care so patients can live better lives. It is comprised of oncology experts who convene regularly to establish the best treatments for patients.<sup>1</sup>

NCCN develops resources to support stakeholders in the health care delivery system including the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

The Guidelines offer broad, high-level, evidence-based recommendations for cancer management. The Compendium extracts the drug and biologic recommendations from the Guidelines detailing their use and level of evidence category. The Templates convert the drug regimens detailed in the Guidelines and Compendium into practical, standardized order sets for safe, clinical use.<sup>2,3</sup>

#### **NCCN Categories of Evidence and Consensus<sup>4</sup>**

- **Category 1:** Based upon high-level evidence, there is uniform (defined as ≥85% panel support) NCCN consensus that the intervention is appropriate.
- **Category 2A:** Based upon lower-level evidence, there is uniform (≥85% panel support) NCCN consensus that the intervention is appropriate.
- **Category 2B:** Based upon lower-level evidence, there is NCCN consensus (50% to <85% panel support) that the intervention is appropriate.
- **Category 3:** Based upon any level of evidence, there is major NCCN disagreement (less than 50% panel support, or at least three institutions opposing the recommendation) that the intervention is appropriate.

## Policy for Regimen Prior Authorization

Regimen prior authorization allows providers to submit a single request for all oncology drugs or biologics within an NCCN Template that require prior authorization. Regimen requests must be initiated through the provider portal. If submitted via phone or fax, each drug or biologic must be requested individually using drug-specific criteria.

Coverage is provided for a regimen request when all the following criteria are met. If all are not met, further review may be required:

1. The request is initiated through the provider portal.
2. The member is eligible for regimen review.
3. The request is for an oncology drug or biologic.
4. The requested regimen and indication align with an NCCN recommendation with a level of evidence category 1 or 2A.
5. The NCCN template is accepted by the provider without modification.
6. The indication is for a cancer type currently eligible for regimen review.
6. The indication is for a cancer type currently eligible for regimen review.
  1. Ampullary Adenocarcinoma
  2. Anal Carcinoma
  3. Appendiceal Neoplasms and Cancers
  4. Basal Cell Skin Cancer
  5. B-Cell Lymphomas
  6. Biliary Tract Cancers
  7. Bladder Cancer
  8. Bone Cancer
  9. Breast Cancer
  10. Castleman Disease
  11. Central Nervous System Cancers
  12. Cervical Cancer
  13. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
  14. Chronic Myeloid leukemia
  15. Colon Cancer
  16. Cutaneous Lymphomas
  17. Dermatofibrosarcoma Protuberans
  18. Esophageal Cancer
  19. Gastric Cancer
  20. Gastrointestinal Stromal Tumors
  21. Gestational Trophoblastic Neoplasms
  22. Hairy Cell Leukemia
  23. Head and Neck Cancers
  24. Hepatocellular Carcinoma
  25. Histiocytic Neoplasms
  26. Hodgkin Lymphoma
  27. Kaposi Sarcoma
  28. Kidney Cancer
  29. Melanoma: Cutaneous

30. Melanoma: Uveal
31. Merkel Cell Carcinoma
32. Mesothelioma: Peritoneal
33. Mesothelioma: Pleural
34. Multiple Myeloma
35. Myelodysplastic Syndromes
36. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
37. Myeloproliferative Neoplasms
38. Neuroendocrine and Adrenal Tumors
39. Non-Small Cell Lung Cancer
40. Occult Primary
41. Ovarian Cancer
42. Pancreatic Cancer
43. Penile Cancer
44. Prostate Cancer
  
45. Rectal Cancer
46. Small Bowel Adenocarcinoma
47. Small Cell Lung Cancer
48. Soft Tissue Sarcoma
49. Squamous Cell Skin Cancer
50. Systemic Light Chain Amyloidosis
51. Systemic Mastocytosis
52. T-Cell Lymphomas
53. Testicular Cancer
54. Thymomas and Thymic Carcinomas
55. Thyroid Carcinoma
56. Uterine Neoplasms
57. Vaginal Cancer
58. Vulvar Cancer
59. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
60. Wilms Tumor (Nephroblastoma)

## Supportive Care: Myeloid Growth Factor Therapy

Granulocyte colony stimulating factors (G-CSFs) are recommended for primary prophylaxis based on the febrile neutropenia (FN) risk of the chemotherapy regimen. The level of FN risk varies by NCCN Template and is indicated at the top of each template. Regimens classified as high or intermediate risk of FN may include a G-CSF as part of the prior authorization

## Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

## Duration of Approval



Authorizations may be granted for 12 months or as medically necessary, based on the member's condition and provider's clinical assessment.

## Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. If no specific template exists for the intended maintenance therapy, the selected template can be modified to include only the appropriate maintenance agents. The modified regimen request will be submitted for further review.

## **REFERENCES:**

### **SECTION 1**

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2. Avgemsi [package insert]. Switzerland: Avyxa Pharma, LLC; July 2025.
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4. Gemcitabine. Lexi-Drugs. UpToDate Lexidrug. UpToDate Inc. <https://online.lexi.com>. Accessed July 21, 2025.
5. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; <https://www.clinicalkey.com/pharmacology> [available with subscription]. Accessed July 21, 2025.
6. Micromedex Solutions [database online]. Ann Arbor, MI: Merative. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed July 21, 2025.
7. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Lung Cancer Clinical Programs. September 2021.

### **SECTION 2**

1. National Comprehensive Cancer Network. *About NCCN*. Available at: <https://www.nccn.org/home/about>. Accessed September 10, 2025.
2. National Comprehensive Cancer Network. *NCCN Guidelines*. Available at: [https://www.nccn.org/guidelines/category\\_1](https://www.nccn.org/guidelines/category_1). Accessed September 10, 2025. (*Note: An account may be required.*)
3. National Comprehensive Cancer Network. *NCCN Drugs and Biologics Compendium*. Available at: <https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia>. Accessed September 10, 2025. (*Note: A subscription may be required.*)
4. National Comprehensive Cancer Network. *NCCN Categories of Evidence and Consensus*. Available at: <https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines>. Accessed September 10, 2025.