



**How to Complete the  
GIVLAARI® (givosiran)  
Start Form**

Please see Important Safety Information on [page 7](#) and full [Prescribing Information](#).



# How to Complete the GIVLAARI® (givosiran) Start Form

This brochure will show you how to complete the Start Form. The notes on each page provide details to help ensure the form is filled out correctly. The Start Form serves as your patient's enrollment in Alynlam Assist® and requires the signature of both you and your patient. The Start Form also initiates your patient's prescription for GIVLAARI.

## It is important to note the following before submitting the Start Form:

- ▷ Ensure highlighted key areas are correctly filled out
- ▷ Confirm that you and your patient sign where indicated

## Options for getting started

1. Complete and submit the **electronic Start Form** with your patient **or**
2. Complete the **paper Start Form** with your patient and fax to 1-833-256-2747 **or**
3. Begin the Start Form, filling in all details needed by a healthcare professional, and then have your patient complete the form via **DocuSign**



All 3 options to get started can be found at [www.AlynlamAssist.com](http://www.AlynlamAssist.com).

# For Patients

## Your Patient's Email

Please make sure your patients fill in this field.

## Preferred Phone Number & Voicemail Checkbox


By allowing Alnylam Assist® to leave voicemails, delays in benefit verification and other communications can be avoided.

## Language Translation


Alnylam Assist® offers translation services for non-English-speaking patients.

## Insurance Information

Patients (or their authorized representatives) can fill in the provided fields or attach copies of both sides of their insurance and pharmacy benefits cards.



# Start Form



▶ Before submitting the Start Form to Alnylam Assist®, patient **and** prescriber signatures are required

### For Patients

#### Alnylam Assist® Enrollment

(Sections 1 – 5 to be read and completed by **Patient** or **Patient's Authorized Representative**)

The purpose of this form is to permit Alnylam Assist® participants to receive information and support ("Patient Support") from Alnylam Pharmaceuticals, Inc., its affiliates, representatives, agents, and contractors ("Alnylam"). Alnylam Assist® provides Patient Support to eligible patients who have been prescribed an Alnylam medicine. This includes: (1) providing reimbursement and financial support to eligible patients (such as investigating your insurance coverage, confirming out-of-pocket costs, and reviewing eligibility for financial assistance); (2) working with you and your provider to fill your prescription; and (3) providing you with disease and medication-related educational resources and communications.

**Please read this form carefully and ask any questions that you may have before signing.**

#### 1. Patient Information

Name (First, MI, Last): Lawrence N. Reele

Date of Birth: Month/Day/Year 05/14/1956 Email: LNReele@email.com

Street Address: 1020 Generic Ave.

City: Springfield State: MA ZIP: 01223

Preferred Phone Number:  **Okay to leave voicemail** (555) 137-1634 Alternative Phone Number (if available):  **Okay to leave voicemail**

Caregiver Name (optional): Diane Reele Caregiver Relationship to Patient (optional): Wife Caregiver Phone (optional): (555) 136-1522

Language translation?  Yes, translation needed  No If yes, please indicate language: Portuguese

#### 2. Insurance Information

Attach a copy of both sides of your **INSURANCE** and **PRESCRIPTION** cards  Check if you do not have insurance


<b>Primary</b> Insurance Provider: <u>ABC Insurance Co.</u>	Employer Name: <u>Company Inc.</u>	Policy Number: <u>123456789101</u>	Group Number: <u>12-34567</u>
Policyholder Name (First, MI, Last), if other than the patient:		Policyholder Date of Birth: Month/Day/Year	Insurance Phone: <u>(555) 136-2222</u>
<b>Pharmacy</b> Plan Provider (if applicable):	Policy Number:	Group Number:	Rx BIN Number: Rx PCN Number:
Policyholder Name (First, MI, Last), if other than the patient:		Policyholder Date of Birth: Month/Day/Year	Insurance Phone:
<b>Secondary</b> Insurance Provider (if applicable):	Employer Name:	Policy Number:	Group Number:
Policyholder Name (First, MI, Last), if other than the patient:		Policyholder Date of Birth: Month/Day/Year	Insurance Phone:

▶ Continue to page 2 to complete the patient portion of the Start Form


Please see [Important Safety Information](#) on page 4, and full [Prescribing Information](#).

