



EveryDay Support.

Sawyer (left), lives with pLGG, and Parker, her sister.

OJEMDA™ (tovorafenib) Access and Reimbursement Guide

Coverage support, financial assistance, and other comprehensive services

INDICATION

OJEMDA™ (tovorafenib) is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

pLGG=pediatric low-grade glioma.

Please see additional <u>Important Safety Information</u> on pages 24-25 and accompanying full Prescribing Information.





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Supporting Access, Affordability, and Administration to Help Patients Start and Stay on OJEMDA™ (tovorafenib)—From Day One

As the complete partner in accessing OJEMDA for you and your patients, EveryDay Support From Day One provides comprehensive services and dosing support (for eligible patients) to help you manage the process from helping initiate and maintain coverage for OJEMDA to helping with affordability throughout the patient's treatment journey.



Our **dedicated Patient Navigators** will work alongside you and your staff to support your patients with personalized access and product support.



We provide **coverage support** to help your patients, their families, and your practice navigate health insurance requirements and provide financial assistance options to help eligible families pay for OJEMDA.



Our **specialty pharmacy partners** will ship OJEMDA to your patient's home, help parent(s) or legal guardian(s) learn how to administer it to their child, educate on what to expect with treatment, and provide ongoing product support.

Call us at **855-DAY1-BIO/855-329-1246** if you have questions or need assistance.



Signing Up for EveryDay Support From Day One Is Simple

To receive help from EveryDay Support From Day One, you must complete the enrollment form and your patient or their legal guardian must provide consent to participate in the program.

There are 2 simple steps to enroll:



Complete the first 2 pages of the enrollment form.



Your patient or their legal guardian (for patients under 18 years) provides consent—we can help with this process.

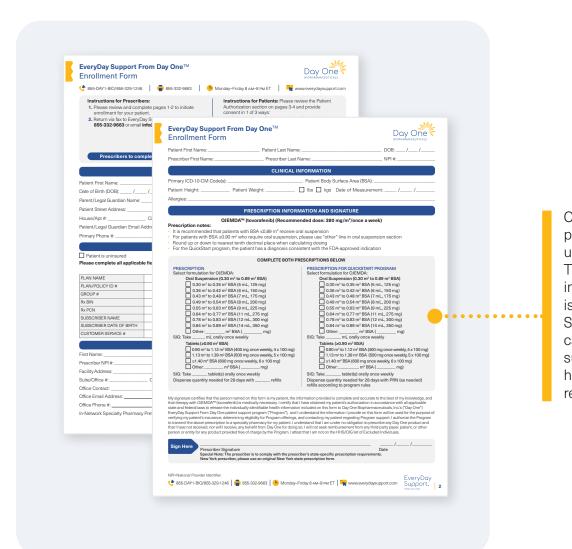






Steps to Enroll

Step 1: Fill out the Enrollment Form as completely as possible



Complete the QuickStart prescription section upon initial enrollment. This way, if the patient's insurance coverage is delayed, EveryDay Support From Day One can assess eligibility for support programs and help them access those resources quickly.



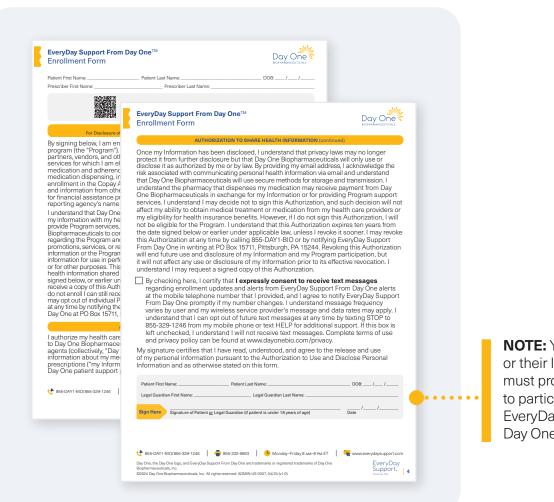
For additional questions, call EveryDay Support From Day One at **855-DAY1-BIO/855-329-1246**. A Patient Navigator can help.

EveryDay Support.

Step 2: Patient or legal guardian provides consent

Your patient or their legal guardian may provide consent in 1 of 2 convenient ways:

- Reviewing and signing the Patient Authorization section (pages 3-4) of the enrollment form in the office.
 - Providing consent electronically at www.everydaysupport.com/consent.



