Opdualag™
(nivolumab and relatlimab-rmbw)
Injection for intravenous use | 480 mg/160 mg

Bristol Myers Squibb®
Access Support®

A REFERENCE GUIDE TO

Reimbursement and Coding OPDUALAG™

(nivolumab and relatlimab-rmbw)

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend nivolumab and relatlimab-rmbw (OPDUALAG™) as a NCCN Category 1, preferred first-line systemic therapy option for metastatic or unresectable melanoma[23]

Please see Important Safety Information on pages 19–21 and U.S. Full Prescribing Information.

For reimbursement assistance, call BMS Access Support® at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday, or visit **www.BMSAccessSupport.com**.

BMS Access Support is dedicated to helping patients access their prescribed BMS medications

This brochure is designed to help appropriate patients get access to our medications by providing helpful reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that oncology offices verify each patient's insurance coverage prior to initiating therapy.

Table of Contents

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices.
The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Indication

OPDUALAG is indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

Dosage and Administration for OPDUALAG

The recommended dosage of OPDUALAG in unresectable or metastatic melanoma is provided in the following table:

Recommended dosing for OPDUALAG in adult and pediatric patients 12 years of age or older weighing at least 40 kg[1]

Recommended Dose and Schedule	Duration of Therapy
480 mg nivolumab and 160 mg relatlimab every 4 weeks (30-minute intravenous infusion)	Until disease progression or unacceptable toxicity

The recommended dosage for pediatric patients 12 years of age or older who weigh less than 40 kg has not been established.

Please refer to section Section 2, Dosage and Administration, in the Full Prescribing Information for additional dosing information.

Select Important Safety Information

SUMMARY OF WARNINGS AND PRECAUTIONS

OPDUALAG (nivolumab and relatlimab-rmbw) is associated with the following Warnings and Precautions: severe and fatal immune-mediated adverse reactions (IMARs); infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); and embryo-fetal toxicity.

- Immune-Mediated Adverse Reactions (IMARs): Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune mediated hepatitis, immune-mediated endocrinopathies, immune-mediated nephritis with renal dysfunction, immune-mediated dermatologic adverse reactions, and immune-mediated myocarditis. Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. Withhold or permanently discontinue OPDUALAG based on severity and type of reaction.
- Infusion-related Reactions: Interrupt, slow the rate of infusion, or permanently discontinue OPDUALAG based on severity of reaction.
- Complications of Allogeneic HSCT: Fatal and other serious complications can occur in patient who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody.
- Embryo-fetal toxicity: OPDUALAG can cause fetal harm. Advise females of reproductive potential of potential risk to a fetus and to use effective contraception.

Authorized Distributors

OPDUALAG can only be purchased through authorized distributors for administration in physician offices, hospital outpatient facilities, institutions, Veterans Affairs, and the Department of Defense. The following distributors are authorized to sell OPDUALAG and are able to service qualified accounts.

Authorized Distributor Network
Physician Offices*
Cardinal Health Specialty Pharmaceutical Distribution Phone: 1-877-453-3972, Monday–Friday, 7:00 AM–6:00 PM CT (24-hour emergency on call) https://specialtyonline.cardinalheath.com
CuraScript Specialty Distribution Phone: 1-877-599-7748, Monday–Friday, 8:00 AM–7:00 PM ET • https://www.curascriptsd.com
HyGen Pharmaceuticals Specialty Division Phone: 877-630-9198 • https://www.hygenpharma.com/#contactus
McKesson Specialty Health Phone: 1-800-482-6700, Monday–Friday, 7:00 AM–7:00 PM CT • https://mscs.mckesson.com
Morris & Dickson Specialty Phone: 1-800-710-6100, Monday–Friday, 8:00 AM–6:00 PM CT • Fax: 1-318-524-3096 http://www.mdspecialtydist.com
Oncology Supply Phone: 1-800-633-7555, Monday–Friday, 8:00 AM–7:00 PM CT • https://www.oncologysupply.com
Hospitals and Infusion Centers
ASD Healthcare Phone: 1-800-746-6273, Monday–Thursday, 7:00 AM–6:30 PM CT; Friday, 7:00 AM–6:00 PM CT • Fax: 1-800-547-9413 https://www.asdhealthcare.com
Cardinal Health Specialty Pharmaceutical Distribution Phone: 1-866-677-4844, Monday–Friday, 7:00 AM–6:00 PM CT (24-hour emergency) • Fax: 1-614-553-6301 https://orderexpress.cardinalhealth.com
DMS Pharmaceutical Group, Inc. Phone: 1-877-788-1100, Monday–Friday, 8:30 AM–5:00 PM CT • Fax: 1-847-518-1105 • www.dmspharma.com
HyGen Pharmaceuticals Specialty Division Phone: 877-630-9198 • https://www.hygenpharma.com/#contactus
McKesson Plasma and Biologics Phone: 1-877-625-2566, Monday–Friday, 8:00 AM–6:30 PM CT • Fax: 1-888-752-7626 • https://connect.mckesson.com
Morris & Dickson Specialty Phone: 1-800-710-6100 • Fax: 1-318-524-3096 • https://www.mdspecialtydist.com

*For offices that prefer to use the services of a specialty pharmacy, specialty pharmacies can obtain OPDUALAG from the distributors listed under Physician Offices.