– 1 of 4 –

# Authorization to Share Protected Health Information/ Authorization for Alnylam Assist® Enrollment



## Start Form



### 3. Authorization to Share Protected Health Information

By signing below, I authorize my healthcare providers, including my physicians and pharmacies ("My Providers") and my health insurance plan ("My Plan") to share my medical information (such as information about my diagnosis, prescriptions, and treatment) and my insurance information ("My Information") with Alnylam so that Alnylam can provide Patient Support. I authorize My Providers to use My Information to provide me with certain offerings related to my medication and treatment. I understand that my pharmacy will receive payment from Alnylam for disclosing My Information to Alnylam. I understand that once My Information has been disclosed, federal privacy laws may no longer protect the information. However, I understand that Alnylam agrees to protect My Information by using and disclosing it only for purposes described in this Authorization or as required by law or regulations. I understand that I may refuse to sign this Authorization, and that my treatment, insurance enrollment, and eligibility for insurance benefits are not conditioned upon signing this Authorization. I also understand, however, that refusing to sign this Authorization means that I may not participate in Alnylam Assist® and may not be able to take advantage of other offerings by Alnylam. I may cancel or revoke this Authorization at any time by mailing a letter to Privacy Officer at Alnylam, Attn: Legal Department, 675 West Kendall Street, Cambridge, MA 02142 or by sending an email to [privacy@alnylam.com](mailto:privacy@alnylam.com). I understand that if I revoke this Authorization, My Providers and Alnylam will stop using and sharing My Information under this Authorization, but my revocation will not affect uses and disclosures of My Information prior to my revocation in reliance upon this Authorization.

This Authorization expires ten (10) years from the date signed below, or earlier if required by state or local law, unless I revoke it before then. I understand that I may receive a copy of this Authorization.

<i>Lawrence N. Reele</i> Print Patient or Authorized Patient Representative Name	<input checked="" type="checkbox"/> <i>Lawrence N. Reele</i> Signature of Patient or Authorized Patient Representative
Relationship to Patient	<i>January 1, 2021</i> Date

### 4. Authorization for Alnylam Assist® and Communications

By signing below, I confirm I would like to enroll in the Alnylam Assist® program and authorize Alnylam to provide me with Patient Support. I understand that Alnylam Assist® is an optional program.

I agree that Alnylam may use My Information and share it with My Providers or My Plan in connection with providing the Patient Support, administering the Alnylam Assist® program, or as otherwise required by Alnylam to meet its legal obligations. For example, Alnylam may communicate with me (such as by mail, phone, email, and/or text message) or my caregiver, use My Information to tailor the Alnylam Assist®-related communications to my needs, and share information with My Providers about dispensing my Alnylam medicine to me. I understand that Alnylam may de-identify My Information, combine it with information about other patients, and use the resulting information for Alnylam's business purposes.

<i>Lawrence N. Reele</i> Print Patient or Authorized Patient Representative Name	<input checked="" type="checkbox"/> <i>Lawrence N. Reele</i> Signature of Patient or Authorized Patient Representative
Relationship to Patient	<i>January 1, 2021</i> Date

### 5. Opt In to Receive Marketing Communications (optional)

By checking this box, I authorize Alnylam, and companies working with Alnylam, to contact me by mail, email, fax, and/or telephone regarding marketing and promotional communications, customer surveys, or for market research surveys. **I understand that I am not required to provide this consent as a condition of receiving any Alnylam medicine or services from Alnylam.**

Please see [Important Safety Information](#) on page 4, and full [Prescribing Information](#).

— 2 of 4 —

**Signature of Patient**

The signature of the patient or authorized patient representative, with the date, is required **twice** on this page in Sections 3 and 4.

# For Healthcare Providers

## Product Acquisition

Select your preferred method of product acquisition (specialty pharmacy or specialty distributor). If acquisition method is unknown, select *Unknown*.

## GIVLAARI® (givosiran) Dosing Information

- ▶ Confirm that your patient is being prescribed GIVLAARI as indicated by **checking the box**
- ▶ Make sure to include the **primary diagnosis code** and **patient's weight (kg)**

## GIVLAARI Prescription


Ensure you fill in this prescription field for your patients.

## Signature of Prescriber


Prescriber should only sign one prescription field and include date in Section 7.

To prevent a generic substitution, sign the "dispense as written" field.

To allow generic substitutions, sign the "substitution permitted" field.