NOTE: Your patient or their legal guardian must provide consent to participate in EveryDay Support From Day One programs.

The enrollment form is also available in Spanish. Patients can download the form at www.everydaysupport.com/patient/get-started.

Please see additional <u>Important Safety Information</u> on pages 24-25 and accompanying full <u>Prescribing Information</u>.



Your Support Team



Patient Navigators

Patient Navigators are the primary contact to help you and your patients' families navigate the health insurance process and entire treatment journey. They can provide personalized support to:

- Explain health insurance coverage for OJEMDA to patients and help them stay informed throughout the insurance approval process
- Determine eligibility for financial assistance options, if needed
- Communicate with the patient's health insurance plan to help minimize treatment delays
- Help with appeals and reauthorizations as needed
- Coordinate with the specialty pharmacy to provide ongoing shipment and treatment support

Our Patient Navigator team has extensive expertise in helping patients and caregivers access their oncology medications. To meet the team, go to www.everydaysupport.com/hcp/your-support-team.

Remind your patients and their families they may receive a phone call from a number they do not recognize. It is important they answer and return all their calls. We recommend saving these numbers to the contact list in their phone.





Field Reimbursement Managers

Field Reimbursement Managers are resources for you and your staff who provide extensive regional health insurance plan expertise, patient-specific support, and help streamline access and reimbursement. Your Field Reimbursement Manager can provide this assistance onsite or via telephone. If needed, they can provide education for providers and office staff about services offered by EveryDay Support From Day One.

A Patient Navigator can connect you to your regional Field Reimbursement Manager.



Specialty Pharmacies

Our specialty pharmacy partners, Biologics and Onco360, will ship OJEMDA to your patient's home.

They will have pharmacists and nurses on staff who can help your patients and their families with product education, dosing and administration, and side effect management. They can also provide ongoing product support and helpful reminders when it is time to refill their prescription. See pages 22-23 for more information.



For questions about EveryDay Support From Day One, contact us at **855-DAY1-BIO/855-329-1246**.





Insurance and Coverage Support

Coordination across stakeholders

You, your staff, your patients, and their families can rely on a dedicated Patient Navigator at EveryDay Support From Day One as the primary point of contact to help navigate the health insurance process.

We provide coverage support for your patients and practice, including:



Benefits investigations



Prior authorization and appeals support



Updates on coverage changes

EveryDay Support From Day One and our specialty pharmacy partners will provide you with regular updates throughout the access journey.

See pages 11-19 for more details on the types of coverage support EveryDay Support From Day One can offer, as well as helpful resources you can use throughout the insurance process.



Benefits Investigations

EveryDay Support From Day One can review your patient's health insurance coverage for OJEMDA.*

We can conduct a benefits investigation to help you, your patients, and their families determine:

- ✓ If OJEM
 - If OJEMDA is covered
- Prior authorization requirements[†]
- The out-of-pocket costs for OJEMDA, so patients and their families can determine if financial assistance might be needed



If there are concerns about out-of-pocket costs for OJEMDA, financial assistance may be available. See pages 20-21 for more information.

^{*}Approval processes and prior authorization requirements vary by health insurance plan.

†Completion and submission of documentation to the health insurance plan is the responsibility of the health care provider and their patients/legal guardians.







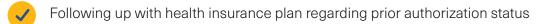
Prior Authorization Support

EveryDay Support From Day One can help you as you prepare a prior authorization request for your patient.*

We can help your practice with prior authorizations by:









Consider submitting a Letter of Medical Necessity and supporting clinical documentation with your prior authorization request (see pages 14-15).

*Approval processes and prior authorization requirements vary by health insurance plan.

[†]Completion and submission of documentation to the health insurance plan is the

responsibility of the health care provider and their patients/legal guardians.

Quick tips to consider when submitting a prior authorization

- Confirm the health insurance plan's process and guidelines for prior authorizations (these may differ across health insurance plans). EveryDay Support From Day One can help you with this
- Double check that the patient information is accurate and complete
- Keep complete records and log all phone calls you make to the patient's health insurance plan

Appeals and Reauthorization Support

Denials and appeals

If the patient's health plan has denied coverage for OJEMDA, it may be necessary to submit an appeal. EveryDay Support From Day One can assist in determining the reason(s) for denial and can help with the appeal process.