Above information is accurate as of 02/24.

The OPDUALAG distribution program includes extended payment terms to Bristol Myers Squibb–authorized OPDUALAG distributors. Healthcare providers and institutions should contact their OPDUALAG distributor to understand specific payment terms that may be available to them from their distributor.

National Drug Code (NDC) Information and Storage for OPDUALAG™ (nivolumab and relatlimab-rmbw)

The NDC for OPDUALAG, listed below, is often necessary in addition to the appropriate J code when filing a claim for reimbursement.

NDC for OPDUALAG[1]

OPDUALAG
240 mg nivolumab and 80 mg relatlimab/20 mL in a single-dose vial (12 mg nivolumab and 4 mg relatlimab/1 mL)

0003-7125-11

Storage[1]

Store OPDUALAG under refrigeration at 2 °C to 8 °C (36 °F to 46 °F). Protect from light by storing in the original package until time of use. Do not freeze or shake.

5010 Electronic Transaction Coding for OPDUALAG™

- For electronic transactions, including 837P and 837I, the 11-digit NDC is to be preceded by the qualifier N4 for payers that require it[2]
- This is typically followed by the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or ML (milliliter), and the quantity administered[2]

5010 Transaction Coding for OPDUALAG[1,2]

How Supplied	NDC	NDC Qualifier	NDC Basis of Measurement	Sample NDC 5010 Format
240 mg nivolumab and 80 mg relatlimab/20 mL in a single-dose vial	00003-7125-11	N4	ML	N400003712511ML40

The example given in the far-right column demonstrates NDC quantity reporting for 2 vials of OPDUALAG. The actual amount of drug used can vary based on factors such as patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format.

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

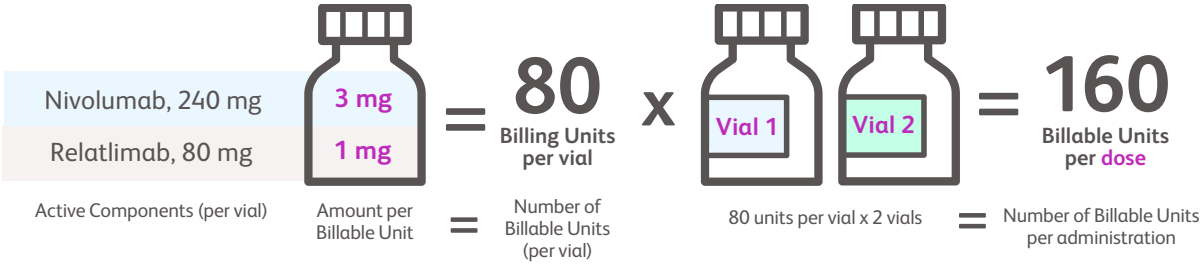
Healthcare Common Procedure Coding System (HCPCS) and Revenue Codes for OPDUALAG™ (nivolumab and relatlimab-rmbw)

Recommended HCPCS Code for OPDUALAG[3]

HCPCS Code	Description	Billing Units
J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	80 units per vial

OPDUALAG J Code Billing Unit Conversion

1 Billing Unit = 3 mg nivolumab/1 mg relatlimab



The information contained herein is not intended to provide specific coding and reimbursement advice for any specific patient or situation. You should check with your coding specialist to ensure appropriate submissions.

Use the following claim formats when OPDUALAG is administered to patients on an outpatient basis and billed to health plans:

- Physician office: CMS-1500 (paper format) or ASC 837P (electronic format)
- Hospital outpatient: UB-04 (CMS-1450) [paper format] or ASC 837I (electronic format)

All the coding information presented is applicable to outpatient procedures only. Please see pages 8-9 for more information.

Revenue Codes[4] (for Use in the Hospital Outpatient Setting)

Revenue Code	Description
0636	Drugs requiring detailed coding
0260	IV therapy
0335	Chemotherapy administration, IV

Revenue codes categorize services in the hospital by revenue center. Medicare and most Medicaid and private payer claims must include revenue codes in field 42 of form UB-04 (CMS-1450).

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Current Procedural Terminology (CPT)* Codes for OPDUALAG™ (nivolumab and relatlimab-rmbw)

CPT codes are used to indicate which medical services and procedures were performed on a patient and/or how a drug or medical supply was administered.

The CPT codes that may be appropriate for administration of OPDUALAG appear in the table below.

CPT Code for OPDUALAG[5]	
CPT Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

Please contact the payer or BMS Access Support® for additional coding information regarding OPDUALAG.

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Sample Claim Form for Physician Office Administration of OPDUALAG™ (nivolumab and relatlimab-rmbw)

Sample Claim Form

Physician Office

(claim form **CMS 1500**/electronic equivalent 837P)[2]

1 **ITEM 19**
Enter the drug name, total dosage, and method of administration

This section gives healthcare providers guidance for submitting claims for the administration of OPDUALAG™ (nivolumab and relatlimab-rmbw) in the physician office

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
OPDUALAG TTL dose: 480 mg nivolumab/160 mg relatlimab per 40 mL IV physician-admin

2 **LINE ITEM 24A[1,2]**
Shaded area above the drug line item
Enter the appropriate 11-digit National Drug Code (NDC) for OPDUALAG preceded by NDC qualifier N4 (eg, N400003712511ML40)

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
N400003712511ML40												
XX	XX	XX	XX	XX	XX	XX		J9298		X	XXXXX XX	160

NOTE: Fields with an "X" are required.

