Reference number(s)
6795-A

Specialty Guideline Management
Opdivo Qvantig

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.

Brand Name	Generic Name
Opdivo Qvantig	nivolumab and hyaluronidase-nvhy

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[1]

Advanced Renal Cell Carcinoma

- Opdivo Qvantig, as monotherapy, is indicated for the first-line treatment of adult patients with intermediate or poor risk advanced renal cell carcinoma (RCC) following treatment with intravenous nivolumab and ipilimumab combination therapy.
- Opdivo Qvantig, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced RCC.
- Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult patients with advanced RCC who have received prior anti-angiogenic therapy.

Unresectable or Metastatic Melanoma

- Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult and pediatric patients (12 years and older who weigh 30 kg or greater) with unresectable or metastatic melanoma.

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- Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult and pediatric patients (12 years and older who weigh 30 kg or greater) with unresectable or metastatic melanoma following treatment with intravenous nivolumab and ipilimumab combination therapy.

Adjuvant Treatment of Melanoma

Opdivo Qvantig, as monotherapy, is indicated for the adjuvant treatment of adult and pediatric patients (12 years and older who weigh 30 kg or greater) with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma.

Neoadjuvant Treatment of Resectable Non-Small Cell Lung Cancer

Opdivo Qvantig, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC).

Neoadjuvant and Adjuvant Treatment of Resectable Non-Small Cell Lung Cancer

Opdivo Qvantig, in combination with platinum-doublet chemotherapy, is indicated for the neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by Opdivo Qvantig as monotherapy in the adjuvant setting after surgical resection.

Metastatic Non-Small Cell Lung Cancer

Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo Qvantig.

Squamous Cell Carcinoma of the Head and Neck

Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.

Urothelial Carcinoma

- Opdivo Qvantig, as monotherapy, is indicated for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC.
- Opdivo Qvantig, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with unresectable or metastatic UC.
- Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult patients with locally advanced or metastatic UC who:
    - have disease progression during or following platinum-containing chemotherapy.
    - have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

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Microsatellite Instability-High or Mismatch Repair Deficient Metastatic Colorectal Cancer

- Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult and pediatric patients (12 years and older who weigh 30 kg or greater) with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) following treatment with intravenous nivolumab and ipilimumab combination therapy.
- Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult and pediatric patients (12 years and older who weigh 30 kg or greater) with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Hepatocellular Carcinoma

Opdivo Qvantig, as monotherapy, is indicated for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) following treatment with intravenous nivolumab and ipilimumab.

Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have been previously treated with sorafenib and following treatment with intravenous nivolumab and ipilimumab combination therapy.

Esophageal Carcinoma

- Opdivo Qvantig, as monotherapy, is indicated for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in adult patients who have received neoadjuvant chemoradiotherapy (CRT).
- Opdivo Qvantig, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).
- Opdivo Qvantig, as monotherapy, is indicated for the treatment of adult patients with unresectable advanced, recurrent or metastatic ESCC after prior fluoropyrimidine- and platinum-based chemotherapy.

Gastric Cancer, Gastroesophageal Junction Cancer, Esophageal Adenocarcinoma

Opdivo Qvantig, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the treatment of adult patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma whose tumors express PD-L1 (≥1).

Limitations of Use

Opdivo Qvantig is not indicated in combination with ipilimumab for the treatment of renal cell carcinoma, unresectable or metastatic melanoma, metastatic NSCLC, unresectable or metastatic MSI-H or dMMR CRC, unresectable or metastatic HCC, or unresectable advanced or metastatic ESCC.

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Compendial Uses[2]

Opdivo Qvantig may be substituted for intravenous nivolumab. Limitation of use: Opdivo Qvantig is not indicated in combination with ipilimumab.