Here are some common reasons for coverage denials that may be resolved through the appeal process:

- New drug: Not yet reviewed by payer and considered non-formulary
- Missing information: Coverage request is missing information or there was a data entry error
- Prior authorization required: Prior authorization not submitted with coverage request[†]
- Health insurance information: Patient's insurance changed or coverage has lapsed



See additional helpful resources, such as a Sample Letter of Appeal and suggested supporting documentation on pages 16-17.

Don't forget reauthorization

Our reauthorization notifications will alert you when a prior authorization is due to expire so your patients don't lose their coverage for OJEMDA. Reauthorization assistance through EveryDay Support From Day One can help avoid gaps in coverage.

Typically, reauthorization is required every 6 to 12 months, but is subject to the individual requirements of each patient's health insurance plan.[†]

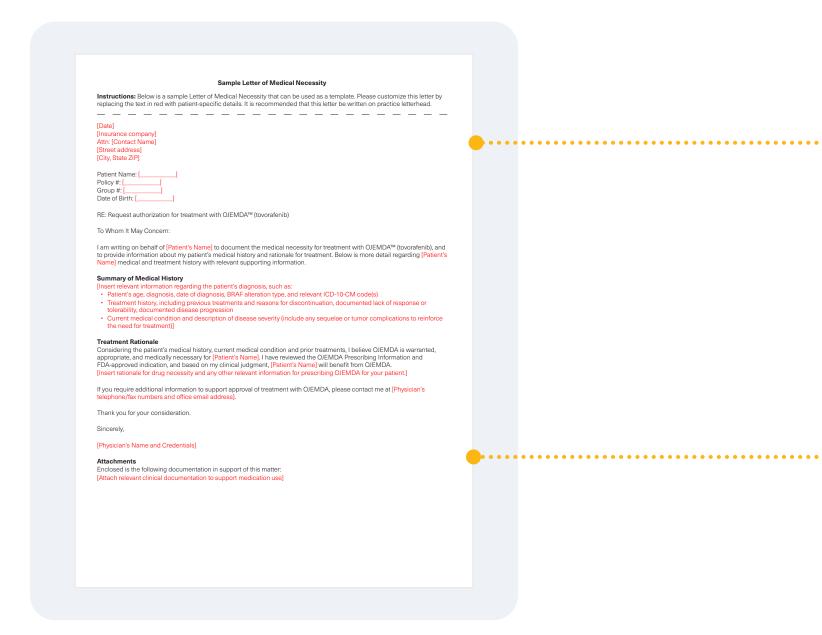
Quick tip: You may need to submit patient clinical documentation for reauthorization.





Sample Letter of Medical Necessity

For use when submitting a prior authorization





Download a Sample Letter of Medical Necessity and checklist at www.everydaysupport.com/hcp/resources.

of Diseases, 10th Revision, Clinical Modification,

BRAF=v-raf murine sarcoma viral oncogene homolog B1; ICD-10-CM=International Classification

Important information to include in your Letter of Medical Necessity:

- Patient name, date of birth, insurance group number, insurance policy number, and patient case ID number
- Patient's age, diagnosis, date of diagnosis, BRAF alteration type
- Patient medical history
- Treatment history, including previous treatment(s) received and reasons for discontinuation
- Clinical rationale for treatment with OJEMDA

Additional information you may want to include along with your prior authorization:

- Patient clinical documentation:
 - Pathology reports and/or molecular testing reports documenting BRAF alteration
- Recent imaging report
- Relevant ICD-10-CM diagnosis code(s)
- Clinical notes and medical record, including:
- Previous treatment(s) and reason for discontinuation
- Documented disease progression or lack of response
- Tumor board recommendation (if available)

Additional information about OJEMDA:

- Relevant peer-reviewed articles
- U.S. Food and Drug Administration (FDA) approval letter
- Prescribing Information

