

NINLARO 1Point Enrollment Form

How to Enroll in NINLARO 1Point

Please review this form in its entirety with your patient and complete applicable sections. This is an interactive PDF. You may type your responses directly into the PDF and then print the form. You may also print the form and complete it by hand. Either version may be faxed along with a copy of a valid prescription.

- 1 Please complete the specialty pharmacy (SP) preference, patient, current insurance, and prescriber information sections on the front of the form.
- 2 Patient (or patient representative) should be certain to read the Patient Authorization section on the front of the form then print, date, and sign their name.
- 3 The physician should complete the prescription information for NINLARO® (ixazomib) and sign their name. **NOTE: The form cannot be processed without an original signature. Stamped signatures cannot be accepted.**
- 4 Please be sure to complete the shipping information.
- 5 To participate in the NINLARO RapidStart Program please be sure to complete the optional RapidStart section of the enrollment form.
- 6 Print and sign the form, and fax it to NINLARO 1Point at 1-844-269-3038.

NINLARO 1Point will contact your office once the benefit verification* is complete and will provide you with a summary of benefits within 2 business days upon receipt of all required information.

To apply for the Patient Assistance Program, please visit NINLARO-hcp.com/1Point

The form cannot be processed without an original signature. Stamped signatures cannot be accepted.

*Verification of benefits is not a guarantee of payment and does not take the place of written policy information.

**For full Indication and Important Safety Information, please see page 2.
Please see accompanying NINLARO (ixazomib) full [Prescribing Information](#).**



PHONE: 1-844-N1POINT (1-844-617-6468), MON-FRI, 8AM-8PM ET

INDICATION

NINLARO (ixazomib) is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Thrombocytopenia** has been reported with NINLARO. During treatment, monitor platelet counts at least monthly, and consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines. Adjust dosing as needed. Platelet nadirs occurred between Days 14-21 of each 28-day cycle and typically recovered to baseline by the start of the next cycle.
- **Gastrointestinal Toxicities**, including diarrhea, constipation, nausea and vomiting, were reported with NINLARO and may occasionally require the use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea resulted in the discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for severe symptoms.
- **Peripheral Neuropathy** (predominantly sensory) was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimens, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (< 1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in both regimens. Monitor patients for symptoms of peripheral neuropathy and adjust dosing as needed.
- **Peripheral Edema** was reported with NINLARO. Monitor for fluid retention. Investigate for underlying causes when appropriate and provide supportive care as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.
- **Cutaneous Reactions:** Rash, most commonly maculo-papular and macular rash, was reported with NINLARO. Rash resulted in discontinuation of one or more of the three drugs in < 1% of patients in both regimens. Manage rash with supportive care or with dose modification.
- **Hepatotoxicity** has been reported with NINLARO. Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in < 1% of patients treated with NINLARO. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes regularly during treatment and adjust dosing as needed.
- **Embryo-fetal Toxicity:** NINLARO can cause fetal harm. Women should be advised of the potential risk to a fetus, to avoid becoming pregnant, and to use contraception during treatment and for an additional 90 days after the final dose of NINLARO. Women using hormonal contraceptives should also use a barrier method of contraception.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 20\%$) in the NINLARO regimen and greater than the placebo regimen, respectively, were diarrhea (42%, 36%), constipation (34%, 25%), thrombocytopenia (78%, 54%; pooled from adverse events and laboratory data), peripheral neuropathy (28%, 21%), nausea (26%, 21%), peripheral edema (25%, 18%), vomiting (22%, 11%), and back pain (21%, 16%). Serious adverse reactions reported in $\geq 2\%$ of patients included thrombocytopenia (2%) and diarrhea (2%).

SPECIAL POPULATIONS

- **Hepatic Impairment:** Reduce the NINLARO starting dose to 3 mg in patients with moderate or severe hepatic impairment.
- **Renal Impairment:** Reduce the NINLARO starting dose to 3 mg in patients with severe renal impairment or end-stage renal disease requiring dialysis. NINLARO is not dialyzable.
- **Lactation:** Advise nursing women not to breastfeed during treatment with NINLARO and for 90 days after the last dose.

DRUG INTERACTIONS: Avoid concomitant administration of NINLARO with strong CYP3A inducers.

Please see accompanying NINLARO (ixazomib) full [Prescribing Information](#).