3 **LINE ITEM 24D[2,3,8,9]**
Procedures, Services, or Supplies
Enter the applicable HCPCS/CPT codes and modifiers for the encounter

4 **LINE ITEM 24G[2]**
Days or Units
Enter the billing units associated with each line item
When billing OPDUALAG (J9298):
1 billing unit equals 3 mg nivolumab/1 mg relatlimab (eg, Enter 160 units per J9298 to denote 2 single-use vials administered)

This sample form is for informational purposes only.

A claim for OPDUALAG should include the following:

- A proper HCPCS code to define the drug and billing unit
- The quantity of billing units provided to the patient
- A CPT code that indicates how the physician administered the drug

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Sample Claim Form for Hospital Outpatient Administration of OPDUALAG™ (nivolumab and relatlimab-rmbw)

1

FIELD LOCATOR 42[8-10]
Revenue Codes
Enter the 4-digit revenue codes (in ascending order) for services provided
- For chemotherapy administration, 0260 (IV therapy) or 0335 (chemotherapy-IV) could be used[1]
- CMS recommends using 0636 (drugs requiring detailed coding)[3]

2

FIELD LOCATOR 43[1,8]
Revenue Description
Enter the modifier "N4" followed by the 11-digit NDC in positions 01-13. For example, use "N400003712511ML40" for two 20-mL vials[2,6]

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
	N400003712511ML40					
0636	Drugs requiring detailed coding (brand)	J9298	XXXXXX	160	XXXXXXXXX XX	

NOTE: Fields with an "X" are required

3

FIELD LOCATOR 44[3,8,10]
HCPCS
Enter HCPCs code (J9298) and code for the outpatient services (and modifier[s]), if applicable

4

FIELD LOCATOR 46[8]
Units of Service
Enter the billing units associated with each line item
1 billing unit equals 3 mg nivolumab/1 mg relatlimab (eg, Enter 160 units per J9298 to denote 2 single-use vials administered)

This sample form is for informational purposes only.

*The number of units required may vary from payer to payer.

UB-04 is used for reimbursement of OPDUALAG administered in an institutional setting, such as a hospital, a clinic, or an ambulatory surgical center.[8] Providers must submit a UB-04 claim form documenting the drug administered and associated services.

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

ICD-10-CM Diagnosis Codes[11]

ICD-10-CM diagnosis codes are used to identify a patient's diagnosis.

- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters

The ICD-10-CM diagnosis codes for the labeled indications for OPDUALAG are provided on the following pages by Bristol Myers Squibb and should be verified with the payer. Some health plan and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call BMS Access Support® at **1-800-861-0048** or visit **www.BMSAccessSupport.com**.

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

ICD-10-CM Diagnosis Codes for OPDUALAG™ (nivolumab and relatlimab-rmbw)

ICD-10-CM Diagnosis Codes for Unresectable or Metastatic Melanoma[11]	
C43 Malignant melanoma of skin	
C43.0	Malignant melanoma of lip
C43.1*	Malignant melanoma of eyelid, including canthus
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11*	Malignant melanoma of right eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.12*	Malignant melanoma of left eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.2*	Malignant melanoma of ear and external auricular canal
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below the category code.

(more C43 codes on the next page)

The code C43 has an Excludes 2 note under it. Per **ICD-10-CM** official guidelines, an Excludes 2 note under a code represents "Not included here." An Excludes 2 note indicates that the condition excluded is not part of the condition represented by the code, but a patient may have both conditions at the same time. When an Excludes 2 note appears under a code, it is acceptable to use both the code and the excluded code together, when appropriate.[11]

Under code C43, the Excludes 2 note lists the following[11]:

- Malignant melanoma of skin of genital organs (C51-C52, C60.-, C63.-)
- Merkel cell carcinoma (C4A.-)
- Sites other than skin – code to malignant neoplasm of the site

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

ICD-10-CM Diagnosis Codes for OPDUALAG™ (nivolumab and relatlimab-rmbw) (cont'd)

ICD-10-CM Diagnosis Codes for Unresectable or Metastatic Melanoma[11]	
C43.3*	Malignant melanoma of other and unspecified parts of face
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.5*	Malignant melanoma of trunk
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.6*	Malignant melanoma of upper limb, including shoulder
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.7*	Malignant melanoma of lower limb, including hip
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below the category code.

(continued on next page)

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

ICD-10-CM Diagnosis Codes for OPDUALAG™ (nivolumab and relatlimab-rmbw) (cont'd)

For sites other than category C43, code to the malignant neoplasm of the site.[6] Some sites where melanoma is commonly seen are shown here and on page 14.

