Voydeya® (danicopan) 50mg·100mg tablets

# How to access VOYDEYA® (danicopan)

## INDICATION

VOYDEYA is indicated as an add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).

Limitation of Use:

VOYDEYA has not been shown to be effective as monotherapy and should only be prescribed as an add-on to ravulizumab or eculizumab.

## IMPORTANT SAFETY INFORMATION

**WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA**

**VOYDEYA, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B [*see Warnings and Precautions (5.1)*]. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.**

- **Complete or update vaccination for encapsulated bacteria specifically, *Neisseria meningitidis* and *Streptococcus pneumoniae* at least 2 weeks prior to the first dose of VOYDEYA, unless the risks of delaying therapy with VOYDEYA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor. See *Warnings and Precautions (5.1)* for additional guidance on the management of the risk of serious infections caused by encapsulated bacteria.**
- **Patients receiving VOYDEYA are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

**Because of the risk of serious infections caused by encapsulated bacteria, VOYDEYA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the VOYDEYA REMS [*see Warnings and Precautions (5.2)*].**

**Please see additional Important Safety Information on pages 16-18 and full Prescribing Information for VOYDEYA (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.**

ALEXION® AstraZeneca Rare Disease

# About this guide

Alexion is committed to providing access and educational support to HCPs and their offices for patients who have been prescribed VOYDEYA.

This guide is intended to provide helpful information for navigating the VOYDEYA access process, including benefit investigations, PAs, appeals and denials (if required), and common reauthorization requirements.

Onco360, Alexion OneSource™, and Alexion FRMs are all available to provide educational support throughout this process. Please refer to pages 10-12 of this guide for more information about these services.

## OneSource and Onco360 are your partners for VOYDEYA access

ONESOURCE® Personalized Patient Support from Alexion

Onco360® ONCOLOGY PHARMACY

**Encourage your patients to enroll in OneSource, a complimentary, personalized patient support program**

Enrollment in OneSource enables:

- Insurance coverage support (benefit verification, appeals, and more)
- Product and disease state education
- Participation in the OneSource CoPay Program and additional programs for eligible patients
- FRMs/OneSource Support Specialist to provide ongoing case-specific support

Eligible patients can enroll in OneSource by completing a OneSource Patient Enrollment Form at AlexionOneSource.com or calling OneSource directly at 1-888-765-4747.

**VOYDEYA will be available through Onco360, the sole specialty pharmacy** that also provides ongoing support, including:

- Insurance benefit verification (coverage support, appeals, and more)
- Expert medication counseling for patients and caregivers
- Digital capabilities, including refill reminders, text messaging, and a mobile application
- Dedicated VOYDEYA support team for patients, caregivers, and prescribers

***This guide is for educational purposes only and does not guarantee patient access to VOYDEYA.***

**FRM,** Field Reimbursement Manager; **HCP,** healthcare provider; **PA,** prior authorization.

# Starting patients on VOYDEYA

Before initiating treatment with VOYDEYA, HCPs must confirm that the patient has been diagnosed with PNH and is currently being treated with ULTOMIRIS® (ravulizumab-cwvz) or SOLIRIS® (eculizumab) and is experiencing EVH. VOYDEYA is to be used as an add-on therapy to ULTOMIRIS or SOLIRIS.[1] Certain laboratory tests related to EVH should be documented before prescribing, as they may be required by a patient's insurance company as part of the PA process.

The recommended starting dose of VOYDEYA is 150 mg 3 times a day administered orally, with or without food. VOYDEYA doses should be taken around the same time every day. Patients may be titrated up to 200 mg 3 times a day if the patient's hemoglobin level has not increased by greater than 2 g/dL after 4 weeks of therapy, if the patient required a transfusion during the previous 4 weeks, or to achieve an appropriate hemoglobin response based on clinical assessment.[1]

## 150 mg dose 3 times a day




Not actual size.

***150 mg carton***

**NDC:** 25682-046-92

## 200 mg dose 3 times a day




Not actual size.

***200 mg carton***

**NDC:** 25682-043-92

The bottles and carton for VOYDEYA should be stored at room temperature between 15°C and 30°C (59°F and 86°F).

**EVH,** extravascular hemolysis; **HCP,** healthcare provider; **NDC,** National Drug Code; **PA,** prior authorization; **PNH,** paroxysmal nocturnal hemoglobinuria.