PHARMACY PREFERENCE (select one)

Specialty pharmacy (SP) name: _____ In-office dispensing No pharmacy preference

For a list of NINLARO 1Point network SPs, refer to the SP list on the back of the NINLARO 1Point Tool Kit or visit NINLARO-hcp.com/1Point

PATIENT INFORMATION

Name (First, Middle, Last): _____ Date of Birth (MM/DD/YYYY): _____ Gender: Male Female

Address: _____ Phone: _____

City: _____ State: _____ Zip: _____

Phone Type: Home Work Mobile OK to leave message? Yes No

PRESCRIBER INFORMATION

Prescriber Name (First, Middle, Last): _____ Practice Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____ Primary Office Contact: _____

State License #: _____ NPI: _____ Medicaid/Medicare Provider #: _____ Reimbursement Contact: _____

PATIENT AUTHORIZATION FOR NINLARO 1POINT SUPPORT PROGRAMS

I understand that the NINLARO 1Point Program is a prescription assistance service offered by Takeda to help eligible patients who have been prescribed NINLARO® (ixazomib) to obtain financial assistance and access other NINLARO patient support programs such as EMPOWER, which provides personalized education and support.*

I allow (give permission) for my healthcare providers, pharmacy and health plans to share my personal and medical information, including information about my insurance, prescriptions, medical condition, and health ("Personal Information") with Takeda and its agents and contractors, including NINLARO Empower and other NINLARO Support Programs (together the "Takeda Group") so that the Takeda Group can: 1) obtain information on insurance coverage for NINLARO; 2) to establish my eligibility for benefits from my health plan or other programs, upon request; 3) coordinate prescription fulfillment of NINLARO; 4) facilitate my access to NINLARO, NINLARO Empower, and other NINLARO Support Programs; 5) manage the NINLARO Empower and other NINLARO Support Programs; 6) provide me with adherence reminders and support; 7) contact me to evaluate therapy, effectiveness of the NINLARO Empower or other NINLARO Support Programs, to conduct market research, and so that I may receive educational, promotional, and/or marketing materials about NINLARO, NINLARO Empower, other NINLARO Support Programs, or Takeda products and services; and 8) for Takeda's internal business purposes, including quality control and assessment in connection with NINLARO Empower, and other NINLARO Support Programs.

I allow (give permission to) the Takeda Group to disclose my Personal Information to any pharmacies, my health insurer(s), healthcare providers, my caregivers, and other third parties for the purposes

described above. I give permission to the Takeda Group to contact me directly for the purposes described above.

I understand that my pharmacy, health insurers and third party vendors may receive remuneration (payment) from the Takeda Group in exchange for disclosing my Personal Information to the Takeda Group and/or for providing me with support services for the purposes described above.

I understand that once my Personal Information is disclosed it may no longer be protected by federal privacy law. I understand that I may refuse to sign this authorization. I also may revoke (withdraw) this authorization at any time in the future by calling 1-844-N1POINT (1-844-617-6468) or by writing PO Box 4280, Gaithersburg, MD 20885-4280. If I do not sign this authorization, I understand my eligibility for health plan benefits and treatment by my doctor will not change but I may no longer be eligible to participate in the NINLARO Empower or other NINLARO Support Programs. If I revoke this authorization, the Takeda Group will stop using or sharing my Personal Information (except as necessary to end my participation in the NINLARO Empower, and other NINLARO Support Programs) but my revocation will not affect uses and disclosures of my Personal Information previously disclosed in reliance on the NINLARO Empower, or other NINLARO Support Programs. I understand that this written authorization will remain valid for 5 years from the date of my signature, unless I revoke it earlier, or unless a shorter period is required under state laws. I understand that I may receive a copy of this authorization.

*Restrictions apply.

➔ Patient Signature: _____ **Date:** _____

CURRENT INSURANCE INFORMATION

Please attach copies of both sides of the patient's insurance card(s). Include both medical and pharmacy information if available.

Insurance Plan: Medicare Medicaid Private/Commercial Other _____

Primary Insurer Name: _____ Insurer Phone: _____

Policy Holder Name (First, Middle, Last): _____ Policy Holder Date of Birth (MM/DD/YYYY): _____

Policy ID #: _____ Group #: _____ RX BIN #: _____ RX PCN #: _____

Secondary Insurer Name: _____ Insurer Phone: _____

Policy Holder Name (First, Middle, Last): _____ Policy Holder Date of Birth (MM/DD/YYYY): _____

Policy ID #: _____ Group #: _____ RX BIN #: _____ RX PCN #: _____

Patient has no insurance Patient's insurance is pending with (include name of insurer here): _____

For full Indication and Important Safety Information, please see page 2. Please see accompanying NINLARO (ixazomib) full [Prescribing Information](#).