ICD-10-CM Diagnosis Codes for Unresectable or Metastatic Melanoma[11]	
C21 Malignant neoplasm of anus and anal canal	
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C51 Malignant neoplasm of vulva	
C51.0	Malignant neoplasm of labium majus
C51.1	Malignant neoplasm of labium minus
C51.2	Malignant neoplasm of clitoris
C51.9	Malignant neoplasm of vulva, unspecified
C52 Malignant neoplasm of vagina	
C57 Malignant neoplasm of other and unspecified female genital organs	
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C60 Malignant neoplasm of penis	
C60.0	Malignant neoplasm of prepuce
C60.1	Malignant neoplasm of glans penis
C60.8	Malignant neoplasm of overlapping sites of penis
C60.9	Malignant neoplasm of penis, unspecified

(continued on next page)

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

ICD-10-CM Diagnosis Codes for OPDUALAG™ (nivolumab and relatlimab-rmbw) (cont'd)

ICD-10-CM Diagnosis Codes for Unresectable or Metastatic Melanoma[11]	
C63 Malignant neoplasm of other and unspecified male genital organs	
C63.0*	Malignant neoplasm of epididymis
C63.00	Malignant neoplasm of unspecified epididymis
C63.01	Malignant neoplasm of right epididymis
C63.02	Malignant neoplasm of left epididymis
C63.1*	Malignant neoplasm of spermatic cord
C63.10	Malignant neoplasm of unspecified spermatic cord
C63.11	Malignant neoplasm of right spermatic cord
C63.12	Malignant neoplasm of left spermatic cord
C63.2	Malignant neoplasm of scrotum
C63.7	Malignant neoplasm of other specified male genital organs
C63.8	Malignant neoplasm of overlapping sites of male genital organs
C63.9	Malignant neoplasm of male genital organ, unspecified

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below the category code.

Note: If infusion for antineoplastic immunotherapy is the only reason for the patient encounter, physicians and hospitals may report the code below as the primary diagnosis[11]:

Z51.12	Encounter for antineoplastic immunotherapy

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Medicare Drug Reimbursement for OPDUALAG™ (nivolumab and relatlimab-rmbw)

What is the Medicare reimbursement allowable for OPDUALAG?

Physicians*

- The payment limit is 106% of average sales price (ASP), not including sequestration, and represents the amount per billable unit, 3 mg nivolumab/1 mg relatlimab[11,12†]
- The amount paid to physicians for OPDUALAG HCPCS code J9298 is published at the beginning of each calendar quarter in "Payment Allowance Limits for Medicare Part B Drugs,"[12] which can be downloaded at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice
- Medicare Part B will pay physicians 80% of the allowed price for OPDUALAG HCPCS code J9298 the patient is responsible for 20% co-insurance, which may be covered by secondary insurance (private supplemental coverage, Medicaid, etc)[13]

Hospital outpatient facilities*

Drugs paid separately under the hospital outpatient fee schedule are based on 106% of ASP, not including sequestration, for one billing unit for the corresponding HCPCS code.

- The Payment Allowance Limits[12] are published each quarter at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice

Hospital inpatient settings

- Reimbursement in the inpatient setting is bundled into the Medicare Diagnosis Related Groups called MS-DRGs[14,15]
- This prospective rate changes on October 1 each year and does not allow for drugs to be paid separately[16,17]

* While the statutory amount that Medicare will reimburse for a Part B Drug in a physician office will remain at ASP +6%, sequestration has resulted in a reduction to the Medicare portion of the payment to Medicare providers. Essentially, all payments from Medicare carriers to the providers (including physician offices, hospitals, etc) will be reduced by 2%.[18]

† See the Centers for Medicare & Medicaid Services' (CMS) Internet Only Manual (IOM) Publication 100-04, Chapter 17-20.1.3.

Commercial Insurance Reimbursement for OPDUALAG™ (nivolumab and relatlimab-rmbw)

Physicians

- Drug reimbursement, like service reimbursement, is usually based on a fee schedule[19]
- The fee schedules are based on the ASP or average wholesale price (AWP), as published by a credible source,[20,21] or an average costing methodology as determined by the payer, such as usual, customary, and reasonable (UC&R)[22]

Hospital outpatient facilities

- In this setting, reimbursement is most commonly based on percentage of charges[21]
- Alternatively, some hospitals use the same ASP or AWP methodologies typically used by physician offices[21]
- Other methodologies include capitated model, cost minus submitted charges, or discount off submitted charges[21]

Hospital inpatient settings

- Inpatient rates are prospective, meaning they are predetermined per discharge[14]
- There are private payers that pay on a version of the DRGs[15]
- There are also payers that pay on a negotiated and fixed rate per day called a "per diem."[15] There are capitated rates for inpatients as well[15]
- New drugs may be carved out of per diems or capitated rates, if the hospital negotiates to do so[22]

Bristol Myers Squibb (BMS) Oncology Reimbursement Support & Co-Pay Assistance Program

BMS Access Support® is committed to helping appropriate patients get access to our medications by providing access and reimbursement support services

BMS supports access to certain BMS Oncology products through the BMS Oncology Co-Pay Assistance Program. The program provides financial assistance with the out-of-pocket deductibles, co-pay, or co-insurance costs for eligible commercially insured patients who have been prescribed certain BMS Oncology products.

How Does This Program Work?	
Enrolled patients pay as little as $0 per product	**Bristol Myers Squibb will cover** the remaining amount up to a maximum of $25,000 per year, per patient, per product

Other restrictions apply. Final determination of Program eligibility is based on review of a completed application. Please see full Terms and Conditions on page 18.

Please note: The Program will cover the out-of-pocket expenses of a BMS product only. It does not cover the costs of any other healthcare provider charges, or any other treatment costs. Patients may be responsible for non-drug-related out-of-pocket costs, depending on their specific healthcare benefits.