**Please see additional Important Safety Information on pages 16-18 and full Prescribing Information for VOYDEYA (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.**

# REMS certification

**Please note that prescribers must be enrolled in REMS and be REMS certified in order to be eligible to prescribe VOYDEYA.** VOYDEYA is available only through a restricted program under a REMS, which can be viewed online at www.VoydeyaREMS.com.

A prescriber, clinical pharmacist, registered nurse, or physician assistant can complete this process and will need a prescriber's NPI number for the REMS requirements.

## Notable requirements of the VOYDEYA REMS include the following:

- ☑ Prescribers must enroll in the REMS
- ☑ Prescribers must counsel patients about the risk of serious infections caused by encapsulated bacteria
- ☑ Prescribers must provide patients with the REMS educational materials
- ☑ Prescribers must assess patient vaccination status for vaccines against encapsulated bacteria and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of VOYDEYA
- ☑ Prescribers must provide a prescription for antibacterial drug prophylaxis if treatment must be started urgently, and the patient is not up to date with vaccines against encapsulated bacteria according to current ACIP recommendations at least two weeks prior to the first dose of VOYDEYA
- ☑ Pharmacies that dispense VOYDEYA must be certified in the VOYDEYA REMS and must verify prescribers are certified
- ☑ Patients must receive counseling from the prescriber about the need to receive vaccinations against encapsulated bacteria per ACIP recommendations, the need to take antibiotics as directed by the prescriber, and the early signs and symptoms of serious infections
- ☑ Patients must be instructed to carry the Patient Safety Card with them at all times during treatment and for 1 week following the last dose of VOYDEYA

**Further information is available by telephone: 1-888-765-4747 or online at www.VoydeyaREMS.com.**



**Prescriber certification consists of reviewing REMS educational materials and enrolling in VOYDEYA REMS. Information about the VOYDEYA REMS program can be viewed online at www.VoydeyaREMS.com.**

**ACIP,** Advisory Committee on Immunization Practices; **NPI,** National Provider Identifier; **REMS,** Risk Evaluation and Mitigation Strategy.

# VOYDEYA access process overview

**Please note that prescribers must be enrolled in REMS and be REMS certified in order to be eligible to prescribe VOYDEYA.** VOYDEYA is available only through a restricted program under a REMS, which can be viewed online at www.VoydeyaREMS.com.

## 1 VOYDEYA is prescribed

### Prescribers send the completed and signed VOYDEYA Prescription Form directly to Onco360

**Phone:**
1-877-662-6633

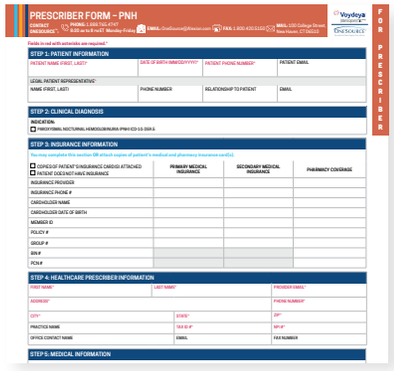
**Fax:**
1-877-662-6355

**e-Prescribe:**
NPI# 1679618151

### Encourage your patients to enroll in OneSource™, which enables:

- Your patient to access the complimentary, personalized patient support program, which includes disease state education, treatment education, and adherence support
- FRMs to provide case-specific educational support to HCPs and their offices
- Participation in the OneSource CoPay Program and additional financial assistance programs for eligible patients

Eligible patients can enroll by completing a OneSource Patient Enrollment Form online or by calling OneSource directly at 1-888-765-4747.


PRESCRIBER FORM – PNH

STEP 1: PATIENT INFORMATION

STEP 2: CLINICAL DIAGNOSIS

STEP 3: INSURANCE INFORMATION

STEP 4: HEALTHCARE PRESCRIBER INFORMATION

STEP 5: MEDICAL INFORMATION

**Note:** The VOYDEYA Prescription Form is part of the VOYDEYA Prescriber and Patient Enrollment Form.

**FRM,** Field Reimbursement Manager; **HCP,** healthcare provider; **NPI,** National Provider Identifier; **REMS,** Risk Evaluation and Mitigation Strategy.