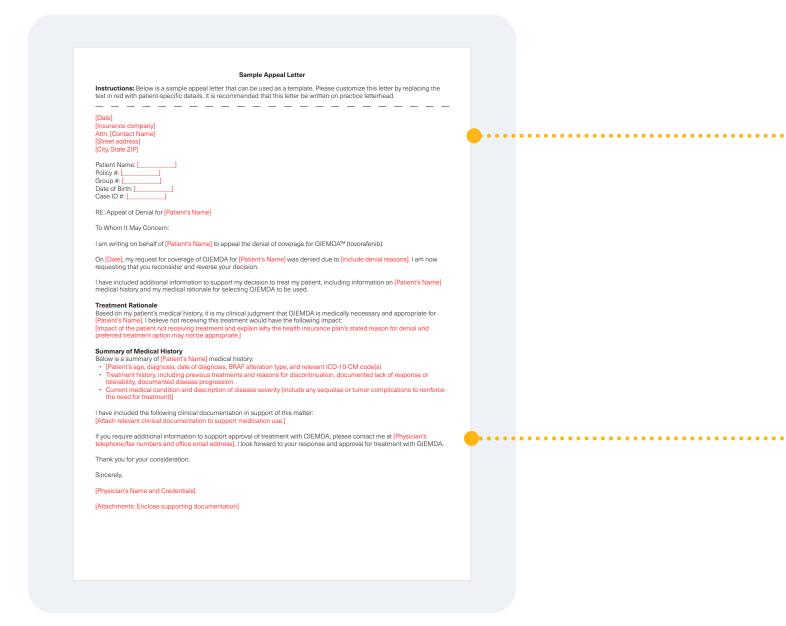
Be sure to confirm the health insurance plan's process and guidelines for prior authorizations. These may vary across health insurance plans. EveryDay Support From Day One can help with this.





Sample Letter of Appeal

For use when appealing a coverage denial



Important additional information to include in your appeal letter:

- Health plan's stated reason for denial, date of denial, and rationale to address
- Information to address denial
- The Letter of Medical Necessity
- Treatment summary, including previous treatment(s) received and reasons for discontinuation
- Clinical rationale for treatment with OJEMDA, including impact of not being treated

Additional information you may want to include with your appeal letter:

- Pathology reports and/or molecular testing reports documenting BRAF alteration
- Recent imaging report
- Relevant ICD-10-CM diagnosis code(s)
- Clinical notes and medical record, including:
- Previous treatment(s) and reason for discontinuation
- Documented disease progression or lack of response
- Tumor board recommendation (if available)

Additional information about OJEMDA:

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- Prescribing Information

Be sure to confirm the health insurance plan's process and guidelines for prior authorizations. These may vary across health insurance plans. EveryDay Support From Day One can help with this.



Download a Sample Letter of Appeal and checklist at www.everydaysupport.com/hcp/resources.



EveryDay Support From Day One Can Help With the Coding Process

The appropriate ICD-10-CM diagnosis codes and NDCs are required for billing, checking benefits, and other documents and forms related to coverage. See sample coding below for pLGG and OJEMDA NDCs*:

ICD-10-CM Diagnosis Codes

CODE	DESCRIPTION		
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles		
C71.1	Malignant neoplasm of frontal lobe		
C71.2	Malignant neoplasm of temporal lobe		
C71.3	Malignant neoplasm of parietal lobe		
C71.4	Malignant neoplasm of occipital lobe		
C71.5	Malignant neoplasm of cerebral ventricle		
C71.6	Malignant neoplasm of cerebellum		
C71.7	Malignant neoplasm of brain stem		
C71.8	Malignant neoplasm of overlapping sites of brain		
C71.9	Malignant neoplasm of brain, unspecified		
C72.0	Malignant neoplasm of spinal cord		
C72.9	Malignant neoplasm of central nervous system, unspecified		
C72.30	Malignant neoplasm of unspecified optic nerve		
C72.31	Malignant neoplasm of right optic nerve		
C72.32	Malignant neoplasm of left optic nerve		
C72.5	Malignant neoplasm of unspecified cranial nerve		
C72.59	Malignant neoplasm of other cranial nerves		
D43.0	Neoplasm of uncertain behavior of brain, supratentorial		
D43.1	Neoplasm of uncertain behavior of brain, infratentorial		
D43.2	Neoplasm of uncertain behavior of brain, unspecified		
D43.3	Neoplasm of uncertain behavior of cranial nerves		
D43.8	Neoplasm of uncertain behavior of other specified parts of central nervous system		
D33.0	Benign neoplasm of brain, supratentorial		
D33.1	Benign neoplasm of brain, infratentorial		
D49.6	Neoplasm of unspecified behavior of brain		