BMS Access Support® Co-Pay Assistance Program Terms & Conditions

[Program only available for EMPLICITI® (elotuzumab), OPDIVO® (nivolumab), OPDIVO® (nivolumab) + YERVOY® (ipilimumab), OPDUALAG™ (nivolumab and relatlimab–rmbw), & YERVOY® (ipilimumab)]

The BMS Co-Pay Assistance Program is designed to assist eligible commercially insured patients who have been prescribed select BMS medications with out-of-pocket deductibles, co-pays, or co-insurance requirements.

Patient Eligibility:

- Patients must have commercial insurance, but their coverage does not cover the full cost of their prescribed Bristol Myers Squibb (BMS) medication. Co-pay assistance is not valid where the entire cost of the medication is reimbursed by insurance.
- Patients are not eligible if they participate in any state or federal healthcare program including Medicaid, Medicare, Medigap, CHAMPVA, TriCare, Veterans Affairs (VA), or Department of Defense (DoD), or any state, patient, or pharmaceutical assistance program. Patients who move from commercial insurance to a state or federal healthcare program will no longer be eligible.
- Cash-paying patients are not eligible for co-pay assistance.
- Patients or their guardian must be 18 years of age or older.
- Patients must live in the United States or Puerto Rico.

Program Benefits:

- For eligible commercially insured patients, the patient may pay as little as $0 per infusion.
- This Program will cover the co-pay for each dose of a BMS medication, up to a maximum of $25,000 per BMS medication during a calendar year.
- Patients are responsible for any costs that exceed the Program's maximum of $25,000 per BMS Medication.
- In order to receive the Program benefits, the patient or provider must submit an Explanation of Benefits (EOB) form or a Remittance Advice (RA). The submitted form must include the name of the insurer, plan information, and show that the BMS medication supported by this Program was the medication that was given. The form must be submitted within 180 days of the date the claim was processed.
- The Program may apply retroactively to out-of-pocket expenses that occurred within 180 days prior to the date of the enrollment. These benefits are subject to the 12-month Program maximum of $25,000 per medication.
- The Program benefits are limited to the co-pay costs for BMS medications covered by this Program that the patient receives as an outpatient. The Program will not cover and shall not be applied toward the cost of any dosing procedure, any other healthcare provider service, supply charges or other treatment costs, or any costs associated with a hospital stay.
- All Program payments are for the benefit of the patient only.

Program Timing:

- The enrollment period is 1 calendar year

Additional Terms and Conditions of Program:

- Patients, pharmacists, and healthcare providers must not seek reimbursement from health insurance or any third party for any part of the benefits received by the patient through this Program. Patients must not seek reimbursement from any health savings, flexible spending, or other healthcare reimbursement accounts for the amount of assistance received from the Program.
- Acceptance of this offer confirms that this offer is consistent with patient's insurance. Patients, pharmacists, and healthcare providers must report the receipt of co-pay assistance benefits as may be required by patient's insurance provider.
- The Program benefits are not transferable and is limited to one (1) per patient, per medication. This offer cannot be combined with any other offer, rebate, coupon or free trial.
- Only valid in the United States and Puerto Rico; this offer is void where prohibited by law, taxed, or restricted.
- The Program benefits are nontransferable.
- No membership fees.
- This Program is not conditioned on any past, present, or future purchase, including additional doses.
- **The Program is Not Insurance.**
- Bristol Myers Squibb reserves the right to rescind, revoke, or amend this offer at any time without notice.

Important Safety Information for OPDUALAG™ (nivolumab and relatlimab-rmbw)

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions (IMARs) listed herein may not include all possible severe and fatal immune-mediated adverse reactions.

IMARs which may be severe or fatal, can occur in any organ system or tissue. IMARs can occur at any time after starting treatment with a LAG-3 and PD-1/PD-L1 blocking antibodies. While IMARs usually manifest during treatment, they can also occur after discontinuation of OPDUALAG. Early identification and management of IMARs are essential to ensure safe use. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying IMARs. Evaluate clinical chemistries including liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected IMARs, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue OPDUALAG depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information). In general, if OPDUALAG requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose IMARs are not controlled with corticosteroid therapy. Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (e.g., endocrinopathies and dermatologic reactions) are discussed below.

Immune-Mediated Pneumonitis

OPDUALAG can cause immune-mediated pneumonitis, which may be fatal. In patients treated with other PD-1/PD-L1 blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.7% (13/355) of patients receiving OPDUALAG, including Grade 3 (0.6%), and Grade 2 (2.3%) adverse reactions. Pneumonitis led to permanent discontinuation of OPDUALAG in 0.8% and withholding of OPDUALAG in 1.4% of patients.

Immune-Mediated Colitis

OPDUALAG can cause immune-mediated colitis, defined as requiring use of corticosteroids and no clear alternate etiology. A common symptom included in the definition of colitis was diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated diarrhea or colitis occurred in 7% (24/355) of patients receiving OPDUALAG, including Grade 3 (1.1%) and Grade 2 (4.5%) adverse reactions. Colitis led to permanent discontinuation of OPDUALAG in 2% and withholding of OPDUALAG in 2.8% of patients.