**Please see additional Important Safety Information on pages 16-18 and full Prescribing Information for VOYDEYA (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.**

# VOYDEYA access process overview

## 2 Benefit investigation

### The benefit investigation is conducted by Onco360

Once a completed and valid VOYDEYA prescription is provided, Onco360 will conduct a benefit investigation.

Health plans can have different requirements,[2] so it is important to understand and complete the benefit investigation for the key coverage criteria that apply to each patient. The benefit investigation will provide you with information regarding a patient's health plan coverage and requirements,[3] including:

- **PA requirements and specific documentation that must be submitted to obtain approval** (eg, laboratory results that may be required)
- **Any additional health plan requirements or guidelines**
- **Specific reauthorization criteria and time frame for continuation of therapy**

**PA,** prior authorization.

# VOYDEYA access process overview

## 3 PA

Health plans often require a PA (also referred to as *precertification* or *coverage determination*) for use of VOYDEYA as an add-on therapy to ULTOMIRIS or SOLIRIS for the treatment of EVH in adult patients with PNH. PAs are common for orphan drugs that treat rare diseases.[4]

Requirements vary by plan. **Please verify the requirements for VOYDEYA for EVH in adult patients with PNH for each individual plan through the benefit investigation.** For OneSource™-enrolled patients, FRMs can provide patient-/case-specific PA and reauthorization criteria education and support based on the patient's insurance coverage.

### Compile the PA requirements

- ☑ Review the health plan's coverage requirements, obtained during the benefit investigation
- ☑ Gather all the requested information to submit to the health plan
- ☑ Ensure that the information is accurate and complete prior to submission

**Onco360 will coordinate with you and your office to ensure documentation required for the PA is completed and included prior to submission to the health plan.**

### Submit all PA information

- ☑ Submit the requested PA information through the appropriate health plan process, and provide current office contact information with your submission

**Once the PA has been submitted, Onco360 will confirm receipt and periodically check the PA status with the health plan. Payer response time will vary by health plan.**

**EVH,** extravascular hemolysis; **FRM,** Field Reimbursement Manager; **PA,** prior authorization; **PNH,** paroxysmal nocturnal hemoglobinuria.

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# VOYDEYA access process overview

## 4 PA approval

### PA approved

If a PA is approved, Onco360 will coordinate shipment with the patient. Onco360 will also verify a patient's out-of-pocket financial responsibilities.

### PA denied

If a PA is denied, you will need to determine the reason and the best course of action. Refer to "Navigating the official denial and appeal process" below for additional information.

**For patients enrolled in OneSource™:**

- The FRM can provide educational support to HCPs and their offices to navigate the denial and appeal process
- OneSource can communicate with your patient to educate them on their role in the process

**For all patients:**

- Onco360 can facilitate coordination for the denial response

## Navigating the official denial and appeal process

### Obtain the official denial letter and determine the denial reason

- Review the denial letter and summary of benefits to determine the specific denial reason

### Determine the best course of action

- Potential options include resubmitting the PA, requesting a peer-to-peer review, or submitting an appeal

### Be mindful of timelines and specific health plan requirements

- Review the health plan's appeal process and timelines to determine specific requirements to appeal the decision

### Follow up

- Onco360 will follow up with your office and the patient's health plan to provide assistance throughout the appeal resubmission process and appeal decision

Additional resources for HCPs and their offices include Sample Letter of Appeal **and Sample Letter of Medical Necessity templates** for VOYDEYA. These resources can be found at AlexionAccessNavigator.com/VOYDEYA.

**FRM,** Field Reimbursement Manager; **HCP,** healthcare provider; **PA,** prior authorization.

# VOYDEYA access process overview

## 5 Reauthorization

Patients may need a reauthorization to confirm that a therapy continues to be medically necessary and that they have responded to it.

Information about reauthorization criteria, timing, and requirements can be found in a patient's coverage policy. The process and specific requirements for requesting reauthorization will vary depending on the patient's health plan, the PBM benefits, or the coverage policy.

**Information needed for reauthorizations may include:**

- Plan-specific requirements
- Baseline measurements
- Supporting documentation
- Ongoing treatment rationale
- Patient outcomes

For OneSource™-enrolled patients, your FRM and a OneSource Support Specialist can provide educational support around the reauthorization process. Onco360 is also available to provide support for all patients—regardless of OneSource enrollment status.