# Start Form



**For Healthcare Providers**  
(Sections 6 – 8 to be read and completed by **Healthcare Provider**)

### 6. Prescriber Information

Name (First, Last): <i>Charles Sample</i>		Practice Name: <i>Sample Co.</i>	Specialty: <i>Neurology</i>
Practice Street Address: <i>530 Pioneer Road</i>		City: <i>Easton</i>	State: <i>MA</i>
ZIP: <i>40520</i>	Phone: <i>(555) 876-5309</i>	Fax:	National Provider ID (NPI) #: <i>1234567890</i>
Office Contact Name: <i>Jane Smith</i>		Phone: <i>(555) 652-5678</i>	State License #: <i>5943072</i>
Product acquisition: <input checked="" type="checkbox"/> Specialty Pharmacy: <input checked="" type="checkbox"/> Accredo <input type="checkbox"/> PANTHERx <input type="checkbox"/> No preference <input type="checkbox"/> Specialty Distributor (McKesson Specialty or McKesson Plasma and Biologics) <input type="checkbox"/> Unknown			Anticipated First Treatment Date: <i>January 1, 2021</i>

### 7. GIVLAARI® (givosiran) Prescription

(This is a prescription; a prescriber's signature and date are required.)

Patient Name: \_\_\_\_\_ Patient Date of Birth: Month/Day/Year: \_\_\_\_\_

E80.20 (Unspecified porphyria)    E80.21 (Acute intermittent (hepatic) porphyria)    E80.29 (Other porphyria)    Other \_\_\_\_\_

GIVLAARI Injection for subcutaneous use, 189 mg/mL <small>(Recommended dose is 2.5 mg/kg monthly)</small>	Date Patient Weight Taken	Patient Weight (in kg)	Total Calculated Dose (SC monthly)	Number of Vials/Treatment	Refills
	<i>1/1/2021</i>	<i>61.23</i>	(mg) <i>153.07</i> (mL) _____	<i>1</i> <small>189 mg/mL vial(s)</small>	<input checked="" type="checkbox"/> Refill x <i>11</i> <input type="checkbox"/> Other _____

Any known allergies?    Yes    No  
If yes, please list: \_\_\_\_\_

List or attach a list of concomitant medications: *Oxycodone*

Special Instructions: *None*

If acquiring through Accredo or PANTHERx, please check here to authorize ancillary supplies, such as needles and syringes, as needed to administer treatment.

I confirm that my patient is being prescribed GIVLAARI for the treatment of acute hepatic porphyria (AHP) in adults.

**I authorize Alnylam to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy. I will comply with my state-specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc.**

<input checked="" type="checkbox"/> <i>[Signature]</i> Prescriber Signature (No Stamps) Dispense as Written	Date <i>January 1, 2021</i>
<input checked="" type="checkbox"/> Prescriber Signature (No Stamps) Substitution Permitted	Date

**Desired Site of Care**

Home Injection (see patient home address)    Physician Office (see provider office address)  
 Alternate Medical Facility (provide facility name and address)    Facility to Home (first dose at facility; remainder at home)  
 Facility Name/Address: \_\_\_\_\_

▶ Continue to page 4 to complete the prescriber portion of the Start Form

Please see [Important Safety Information](#) on page 4, and full [Prescribing Information](#).

— 3 of 4 —

## Desired Site of Care

Ask your patient where he or she would like to receive treatment.

# Prescriber Declaration



### 8. Prescriber Declaration

By signing below, I certify that:

- ▷ The information contained in this form is complete and accurate to the best of my knowledge
- ▷ I understand that Alylam is not responsible for filing claims or submitting other information to my patient's insurer and that the information provided by Alylam Assist® is educational in nature
- ▷ I understand that my patient may authorize Alylam Assist® to provide Patient Support. I understand that this program does not include individual treatment or medical advice to the patient, and it does not replace the medical treatment and care provided by me as the patient's healthcare provider.
- ▷ I further certify that I understand that any support provided by Alylam Assist® on behalf of any patient is not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use GIVLAARI® (givosiran) or any other Alylam product, and any decision to prescribe GIVLAARI was, and in the future will be, based solely on my determination of medical necessity
- ▷ I have obtained the required authorizations from my patient to release the referenced medical and/or other patient information relating to my patient's treatment to Alylam Assist®

 Prescriber signature (stamps not acceptable)	January 1, 2021 Date
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#### INDICATION

GIVLAARI® (givosiran) is indicated for the treatment of adults with acute hepatic porphyria (AHP).

#### IMPORTANT SAFETY INFORMATION

##### Contraindications

GIVLAARI is contraindicated in patients with known severe hypersensitivity to givosiran. Reactions have included anaphylaxis.

##### Anaphylactic Reaction

Anaphylaxis has occurred with GIVLAARI treatment (<1% of patients in clinical trials). Ensure that medical support is available to appropriately manage anaphylactic reactions when administering GIVLAARI. Monitor for signs and symptoms of anaphylaxis. If anaphylaxis occurs, immediately discontinue administration of GIVLAARI and institute appropriate medical treatment.