Immune-Mediated Hepatitis

OPDUALAG can cause immune-mediated hepatitis, defined as requiring the use of corticosteroids and no clear alternate etiology.

Immune-mediated hepatitis occurred in 6% (20/355) of patients receiving OPDUALAG, including Grade 4 (0.6%), Grade 3 (3.4%), and Grade 2 (1.4%) adverse reactions. Hepatitis led to permanent discontinuation of OPDUALAG in 1.7% and withholding of OPDUALAG in 2.3% of patients.

Immune-Mediated Endocrinopathies

OPDUALAG can cause primary or secondary adrenal insufficiency, hypophysitis, thyroid disorders, and Type 1 diabetes mellitus, which can be present with diabetic ketoacidosis. Withhold or permanently discontinue OPDUALAG depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information).

For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. In patients receiving OPDUALAG, adrenal insufficiency occurred in 4.2% (15/355) of patients receiving OPDUALAG, including Grade 3 (1.4%) and Grade 2 (2.5%) adverse reactions. Adrenal insufficiency led to permanent discontinuation of OPDUALAG in 1.1% and withholding of OPDUALAG in 0.8% of patients.

(continued on next page)

Important Safety Information for OPDUALAG™ (nivolumab and relatlimab-rmbw) (cont'd)

Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism; initiate hormone replacement as clinically indicated. Hypophysitis occurred in 2.5% (9/355) of patients receiving OPDUALAG, including Grade 3 (0.3%) and Grade 2 (1.4%) adverse reactions. Hypophysitis led to permanent discontinuation of OPDUALAG in 0.3% and withholding of OPDUALAG in 0.6% of patients.

Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism; initiate hormone replacement or medical management as clinically indicated. Thyroiditis occurred in 2.8% (10/355) of patients receiving OPDUALAG, including Grade 2 (1.1%) adverse reactions. Thyroiditis did not lead to permanent discontinuation of OPDUALAG. Thyroiditis led to withholding of OPDUALAG in 0.3% of patients. Hyperthyroidism occurred in 6% (22/355) of patients receiving OPDUALAG, including Grade 2 (1.4%) adverse reactions. Hyperthyroidism did not lead to permanent discontinuation of OPDUALAG. Hyperthyroidism led to withholding of OPDUALAG in 0.3% of patients. Hypothyroidism occurred in 17% (59/355) of patients receiving OPDUALAG, including Grade 2 (11%) adverse reactions. Hypothyroidism led to the permanent discontinuation of OPDUALAG in 0.3% and withholding of OPDUALAG in 2.5% of patients.

Monitor patients for hyperglycemia or other signs and symptoms of diabetes; initiate treatment with insulin as clinically indicated. Diabetes occurred in 0.3% (1/355) of patients receiving OPDUALAG, a Grade 3 (0.3%) adverse reaction, and no cases of diabetic ketoacidosis. Diabetes did not lead to the permanent discontinuation or withholding of OPDUALAG in any patient.

Immune-Mediated Nephritis with Renal Dysfunction

OPDUALAG can cause immune-mediated nephritis, which is defined as requiring use of steroids and no clear etiology. In patients receiving OPDUALAG, immune-mediated nephritis and renal dysfunction occurred in 2% (7/355) of patients, including Grade 3 (1.1%) and Grade 2 (0.8%) adverse reactions. Immune-mediated nephritis and renal dysfunction led to permanent discontinuation of OPDUALAG in 0.8% and withholding of OPDUALAG in 0.6% of patients.

Withhold or permanently discontinue OPDUALAG depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information).

Immune-Mediated Dermatologic Adverse Reactions

OPDUALAG can cause immune-mediated rash or dermatitis, defined as requiring use of steroids and no clear alternate etiology. Exfoliative dermatitis, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and Drug Rash with eosinophilia and systemic symptoms has occurred with PD-1/L-1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes.

Withhold or permanently discontinue OPDUALAG depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information).

Immune-mediated rash occurred in 9% (33/355) of patients, including Grade 3 (0.6%) and Grade 2 (3.4%) adverse reactions. Immune-mediated rash did not lead to permanent discontinuation of OPDUALAG. Immune-mediated rash led to withholding of OPDUALAG in 1.4% of patients.

Immune-Mediated Myocarditis

OPDUALAG can cause immune-mediated myocarditis, which is defined as requiring use of steroids and no clear alternate etiology. The diagnosis of immune-mediated myocarditis requires a high index of suspicion. Patients with cardiac or cardio-pulmonary symptoms should be assessed for potential myocarditis. If myocarditis is suspected, withhold dose, promptly initiate high dose steroids (prednisone or methylprednisolone 1 to 2 mg/kg/day) and promptly arrange cardiology consultation with diagnostic workup. If clinically confirmed, permanently discontinue OPDUALAG for Grade 2–4 myocarditis.

Myocarditis occurred in 1.7% (6/355) of patients receiving OPDUALAG, including Grade 3 (0.6%), and Grade 2 (1.1%) adverse reactions. Myocarditis led to permanent discontinuation of OPDUALAG in 1.7% of patients.