**FRM,** Field Reimbursement Manager; **PBM,** pharmacy benefit manager.

# VOYDEYA access resources

## Onco360 is available to provide support and assistance for HCPs and office staff

Onco360, the sole specialty pharmacy for VOYDEYA, is committed to providing a high degree of communication and coordination with physicians and their offices to ensure a seamless experience.

### The team at Onco360 can:

- ☑ Submit a claim to evaluate potential coverage considerations for VOYDEYA; if issues are identified, a more in-depth investigation may be undertaken
- ☑ Provide support to prescribers and their offices during the PA process; this includes obtaining information about the PA criteria from the patient's health plan and addressing requirements that arise during coverage evaluation
- ☑ Educate patients and caregivers on their insurance coverage and out-of-pocket costs, as well as all available financial assistance options
- ☑ Confirm with the prescriber that the patient's vaccination requirements have been met prior to shipping VOYDEYA
- ☑ Provide support if a denial is received
- ☑ Arrange drug shipment to the patient upon payer approval
- ☑ Follow up regularly with patients on VOYDEYA, via MTM calls, and schedule refills for VOYDEYA
- ☑ Provide support to prescribers and their offices for reauthorizations, including understanding health plan requirements for ongoing care with VOYDEYA

**Onco360**

| **Call:** | **Fax:** | **Website:** | **OncoMed Dba Onco360 or e-Prescribe:** |
|---|---|---|---|
| 1-877-662-6633 | 1-877-662-6355 | Onco360.com | NPI# 1679618151 |

**HCP,** healthcare provider; **MTM,** medication therapy management; **NPI,** National Provider Identifier; **PA,** prior authorization.

**Please see additional Important Safety Information on pages 16-18 and full Prescribing Information for VOYDEYA (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.**

# VOYDEYA access resources

## Alexion OneSource™

ONESOURCE® Personalized Patient Support from Alexion

OneSource is a complimentary, personalized patient support program offered by Alexion. The program is available to enrolled adult patients receiving treatment for EVH associated with PNH.

## OneSource services

### Education

**Our team of specialists can provide your patients with:**

- Educational materials about their condition
- Details about their Alexion treatment and the treatment process

### Access and financial support

- Providing your patients with information that explains the insurance coverage for their prescribed Alexion treatment
- Addressing financial concerns or gaps in coverage, including providing resources that may be able to help cover the costs of your patient's Alexion treatment
- Offering comprehensive vaccination support for your patients

### Community connections

**We can help your patients and their caregivers connect with others in the rare disease community by sharing information about:**

- Attending in-person and online events specific to your patient's condition
- Learning about advocacy groups
- Talking to other patients through the Alexion Peer Connects program

### Ongoing support

- Collaborating with HCPs, office staff, and the specialty pharmacy to ensure patients keep receiving their medicine as prescribed
- Navigating your patient's treatment through life events, such as getting married, starting a new job, moving, or traveling




## OneSource Brochure

- Provides an overview of services offered by the Alexion patient support program

Access here

### Personalized support available from OneSource

| Call: | Email: | Visit: |
|---|---|---|
| 1-888-765-4747 | OneSource@alexion.com | AlexionOneSource.com |

**EVH,** extravascular hemolysis; **HCP,** healthcare provider; **PNH,** paroxysmal nocturnal hemoglobinuria.

**Please see additional Important Safety Information on pages 16-18 and full Prescribing Information for VOYDEYA (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.**

# VOYDEYA access resources

## Alexion FRMs

FRMs are available to provide educational support to HCPs and office staff to facilitate patient access to prescribed Alexion medications.

## Alexion FRMs can provide:

### General access and reimbursement education, including:

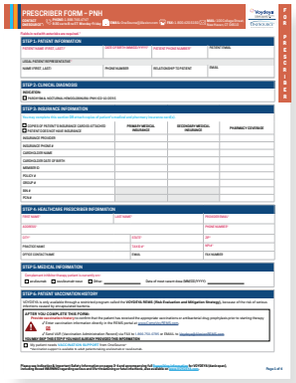
- Payer policy information and general PA and reauthorization criteria
- Preinitiation vaccination requirements and needed documentation

### Case-specific education* to assist with getting patients on therapy, including:

- Patient-specific PA and reauthorization criteria educational support
- Preinitiation vaccination options and required documentation needed for patients' health plans

**FRM,** Field Reimbursement Manager; **HCP,** healthcare provider; **PA,** prior authorization.
*When an FRM is involved in patient-specific casework, the patient must be enrolled in OneSource™, and patient-specific information must be redacted.