##### Hepatic Toxicity

Transaminase elevations (ALT) of at least 3 times the upper limit of normal (ULN) were observed in 15% of patients receiving GIVLAARI in the placebo-controlled trial. Transaminase elevations primarily occurred between 3 to 5 months following initiation of treatment. Measure liver function tests prior to initiating treatment with GIVLAARI, repeat every month during the first 6 months of treatment, and as clinically indicated thereafter. Interrupt or discontinue treatment with GIVLAARI for severe or clinically significant transaminase elevations. In patients who have dose interruption and subsequent improvement, reduce the dose to 1.25 mg/kg once monthly. The dose may be increased to the recommended dose of 2.5 mg/kg once monthly if there is no recurrence of severe or clinically significant transaminase elevations at the 1.25 mg/kg dose.

##### Renal Toxicity

Increases in serum creatinine levels and decreases in estimated glomerular filtration rate (eGFR) have been reported during treatment with GIVLAARI. In the placebo-controlled study, 15% of patients receiving

GIVLAARI experienced a renally-related adverse reaction. The median increase in creatinine at Month 3 was 0.07 mg/dL. Monitor renal function during treatment with GIVLAARI as clinically indicated.

##### Injection Site Reactions

Injection site reactions were reported in 25% of patients receiving GIVLAARI in the placebo-controlled trial. Symptoms included erythema, pain, pruritus, rash, discoloration, or swelling around the injection site. One (2%) patient experienced a single, transient, recall reaction of erythema at a prior injection site with a subsequent dose administration.

##### Blood Homocysteine Increased

Increases in blood homocysteine levels have occurred in patients receiving GIVLAARI. In the ENVISION study, during the open label extension, adverse reactions of blood homocysteine increased were reported in 15 of 93 (16%) patients treated with GIVLAARI. Measure blood homocysteine levels prior to initiating treatment and monitor for changes during treatment with GIVLAARI. In patients with elevated blood homocysteine levels, assess folate, vitamins B12 and B6. Consider treatment with a supplement containing vitamin B6 (as monotherapy or a multivitamin preparation).

##### Drug Interactions

Concomitant use of GIVLAARI increases the concentration of CYP1A2 or CYP2D6 substrates, which may increase adverse reactions of these substrates. Avoid concomitant use of GIVLAARI with CYP1A2 or CYP2D6 substrates for which minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, decrease the CYP1A2 or CYP2D6 substrate dosage in accordance with approved product labeling.

##### Adverse Reactions

The most common adverse reactions that occurred in patients receiving GIVLAARI were nausea (27%) and injection site reactions (25%).

**For additional information about GIVLAARI, please see full Prescribing Information.**

Fax the completed Start Form to 1-833-256-2747

Call Alylam Assist® at 1-833-256-2748 8AM-6PM ET, Monday-Friday

For more information, visit [www.AlylamAssist.com](http://www.AlylamAssist.com)



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— 4 of 4 —

## Signature of Prescriber

Sign and date the declaration on the last page, certifying the information provided in the form and authorization of services. Before submitting the form, ensure **both prescriber signatures** are provided in Sections 7 and 8.

## INDICATION

GIVLAARI® (givosiran) is indicated for the treatment of adults with acute hepatic porphyria (AHP).

## IMPORTANT SAFETY INFORMATION

### Contraindications

GIVLAARI is contraindicated in patients with known severe hypersensitivity to givosiran. Reactions have included anaphylaxis.

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### Hepatic Toxicity

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### Renal Toxicity

Increases in serum creatinine levels and decreases in estimated glomerular filtration rate (eGFR) have been reported during treatment with GIVLAARI. In the placebo-controlled study, 15% of patients receiving GIVLAARI experienced a renally-related adverse reaction. The median increase in creatinine at Month 3 was 0.07 mg/dL. Monitor renal function during treatment with GIVLAARI as clinically indicated.

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Injection site reactions were reported in 25% of patients receiving GIVLAARI in the placebo-controlled trial.

Symptoms included erythema, pain, pruritus, rash, discoloration, or swelling around the injection site. One (2%) patient experienced a single, transient, recall reaction of erythema at a prior injection site with a subsequent dose administration.