National Drug Codes (NDCs)¹

CODE		DESCRIPTION
10-digit	11-digit	
82950-012-01	82950-0012-01	Each bottle delivers 300 mg of tovorafenib in 12 mL
82950-001-16	82950-0001-16	Tovorafenib 100-mg tablets, 16 count
82950-001-20	82950-0001-20	Tovorafenib 100-mg tablets, 20 count
82950-001-24	82950-0001-24	Tovorafenib 100-mg tablets, 24 count

Health insurance plan requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.

Note: There is no ICD-10-CM code specific to pLGG. The codes provided here are not a complete list of potential ICD-10-CM codes. Correct coding is the responsibility of the provider submitting the claim. Health insurance plan requirements for coding may vary. Be sure to check with individual health insurance plans for their preferred coding.



pLGG=pediatric low-grade glioma.

Please see additional <u>Important Safety Information</u> on pages 24-25 and accompanying full <u>Prescribing Information</u>.



^{*}Correct coding is the responsibility of the health care provider.

EveryDay Support From Day One Can Help Your Patients Pay for OJEMDA™ (tovorafenib)

After your patient is prescribed OJEMDA and is enrolled in EveryDay Support From Day One, the patient or legal guardian will receive a welcome call from their Patient Navigator to discuss financial support options. Their Patient Navigator will determine if the patient qualifies for financial assistance and can help connect patients and their families with outside organizations that may be able to assist with other treatment-related costs.



OJEMDA Copay Program

Your patients may be eligible to participate in the copay program and reduce their out-of-pocket costs for OJEMDA (copay, co-insurance, or deductible) to as little as \$0 per month.*

Once enrolled in EveryDay Support From Day One, a Patient Navigator will review the eligibility criteria and process with the legal guardian and/or patient.

Eligibility criteria

Patients must:

Have a valid prescription for OJEMDA

Be commercially insured

Reside in the United States or Puerto Rico†



Patient Assistance Program

Eligible families who don't have health insurance or are underinsured may be able to get OJEMDA for free through EveryDay Support From Day One.

Eligibility criteria

Patients must:

Have a valid prescription for OJEMDA

Meet certain income criteria

Reside in the United States or Puerto Rico†



QuickStart or Coverage Interruption Programs

If your patient's treatment with OJEMDA is delayed or interrupted due to insurance-related issues, EveryDay Support From Day One can determine if they may be eligible for support to help avoid treatment interruptions.





Referrals to charitable foundations

EveryDay Support From Day One will connect your patients and their families to charitable foundations that may be able to provide assistance for other treatment-related costs.[‡]



Referrals to patient support organizations

EveryDay Support From Day One can refer your patients and their families to independent organizations that may be able to provide important support and education so they can make informed decisions about their next steps.



For more information about financial assistance and referrals to independent organizations for your patients, reach out to EveryDay Support From Day One at **855-DAY1-BIO/855-329-1246** from 8 AM–8 PM ET, Monday–Friday.

[‡]Day One Biopharmaceuticals has no involvement or influence in independent organizations' decision-making or eligibility criteria. These organizations have their own eligibility criteria. EveryDay Support From Day One does not influence or control the decisions of these outside organizations.



*Restrictions and eligibility requirements apply. Not available for those with government insurance.

Maximum benefit applies. Please see www.everydaysupport.com/hcp/copay-terms-and-conditions
for full terms and conditions.

†Documentation of residency is not required.



Specialty Pharmacies

EveryDay Support From Day One and our specialty pharmacy partners will work together seamlessly throughout your patient's treatment journey.

Our specialty pharmacy partners are staffed with nurses and pharmacists with deep expertise in working with children and families with cancer. They will provide your patients and their families with ongoing treatment education and support.

They will:



Call patients to schedule shipments and text refill reminders



Provide counseling with a pharmacist on how to take OJEMDA



Prepare patients for potential side effects and ways to manage them*



Advise patients or their legal guardians on how to prepare, measure, and administer a liquid formulation of the medicine with live video calls for assistance, if needed



Provide ongoing clinical support for OJEMDA treatment as needed



Our specialty pharmacy partners are here to provide high-touch, personalized support for OJEMDA.