# VOYDEYA Prescriber and Patient Enrollment Form


PRESCRIBER FORM - PNH

Prescribers can download the VOYDEYA Prescriber and Patient Enrollment Form from **AlexionOneSource.com** or call **1-888-765-4747** for assistance.

**Access here**

## Where to send the enrollment form

Please fax or email the completed VOYDEYA Prescriber and Patient Enrollment Form to OneSource™, along with copies of your patient's medical insurance and pharmacy coverage cards.

### OneSource

**Fax:**
1-800-420-5150

**Email:**
OneSource@alexion.com

Alternatively, you may send the completed form or a written prescription for VOYDEYA to Onco360, the sole specialty pharmacy for VOYDEYA.

### Onco360

**Phone:**
1-877-662-6633

**Fax:**
1-877-662-6355

**e-Prescribe:**
OncoMed Dba Onco360
NPI# 1679618151

**NPI,** National Provider Identifier.

**Please see additional Important Safety Information on pages 16-18 and full Prescribing Information for VOYDEYA (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.**

# Financial assistance & access programs

Alexion is committed to providing patients with access to our medicines. We have developed a number of financial assistance and patient support programs to help patients obtain access to VOYDEYA.

## Alexion OneSource™ CoPay Program*

With the Alexion OneSource CoPay Program, patients can save on their medications if they:

- Do not have Medicare, Medicaid, or other government insurance*
- Are enrolled in OneSource
- Have commercial insurance that covers some portion of the drug cost
- Have a valid VOYDEYA prescription
- Are a citizen or permanent resident of the United States or its territories

**Pay as little as $0 in out-of-pocket costs**

### VOYDEYA 30-Day Free Trial Program

The Free Trial Program is an offering for new patients and HCPs who would like to assess tolerability and efficacy of VOYDEYA.†

### Free Limited Supply Program

The Free Limited Supply Program is a patient support offering to support commercially insured patients looking to start treatment who are experiencing a coverage delay of 5 days or more due to a payer's approval process. Both OneSource and Onco360 are available to initiate the process for patients.

### Third-Party Resources

Alexion can connect patients on Medicare, Medicaid, or another federal- or state-funded insurance plan to third-party resources or foundations that may be able to help with financial assistance.

**Have a question? Contact OneSource**

**Web:** AlexionOneSource.com **Phone:** 1-888-765-4747

**HCP,** healthcare provider; **PA,** prior authorization.

*The Alexion OneSource™ CoPay Program is not valid for costs eligible to be reimbursed by government insurance programs or other federal or state programs (including any state prescription drug assistance programs), including Medicaid, Medicare (including Medicare Part D), Medicare Advantage plans, Medigap, Veterans Affairs, Department of Defense, or TRICARE.

†Before registering patients for the VOYDEYA 30-Day Free Trial Program, prescribers should ensure all PA criteria have been met to support a successful transition to commercial product.

# Select codes for your reference[1,5]

| Type | Code | Description |
|---|---|---|
| NDC | **150 mg carton**<br>25682-046-92 (10 digit) 25682-0046-92 (11 digit) | White to off-white round, film-coated tablets |
| NDC | **200 mg carton**<br>25682-043-92 (10 digit) 25682-0043-92 (11 digit) | White to off-white round, film-coated tablets |
| *ICD-10-CM** | D59.5 | Paroxysmal nocturnal hemoglobinuria (Marchiafava-Micheli) |
| | D59.4 | Other nonautoimmune hemolytic anemias |
| | D64.9 | Anemia, unspecified |
| | R53.83 | Other fatigue |

**HCP,** healthcare provider; **ICD-10-CM,** International Classification of Diseases, 10th Revision, Clinical Modification; **NDC,** National Drug Code.
*The diagnosis codes identified above are provided for reference and educational purposes only and are not a guarantee of coverage or reimbursement. Coverage and reimbursement may vary by payer, plan, pharmacy benefit manager, patient, and setting of care. HCPs are responsible for selecting the proper codes for each patient and ensuring the accuracy of all statements when seeking coverage and reimbursement for an individual patient.