- Renal cell carcinoma
- Melanoma
    - Cutaneous
    - Uveal
- Non-small cell lung cancer
- Head and neck cancers
- Urothelial carcinoma
    - Bladder cancer
    - Primary carcinoma of the urethra
    - Upper genitourinary tract tumors
    - Urothelial carcinoma of the prostate
- Colorectal cancer, including anal adenocarcinoma
- Appendiceal neoplasms and cancers
- Hepatocellular carcinoma
- Esophageal/Esophagogastric junction cancers
- Gastric cancer
- Anal carcinoma
- Merkel cell carcinoma
- Central Nervous System (CNS) brain metastases
- Gestational trophoblastic neoplasia
- Pleural mesothelioma
- Peritoneal mesothelioma
- Endometrial carcinoma
- Vulvar cancer
- Small cell lung cancer
- Cervical cancer
- Kaposi sarcoma
- Bone cancer
- Soft tissue sarcoma
    - Extremity/body wall sarcoma
    - Head/neck sarcoma
    - Retroperitoneal/intra-abdominal sarcoma
    - Rhabdomyosarcoma
    - Dedifferentiated liposarcoma
    - Epithelioid hemangioendothelioma
    - Angiosarcoma
- Anaplastic thyroid carcinoma
- Histologic (Richter) transformation to diffuse large B-cell lymphoma

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- Vaginal cancer
- Squamous cell skin carcinoma
- Ampullary adenocarcinoma
- Small bowel adenocarcinoma

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of laboratory report confirming microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.
- Documentation of the absence of EGFR exon 19 deletion and exon 21 L858R mutations, ALK, RET, and ROS1 gene fusions, where applicable.
- Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.
- Documentation of human epidermal growth factor receptor 2 (HER2) status, where applicable.

Exclusions

Coverage will not be provided for members who have experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy unless any of the following apply:

- The requested medication will be used for treatment of metastatic or unresectable melanoma.
- The requested medication will be used for treatment of hepatocellular carcinoma following progression on therapy with atezolizumab plus bevacizumab.

Coverage Criteria

Renal Cell Carcinoma[1,2]

Authorization of 6 months may be granted for treatment of renal cell carcinoma when any of the following criteria are met:

- The member has relapsed, advanced, or stage IV disease with clear cell histology and either of following are met:
  - The requested medication will be used as a single agent for subsequent therapy.
  - The requested medication will be used following treatment with intravenous nivolumab and ipilimumab as a single agent

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- The member has relapsed, advanced, or stage IV disease with non-clear cell histology and the requested medication will be used as a single agent.
- The requested medication will be used in combination with cabozantinib and either of the following are met:
    - The member has relapsed, advanced, or stage IV disease.
    - The member has non-clear cell histology including hereditary leiomyomatosis and renal cell cancer (HLRCC).

Melanoma[1,2]

Authorization of 6 months may be granted for treatment of melanoma (including cutaneous and uveal) when the requested medication will be used in any of the following settings:

- As a single agent for unresectable or metastatic disease.
- As a single agent for adjuvant treatment of stage IIB/IIC, stage III, local satellite/in-transit recurrence, resectable, or oligometastatic disease
- As a single agent as neoadjuvant treatment.

Non-Small Cell Lung Cancer (NSCLC)[1,2]

Authorization of 6 months may be granted for treatment of recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC) when both of the following criteria are met:

- There are no EGFR exon 19 deletions, exon 21 L858R mutations, or ALK, RET, or ROS1 gene fusions (unless testing is not feasible due to insufficient tissue).
- The requested medication will be used as single agent subsequent therapy.

Authorization of 3 months (for up to 4 cycles total) may be granted for neoadjuvant treatment of resectable NSCLC in combination with platinum based chemotherapy when there are no known EGFR exon 19 deletions, exon 21 L858R mutations, or ALK, RET, or ROS1 gene fusions (unless testing is not feasible due to insufficient tissue.

Authorization of 6 months may be granted for neoadjuvant and adjuvant treatment of resectable NSCLC when both of the following criteria are met:

- There are no EGFR exon 19 deletions, exon 21 L858R mutations, or ALK, RET, or ROS1 gene fusions (unless testing is not feasible due to insufficient tissue).
- The requested medication will be used in combination with platinum based chemotherapy (for up to 4 cycles total), followed by single agent adjuvant therapy (for up to 13 cycles).

Head and Neck Cancer[1,2]

Authorization of 6 months may be granted for treatment of head and neck cancers in members with either of the following:

- Non-nasopharyngeal very advanced head and neck cancer that is unresectable, recurrent, persistent, or metastatic, in combination with cetuximab or as a single agent.

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- Nasopharyngeal cancer in combination with cisplatin and gemcitabine for unresectable, recurrent, persistent, or metastatic disease.