OJEMDA is available through 2 specialty pharmacies:



Phone number: 800-850-4306 Fax number: 800-823-4506

Website: www.biologicsinc.com

Available 8 Am to 8 PM ET, Monday through Friday.



Phone number: 877-662-6633 Fax number: 877-662-6355

Website: www.onco360.com

Available 8 Am to 8 PM ET, Monday through Friday.

Remind your patients and/or their legal guardian:

The specialty pharmacy will contact them regarding product shipment, product administration, and education.



They may receive a phone call from a number they do not recognize. It is important they answer and return all their calls to minimize delays.



^{*}Patients should contact their care team for medical advice about side effects.

Important Safety Information

INDICATION

OJEMDA™ (tovorafenib) is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hemorrhage

Hemorrhage, including major hemorrhage defined as symptomatic bleeding in a critical area or organ, can occur with OJEMDA. Advise patients and caregivers of the risk of hemorrhage during treatment with OJEMDA. Monitor for signs and symptoms of hemorrhage and evaluate as clinically indicated. Withhold and resume at reduced dose upon improvement, or permanently discontinue based on severity.

Skin Toxicity Including Photosensitivity

OJEMDA can cause rash, including maculopapular rash and photosensitivity. Monitor for new or worsening skin reactions. Consider dermatologic consultation and initiate supportive care as clinically indicated. Withhold, reduce the dose, or permanently discontinue OJEMDA based on severity of adverse reaction.

Photosensitivity

Advise patients to use precautionary measures against ultraviolet exposure such as use of sunscreen, sunglasses, and/or protective clothing during treatment with OJEMDA. Withhold, reduce the dose, or permanently discontinue OJEMDA based on severity of adverse reaction.

Hepatotoxicity

OJEMDA can cause hepatotoxicity. Monitor liver function tests, including ALT, AST and bilirubin, before initiation of OJEMDA, one month after initiation and then every three months thereafter and as clinically indicated. Withhold and resume at the same or reduced dose upon improvement, or permanently discontinue OJEMDA based on the severity.

Effect on Growth

OJEMDA can cause reductions in growth velocity. Growth velocity recovered after interruption of treatment with OJEMDA. Routinely monitor patient growth during treatment with OJEMDA.

Embryo-Fetal Toxicity

Based on findings from animal studies and its mechanism of action, OJEMDA may cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Advise females of reproductive potential to use effective nonhormonal contraception during treatment with OJEMDA and for 28 days after the last dose, since OJEMDA can render some hormonal contraceptives ineffective. Advise male patients with female partners of reproductive potential to use effective nonhormonal contraception during treatment with OJEMDA and for 2 weeks after the last dose.

NF1 Associated Tumors

Based on nonclinical data in NF1 models without BRAF alterations, tovorafenib may promote tumor growth in patients with NF1 tumors. Confirm evidence of a BRAF alteration prior to initiation of treatment with OJEMDA.

Adverse Reactions

The most common adverse reactions (≥30%) were rash, hair color changes, fatigue, viral infection, vomiting, headache, hemorrhage, pyrexia, dry skin, constipation, nausea, dermatitis acneiform, and upper respiratory tract infection.

Please see accompanying full <u>Prescribing Information</u>.







EveryDay Support From Day One—Simplifying the Process to Help Patients Start and Stay on OJEMDA™ (tovorafenib)



Sawyer, lives with pLGG.

With EveryDay Support From Day One, you can expect:

- Coordination with your patients' health insurance to obtain initial and ongoing coverage
- Financial support options to help with affordability for your patients and their families
- Support to ensure OJEMDA is shipped from our specialty pharmacy partners to your patients' home
- Education and dosing support as needed for your patients and their families
- Ongoing shipment and treatment support



Enroll your patients in EveryDay Support From Day One by downloading the enrollment form at **www.everydaysupport.com/hcp/enroll-now**.

Reach out to EveryDay Support From Day One for any questions at **855-DAY1-BIO/855-329-1246** from 8 AM-8 PM ET, Monday-Friday.

Reference: 1. OJEMDA. Prescribing Information. Day One Biopharmaceuticals, Inc.; 2024.

Please see additional <u>Important Safety Information</u> on pages 24-25 and accompanying full <u>Prescribing Information</u>.

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