# IMPORTANT SAFETY INFORMATION FOR VOYDEYA (danicopan) (cont'd)

## CONTRAINDICATIONS

Initiation in patients with unresolved serious infection caused by encapsulated bacteria, including *Neisseria meningitidis*, *Streptococcus pneumoniae*, or *Haemophilus influenzae* type B.

## WARNINGS AND PRECAUTIONS

### Serious Infections Caused by Encapsulated Bacteria

VOYDEYA, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by encapsulated bacteria, including *Neisseria meningitidis* (caused by any serogroup, including non-groupable strains), *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B. Life-threatening and fatal infections with encapsulated bacteria have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.

Complete, update, or revaccinate patients in accordance with ACIP recommendations considering the duration of VOYDEYA therapy. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent VOYDEYA therapy is indicated in a patient who is not up to date with vaccines against encapsulated bacteria according to ACIP recommendations, provide antibacterial drug prophylaxis and administer these vaccines as soon as possible. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including VOYDEYA. The benefits and risks of treatment with VOYDEYA, as well as those associated with antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by encapsulated bacteria.

Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination. Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of VOYDEYA in patients who are undergoing treatment for serious infections.

### VOYDEYA REMS

Due to the risk of serious infections caused by encapsulated bacteria, VOYDEYA is available only through a restricted program called VOYDEYA REMS. Per the REMS requirements:

Prescribers must enroll in the REMS, counsel patients about the risk of serious infections caused by encapsulated bacteria, provide patients with the REMS educational materials, assess patient vaccination status for vaccines against encapsulated bacteria, and vaccinate if needed according to current ACIP recommendations 2 weeks prior to the first dose of VOYDEYA. Antibacterial drug prophylaxis must be prescribed if treatment must be started urgently and the patient is not up to date with vaccines against encapsulated bacteria according to current ACIP recommendations at least 2 weeks prior to the first dose of VOYDEYA.

Pharmacies that dispense VOYDEYA must be certified in the VOYDEYA REMS and must verify prescribers are certified.

Patients must receive counseling from the prescriber about the need to receive vaccinations against encapsulated bacteria per ACIP recommendations, to take antibiotics as directed, the early signs and symptoms of serious infection, and be instructed to carry the Patient Safety Card at all times during and for 1 week following the last dose of VOYDEYA.

Further information is available at www.voydeyarems.com or 1-888-765-4747.

**Please see full Prescribing Information for VOYDEYA (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.**

# IMPORTANT SAFETY INFORMATION FOR VOYDEYA (danicopan) (cont'd)

## WARNINGS AND PRECAUTIONS (cont'd)

### Hepatic Enzyme Increases

Hepatic enzyme elevations have been observed in patients treated with VOYDEYA. A total of 14% of patients receiving VOYDEYA had elevations in serum alanine aminotransferase (ALT). ALT elevations >3× the upper limit of normal (ULN) and ≤5× ULN occurred in 9% of VOYDEYA-treated patients, and ALT elevations >5× ULN and ≤10× ULN occurred in 5% of VOYDEYA-treated patients.

Assess liver enzyme test results prior to the initiation of VOYDEYA and periodically during treatment. Consider treatment interruption or discontinuation if elevations are clinically significant or if the patient becomes symptomatic. VOYDEYA has not been studied in patients with severe hepatic impairment.

### Monitoring of PNH Manifestations After VOYDEYA Discontinuation

After discontinuing treatment with VOYDEYA, closely monitor patients for at least 2 weeks after the last dose for signs and symptoms of hemolysis. If discontinuation of VOYDEYA is necessary, continue background treatment with ravulizumab or eculizumab or consider alternative therapy if necessary. The signs and symptoms of hemolysis may include sudden decrease in hemoglobin or fatigue.

If hemolysis occurs after discontinuation of VOYDEYA, consider restarting treatment with VOYDEYA, if appropriate.