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### Drug Interactions

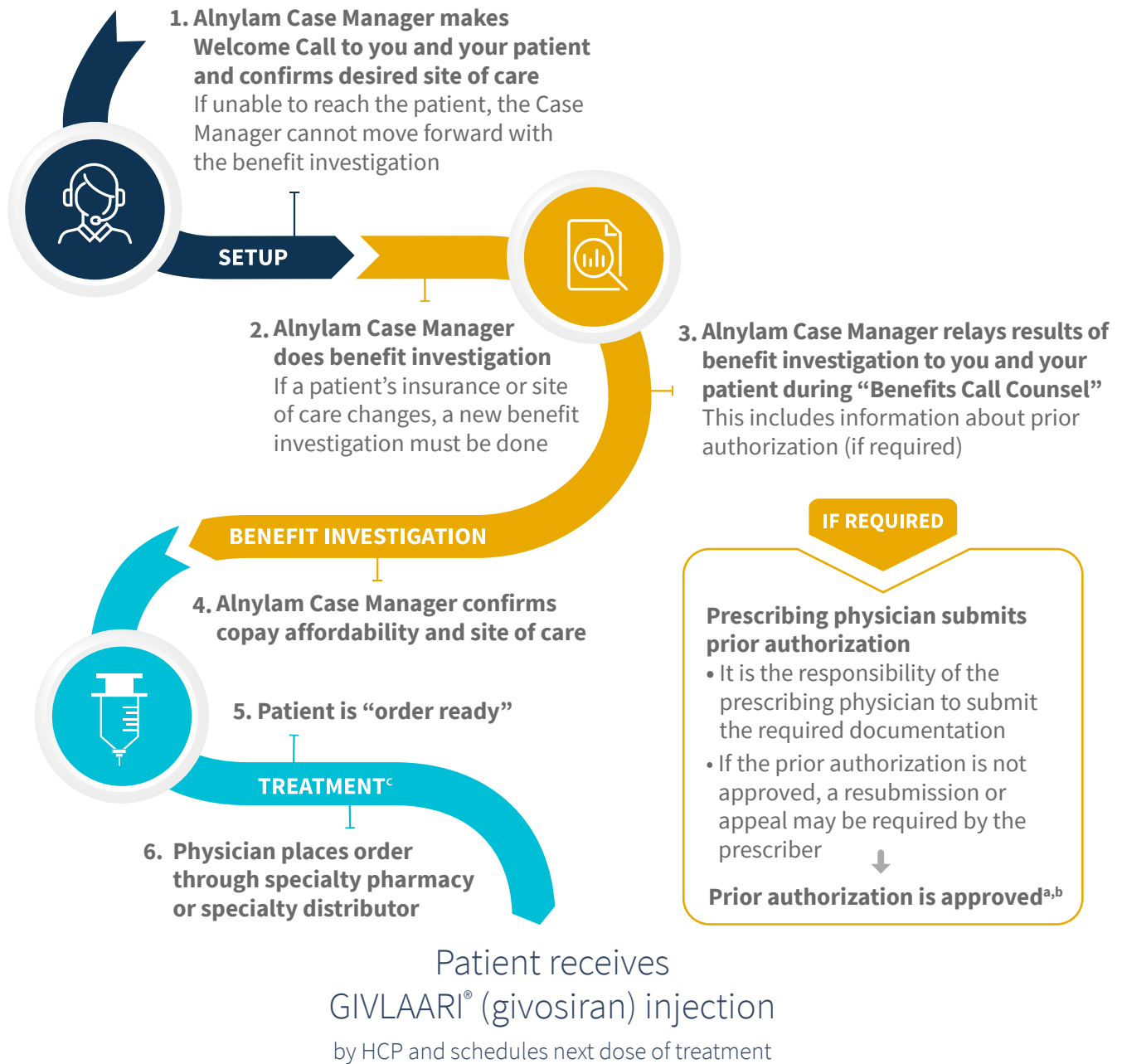
Concomitant use of GIVLAARI increases the concentration of CYP1A2 or CYP2D6 substrates, which may increase adverse reactions of these substrates. Avoid concomitant use of GIVLAARI with CYP1A2 or CYP2D6 substrates for which minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, decrease the CYP1A2 or CYP2D6 substrate dosage in accordance with approved product labeling.

### Adverse Reactions

The most common adverse reactions that occurred in patients receiving GIVLAARI were nausea (27%) and injection site reactions (25%).

**For additional information about GIVLAARI, please see full [Prescribing Information](#).**

# Once the Completed Start Form Is Received by Anylam Assist<sup>®</sup>



<sup>a</sup>If a reauthorization is required, a new request must be submitted.

<sup>b</sup>Anylam Assist<sup>®</sup> can provide education on prior authorization requirements and processes, but cannot guarantee that a patient's prior authorization will be approved.

<sup>c</sup>If your patient has a new prescribing physician, a new Start Form is required and the process must be repeated.

For additional information about GIVLAARI, please see the full [Prescribing Information](#).







8 AM–6 PM ET, Monday–Friday

: 1-833-256-2748 | : 1-833-256-2747

To learn more,  
visit [www.AlylamAssist.com](http://www.AlylamAssist.com).