Urothelial Carcinoma[1,2]

Authorization of 6 months may be granted in combination with gemcitabine and cisplatin for up to 6 cycles for first-line treatment of unresectable or metastatic urothelial carcinoma.

Authorization of 6 months may be granted as a single agent for treatment of urothelial carcinoma when any of the following conditions are met:

- The requested medication will be used to treat locally advanced or metastatic disease in members who:
  - have disease progression during or following platinum-containing chemotherapy.
  - have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- The requested medication will be used as adjuvant therapy in members who are at high risk of recurrence after undergoing radical resection.

Colorectal Cancer[1-3]

Authorization of 6 months may be granted for treatment of colorectal cancer, including anal adenocarcinoma, for microsatellite-instability high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb) when used as a single agent.

Appendiceal Neoplasms and Cancers[2]

Authorization of 6 months may be granted for treatment of appendiceal neoplasms and appendiceal cancers (including appendiceal adenocarcinoma, goblet cell adenocarcinoma, and undifferentiated carcinoma not otherwise specified) for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb) when used as a single agent.

Hepatocellular Carcinoma[1,2]

Authorization of 6 months may be granted as a single agent for treatment of unresectable or metastatic hepatocellular carcinoma.

Esophageal and Esophagogastric Junction Cancer[1,2]

Authorization of 6 months may be granted for treatment of esophageal or esophagogastric junction cancer in members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease for either of the following:

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- First-line therapy when PD-L1 ≥ in combination with chemotherapy.
- Subsequent therapy.

Authorization of 6 months may be granted for adjuvant treatment of completely resected esophageal or esophagogastric junction cancer with residual pathologic disease.

Authorization of 6 months may be granted as a single agent or in combination with chemotherapy for treatment of esophageal or esophagogastric junction cancer if tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Authorization of 6 months may be granted for induction therapy for relieving dysphagia in combination with chemotherapy for members with esophageal or esophagogastric junction squamous cell carcinoma with PD-L1 ≥ 1 planned for esophagectomy.

Gastric Cancer[1,2]

Authorization of 6 months may be granted for treatment of gastric adenocarcinoma in any of the following settings:

- When the requested medication will be used as first-line therapy in combination with chemotherapy for members who are not surgical candidates or have unresectable, recurrent, or metastatic disease that is HER2 negative and PD-L1 ≥ 1.
- When the requested medication will be used as a single agent or in combination with chemotherapy for treatment of gastric adenocarcinoma if tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Anal Carcinoma[2]

Authorization of 6 months may be granted for treatment of anal carcinoma and either of the following are met:

- Member has inguinal node recurrent or metastatic disease when used in combination with paclitaxel and carboplatin.
- Member has metastatic disease when used as a single agent for subsequent therapy.

Merkel Cell Carcinoma[2]

Authorization of 6 months may be granted for treatment of Merkel cell carcinoma in any of the following settings:

- Metastatic disease.
- In-transit, locally advanced or regional disease when used as a single agent.
- Unresectable, recurrent, regional, in-transit, or stage IV disease when used as a single agent following treatment with intravenous nivolumab and ipilimumab.

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Central Nervous System (CNS) Brain Metastases[2]

Authorization of 6 months may be granted for treatment of CNS brain metastases when either of the following criteria are met:

- The requested medication will be used as a single agent in members with BRAF non-specific melanoma.
- The requested medication will be used as a single agent in members with PD-L1 positive non-small cell lung cancer.

Gestational Trophoblastic Neoplasia[2]

Authorization of 6 months may be granted as a single agent for treatment of multiagent chemotherapy-resistant gestational trophoblastic neoplasia when either of the following criteria is met:

- Member has recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor).
- Member has high-risk disease.

Pleural or Peritoneal Mesothelioma[2]

Authorization of 6 months may be granted for the subsequent treatment of pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma, as a single agent.

Endometrial Carcinoma[2]

Authorization of 6 months may be granted as a single agent for subsequent treatment of recurrent unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) endometrial carcinoma.

Vulvar Cancer[2]

Authorization of 6 months may be granted for subsequent treatment of HPV-related advanced or recurrent/metastatic vulvar cancer as a single agent.

Small Cell Lung Cancer[2]

Authorization of 6 months may be granted for subsequent treatment of relapsed or progressive small cell lung cancer as a single agent.