### Hyperlipidemia

VOYDEYA increases total cholesterol and LDL-cholesterol. Of the 50 VOYDEYA-treated patients who had a normal total cholesterol level at baseline, 30% developed Grade 1 hypercholesterolemia. Of the 6 VOYDEYA-treated patients who had Grade 1 hypercholesterolemia at baseline, 1 patient experienced increased total cholesterol that worsened to Grade 2. Of the 54 VOYDEYA-treated patients who had LDL-cholesterol ≤130 mg/dL at baseline, 13% developed LDL-cholesterol >130-160 mg/dL, and 9% developed LDL-cholesterol >160-190 mg/dL.

Some patients required cholesterol-lowering medications. Monitor serum lipid parameters periodically during treatment with VOYDEYA and initiate cholesterol-lowering medication, if indicated.

## ADVERSE REACTIONS

The most common adverse reaction reported in ≥10% of patients treated with VOYDEYA was headache. Serious adverse reactions were reported in 5% of patients who received VOYDEYA and included pancreatitis, cholecystitis, and increased blood bilirubin. No specific serious adverse reaction was reported in more than 1 patient treated with VOYDEYA. Adverse reactions reported in ≥5% of patients treated with VOYDEYA and greater than placebo in the randomized, controlled period included vomiting, pyrexia, increased alanine aminotransferase, hypertension, and pain in the extremities. Clinically relevant adverse reactions in <5% of patients included increased serum triglycerides.

## DRUG INTERACTIONS

BCRP Substrates

Danicopan is a Breast Cancer Resistance Protein (BCRP) inhibitor. Concomitant use of VOYDEYA with a BCRP substrate increases the plasma concentrations of the BCRP substrate, which may increase the risk for adverse reactions associated with the BCRP substrate. If used together, monitor patients more frequently for adverse reactions associated with the BCRP substrate and consider dose reduction of the BCRP substrate according to its prescribing information.

**Please see full Prescribing Information for VOYDEYA (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.**

# IMPORTANT SAFETY INFORMATION FOR VOYDEYA (danicopan) (cont'd)

## DRUG INTERACTIONS (cont'd)

*Rosuvastatin*

Danicopan significantly increased rosuvastatin exposure. The dose of rosuvastatin should not exceed 10mg once daily when concomitantly used with VOYDEYA.

P-glycoprotein Substrates

Danicopan is an inhibitor of P-glycoprotein (P-gp). Concomitant administration of VOYDEYA with P-gp substrates may increase the plasma concentrations of the P-gp substrates. Dose adjustment might be necessary for P-gp substrates where minimal concentration changes may lead to serious adverse reactions.

## USE IN SPECIFIC POPULATIONS

### Pregnancy

There are no available data on VOYDEYA use in pregnant individuals to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with untreated PNH in pregnancy. The use of VOYDEYA in pregnant women or women planning to become pregnant may be considered following an assessment of the risks and benefits.

### Lactation

There are no data on the presence of VOYDEYA in human milk, the effects on the breastfed child, or the effect on milk production. VOYDEYA is present in animal milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk.

Because of the potential for serious adverse reactions in the breastfed child, including serious infections with encapsulated bacteria and liver enzyme increases, advise patients not to breastfeed during treatment with VOYDEYA and for 3 days after the last dose.

### Hepatic Impairment

No dose adjustment is required in patients with mild to moderate hepatic impairment. Studies have not been conducted in patients with severe hepatic impairment, therefore, avoid use of VOYDEYA in this patient population.

**To report SUSPECTED ADVERSE REACTIONS, contact Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**References: 1.** VOYDEYA. Prescribing Information. Alexion Pharmaceuticals, Inc. **2.** Academy of Managed Care Pharmacy. Prior authorization. Accessed June 3, 2026. https://www.amcp.org/concepts-managed-care-pharmacy/prior-authorization **3.** Centers for Medicare & Medicaid Services. Health insurance basics. Updated September 2023. Accessed June 3, 2026. https://www.cms.gov/files/document/nsa-health-insurance-basics.pdf **4.** Pearson C, Schapiro L, Pearson SD; Institute for Clinical and Economic Review. The next generation of rare disease drug policy: ensuring both innovation and affordability. Published April 7, 2022. Accessed June 3, 2026. https://icer.org/wp-content/uploads/2022/04/ICER-White-Paper_The-Next-Generation-of-Rare-Disease-Drug-Policy_040722.pdf **5.** Centers for Medicare & Medicaid Services. 2026 ICD-10-CM. Updated March 10, 2026. Accessed June 3, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes

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