Other Immune-Mediated Adverse Reactions

The following clinically significant IMARs occurred at an incidence of <1% (unless otherwise noted) in patients who received OPDUALAG or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions: *Cardiac/Vascular:* pericarditis, vasculitis; *Nervous System:* meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia

(continued on next page)

Important Safety Information for OPDUALAG™ (nivolumab and relatlimab-rmbw) (cont'd)

gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy; *Ocular:* uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other IMARs, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss; *Gastrointestinal:* pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis; *Musculoskeletal and Connective Tissue:* myositis/polymyositis, rhabdomyolysis (and associated sequelae including renal failure), arthritis, polymyalgia rheumatica; *Endocrine:* hypoparathyroidism; *Other (Hematologic/Immune):* hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

OPDUALAG can cause severe infusion-related reactions. Discontinue OPDUALAG in patients with severe or life-threatening infusion-related reactions. Interrupt or slow the rate of infusion in patients with mild to moderate infusion-related reactions. In patients who received OPDUALAG as a 60-minute intravenous infusion, infusion-related reactions occurred in 7% (23/355) of patients.

Complications of Allogenic Hematopoietic Stem Cell Transplantation (HSCT)

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1 receptor blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1 receptor blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on its mechanism of action and data from animal studies, OPDUALAG can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with OPDUALAG for at least 5 months after the last dose of OPDUALAG.

Lactation

There are no data on the presence of OPDUALAG in human milk, the effects on the breastfed child, or the effect on milk production. Because nivolumab and relatlimab may be excreted in human milk and because of the potential for serious adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with OPDUALAG and for at least 5 months after the last dose.

Serious Adverse Reactions

In Relativity-047, fatal adverse reactions occurred in 3 (0.8%) patients who were treated with OPDUALAG; these included hemophagocytic lymphohistiocytosis, acute edema of the lung, and pneumonitis. Serious adverse reactions occurred in 36% of patients treated with OPDUALAG. The most frequent serious adverse reactions reported in ≥1% of patients treated with OPDUALAG were adrenal insufficiency (1.4%), anemia (1.4%), colitis (1.4%), pneumonia (1.4%), acute myocardial infarction (1.1%), back pain (1.1%), diarrhea (1.1%), myocarditis (1.1%), and pneumonitis (1.1%).

Common Adverse Reactions and Laboratory Abnormalities

The most common adverse reactions reported in ≥20% of the patients treated with OPDUALAG were musculoskeletal pain (45%), fatigue (39%), rash (28%), pruritus (25%), and diarrhea (24%).

The most common laboratory abnormalities that occurred in ≥20% of patients treated with OPDUALAG were decreased hemoglobin (37%), decreased lymphocytes (32%), increased AST (30%), increased ALT (26%), and decreased sodium (24%).

References

1. OPDUALAG [package insert draft]. Princeton, NJ: Bristol-Myers Squibb Company. March 2022.
2. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26 – Completing and Processing Form CMS-1500 Data Set. Revision 4388. September 6, 2019. Accessed August 11, 2022. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf.
3. American Medical Association. 2022 HCPCS Level II. Professional ed. Chicago, IL: American Medical Association; 2022.
4. National Uniform Billing Committee (NUBC). *Official UB-04 Data Specifications Manual 2020*. Chicago, IL: American Hospital Association; 2020.
5. American Medical Association. *CPT Professional 2020*. Professional ed. Chicago, IL: American Medical Association; 2020.
6. American Medical Association. Current Procedural Terminology 2022. Professional ed. Chicago, IL: \American Medical Association; 2022.
7. Centers for Medicare & Medicaid Services. MLN Matters, Number MM9603 Revised. Revised June 10, 2016. Accessed December 14, 2023. https://www.cms.gov/Outreach-and-Education/ Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf
8. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25 – Completing and Processing the Form CMS-1450 Data Set. Revision 4194, January 11, 2019. Accessed December 14, 2023. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf
9. Noridian Healthcare Solutions. Revenue codes. September 2016. Accessed December 14, 2023. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes
10. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17 – Drugs and Biologicals. Revision 4384, August 30, 2019. Accessed December 14, 2023. https://www.cms.gov/ Regulations-and-Guidance/Guidance/Manuals/downloads/clm 104c17.pdf
11. American Medical Association. *2022 ICD-10-CM: The Complete Official Codebook*. Chicago, IL: American Medical Association; 2022.
12. Centers for Medicare & Medicaid Services. Payment allowance limits for Medicare Part B drugs. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files. Accessed September 17, 2020.
13. Centers for Medicare & Medicaid Services. CMS Medicare FFS Provider e-news. March 8, 2013. Accessed November 7, 2021. https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf.
14. Centers for Medicare & Medicaid Services. Acute inpatient PPS. Accessed November 7, 2021. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/acuteinpatientpps.
15. AMCP Task Force on Drug Payment Methodologies. AMCP Guide to Pharmaceutical Payment Methods, Executive Edition. *J Manag Care Pharm*. 2007;13(8 suppl C):S1-S39.
16. Centers for Medicare & Medicaid Services. Drug coverage under different parts of Medicare. https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf. Accessed September 17, 2020.
17. CMS.gov. MS-DRG Classifications and Software. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software. Accessed July 22, 2020.
18. Robinson JC. Insurers' strategies for managing the use and cost of biopharmaceuticals. *Health Aff (Millwood)*. 2006;25(5):1205-1217.
19. American Society of Clinical Oncology. Payment reform glossary. ASCO website. https://www.asco.org/sites/new-www.asco.org/files/content-files/blog-release/pdf/Payment-Reform-Glossary.pdf. Accessed October 10, 2019.
20. Magellan Rx Management. Medical Pharmacy Trend Report 2016. http://www.magellanrxinsights.com. Accessed March 13, 2020.
21. US Bureau of Labor Statistics. Definitions of health insurance terms. Accessed November 8, 2021. http://www.bls.gov/ncs/ebs/sp/healthterms.pdf.
22. Academy of Managed Care Pharmacy. Managed care glossary. AMCP website. Accessed November 8, 2021. https://www.amcp.org/about/managed-care-pharmacy-101/managed-care-glossary.
23. Referenced with permission from The NCCN* Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Melanoma: Cutaneous Version 2. 2024.© National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed February 12, 2024. To view the most recent and complete versions of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