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Cervical Cancer[2]

Authorization of 6 months may be granted for subsequent treatment of cervical cancer when one of the following criteria is met:

- The requested medication will be used as a single agent and member has recurrent or metastatic PD-L1 positive (combined positive score [CPS] ≥1) disease.
- The requested medication will be used as a single agent following treatment with intravenous nivolumab and ipilimumab and either of the following is met:
  - Disease is recurrent or metastatic.
  - Disease is persistent small cell neuroendocrine carcinoma of the cervix (NECC).

Kaposi Sarcoma[2]

Authorization of 6 months may be granted as a single agent for subsequent treatment of relapsed/refractory advanced Kaposi Sarcoma.

Bone Cancer[2]

Authorization of 6 months may be granted as a single agent or in combination with sunitinib for dedifferentiated chondrosarcoma.

Soft Tissue Sarcoma[2]

Authorization of 6 months may be granted for treatment of soft tissue sarcoma in the following settings:

- The requested medication will be used as a single agent for treatment of extremity/body wall sarcomas, head/neck sarcomas, retroperitoneal/intra-abdominal sarcomas, and dedifferentiated liposarcoma.
- The requested medication will be used as a single agent for treatment of borderline/malignant phyllodes tumor of the breast, pleomorphic rhabdomyosarcoma, and epithelioid hemangioendothelioma that is tumor mutational burden-high (TMB-H) [≥10 mut/Mb].
- The requested medication will be used as a single agent for the treatment of angiosarcoma following treatment with intravenous nivolumab and ipilimumab.

Anaplastic Thyroid Carcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of stage IVC anaplastic thyroid carcinoma.

Histologic (Richter) Transformation to Diffuse Large B-cell Lymphoma[2]

Authorization of 6 months may be granted for treatment of Histologic (Richter) transformation to diffuse large B-cell lymphoma as a single agent or in combination ibrutinib.

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Vaginal Cancer[2]

Authorization of 6 months may be granted as subsequent therapy for recurrent or metastatic vaginal cancer when the requested medication will be used as a single agent.

Squamous Cell Skin Carcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of squamous cell skin carcinoma and either of the following is met:

- Disease is locally advanced, recurrent, unresectable, inoperable, or incompletely resected that is not curable by surgery or radiation.
- Disease is metastatic.

Ampullary Adenocarcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of progressive or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) ampullary adenocarcinoma following treatment with intravenous nivolumab and ipilimumab.

Small Bowel Adenocarcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of unresectable, medically inoperable, advanced, or metastatic small bowel adenocarcinoma for microsatellite-instability high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Authorization of 6 months may be granted as a single agent for neoadjuvant treatment of small bowel adenocarcinoma for microsatellite-instability high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Continuation of Therapy

Adjuvant Treatment of Melanoma

Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization for melanoma who have not experienced disease recurrence or unacceptable toxicity.

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Urothelial Carcinoma

Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization for adjuvant treatment of urothelial carcinoma who have not experienced disease recurrence or unacceptable toxicity.

Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for first line treatment of urothelial carcinoma when the requested medication is used in combination with gemcitabine and cisplatin for up to 6 cycles followed by single agent maintenance therapy when the member has not experienced disease progression or unacceptable toxicity.

Non-Small Cell Lung Cancer

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for metastatic non-small cell lung cancer (NSCLC) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Authorization of 3 months of therapy total (up to 4 cycles total) may be granted for neoadjuvant treatment of resectable NSCLC when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Authorization of 6 months may be granted for neoadjuvant followed by adjuvant treatment of resectable NSCLC (up to 4 cycles in combination with chemotherapy, followed by single agent adjuvant treatment up to 13 cycles) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Renal Cell Carcinoma

Authorization of 6 months may be granted (up to 24 months total when used in combination with cabozantinib) for continued treatment in members requesting reauthorization for renal cell carcinoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Esophageal, Esophagogastric Junction, and Gastric Cancer

Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for esophageal squamous cell carcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for esophageal, esophagogastric junction, and gastric cancer when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant treatment of resected esophageal or gastroesophageal junction cancer will be limited to 12 months total therapy.

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Squamous Cell Skin Carcinoma[2]

Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for squamous cell skin carcinoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

All Other Indications

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

References

1. Opdivo Qvantig [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2025.
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3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 1.2026. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf Accessed March 4, 2026.

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