*NCCN = National Comprehensive Cancer Network® (NCCN®)

Bristol Myers Squibb®

Access Support®

Looking for support? We're here for you.

Patient access support, reimbursement resources, and financial support options may be available through **BMS Access Support®**

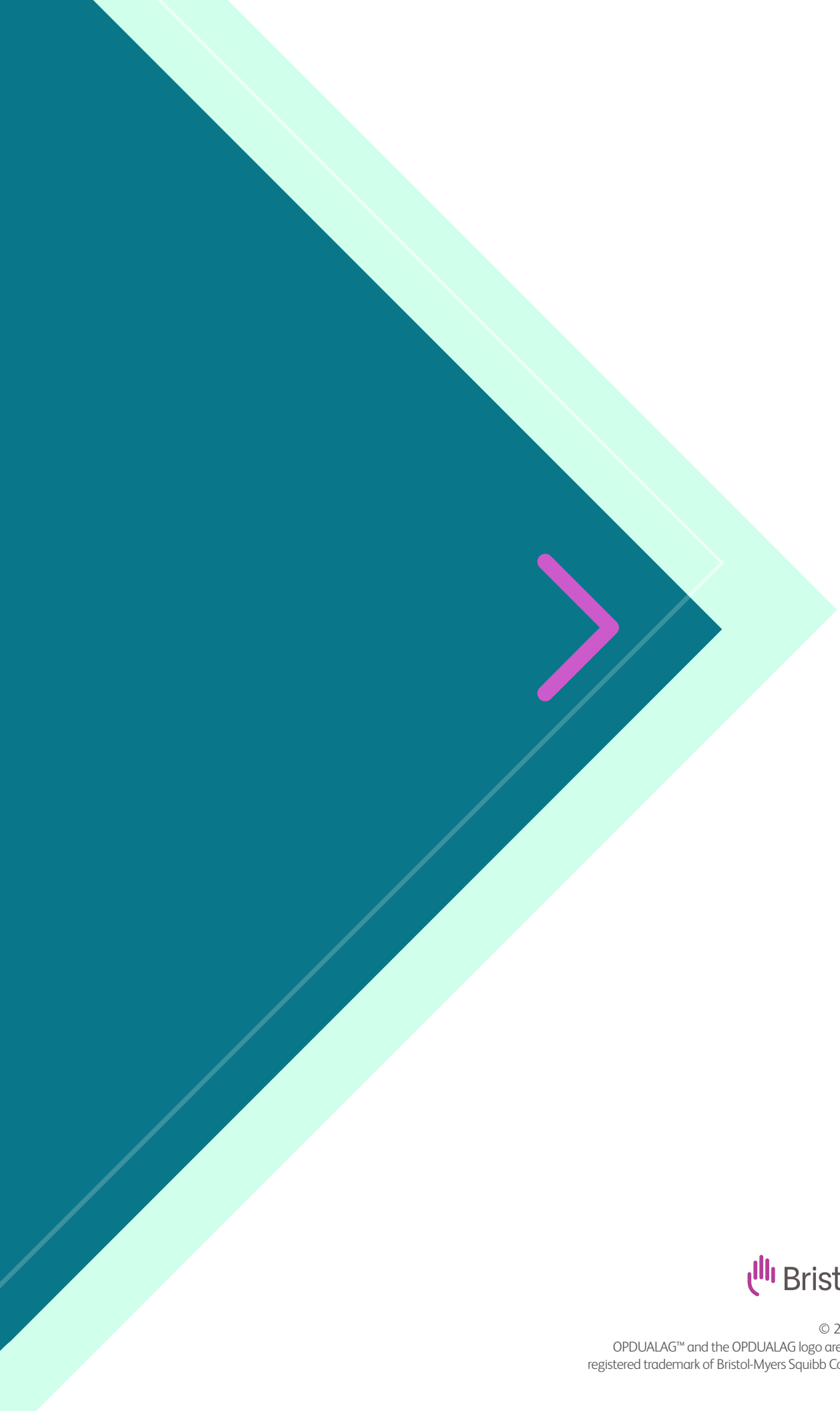
Call a Patient Access Specialist at **1-800-861-0048**, 8 AM to 8 PM ET, Monday - Friday

Visit **www.BMSAccessSupport.com**

Schedule a meeting with a BMS Access and Reimbursement Manager on the BMS Access Support website

Bristol Myers Squibb is committed to helping appropriate patients get access to our medications by providing access and reimbursement support services.

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.



Bristol Myers Squibb®