SHIPPING INFORMATION

Ship to patient's home address indicated above? Yes No – Ship to address below **Please note: Product cannot be shipped to a PO box**

Patient Name: _____ Contact Person Name: _____ Phone: _____

Address: _____ City: _____ State: _____ Zip: _____

STATEMENT OF MEDICAL NECESSITY

ICD-10 Code: _____

TO REQUEST A NINLARO® (IXAZOMIB) PRESCRIPTION

In order for us to send medication to your patient, the prescription information must be complete and accurate. NINLARO capsules (check 1):

4.0 mg capsule (3 pack); 63020-080-02 **3.0 mg** capsule (3 pack); 63020-079-02 **2.3 mg** capsule (3 pack); 63020-078-02

4.0 mg capsule (1 pack); 63020-080-01 **3.0 mg** capsule (1 pack); 63020-079-01 **2.3 mg** capsule (1 pack); 63020-078-01

Dispense: 28-day supply Dosing Instructions: Take 1 capsule weekly for 3 weeks Refill: _____

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. By my signature, I also acknowledge that I have obtained the patient's authorization to release the above information and such other information as may be required by Takeda and its employees or agents to assist the patient in obtaining coverage for NINLARO and/or to assist the patient in initiating or continuing NINLARO therapy. I authorize NINLARO 1Point to convey this prescription to the dispensing pharmacy.

Prescriber Signature (no stamp allowed): _____ **Date:** _____

Prescription is only valid if received by fax. **Original Signature Required. No Stamps Allowed.** Special Note: New York Prescribers, please submit prescription on an original NY State prescription blank. For all other States, if not faxed, must be on State-specific blank if applicable for your State.

OPTIONAL - NINLARO RAPIDSTART PROGRAM

Complete this additional NINLARO RapidStart Prescription and Certification for insured patients who are receiving their first prescription of NINLARO and are experiencing a delay in insurance coverage. NINLARO RapidStart Program can provide these patients with a 28-day (1-cycle) supply of NINLARO at no charge. Terms and conditions apply.*

Product Name: NINLARO Dosing Instructions: Take 1 capsule weekly for 3 weeks

Rx: **4.0 mg** capsule (3 pack) **3.0 mg** capsule (3 pack) **2.3 mg** capsule (3 pack) Day Supply: _____ 28 days

Ship to patient's home address indicated on front? Yes No – Ship to address below **Please note: Product cannot be shipped to a PO box**

Patient Name: _____ Contact Person Name: _____ Phone: _____

Address: _____ City: _____ State: _____ Zip: _____

*The RapidStart Program provides a 28-day (1-cycle) supply of treatment of NINLARO at no charge for eligible patients new to NINLARO experiencing a delay in insurance coverage. There is no purchase obligation by virtue of a patient's participation in the RapidStart Program. Patients must have an on-label prescription for NINLARO consistent with the FDA-approved label for NINLARO and be enrolled in the NINLARO 1Point Program to qualify. Free product for the RapidStart Program will only be available through the RapidStart non-commercial specialty pharmacy. A minimum 7-business day insurance verification is required for patients to be eligible for the RapidStart Program. The program may not be combined with any other offer and is not available to patients whose insurers have made a final determination to deny the patient coverage for NINLARO. Takeda reserves the right to change or end the program at any time. Benefits provided under the program are not transferable.

NINLARO is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. By signing below, I certify that this prescription is on label and that the patient is new to NINLARO treatment. I have read and understand the RapidStart Program terms and conditions and I agree that I shall not seek reimbursement for any NINLARO dispensed to the patient through the RapidStart Program from any government program or third-party insurer. I further certify that I will not attempt to sell, barter, or return for credit any NINLARO provided under this program. I understand that I am under no obligation to prescribe or purchase NINLARO or any other product manufactured by Takeda, and I certify I have received nothing of value from Takeda or its agents or representatives for prescribing a Takeda product.

Prescriber Signature (no stamp allowed): _____ **Date:** _____

By signing below and accepting the benefits of the program, I certify that I have not previously been prescribed NINLARO, and I will not seek reimbursement or credit from any insurer, healthcare plan or government program and will not sell or trade NINLARO provided under the program. If I am enrolled in a Medicare Part D plan, I certify that I will not attempt to have this prescription or any cost associated with it counted as any portion of my true out-of-pocket ("TrOOP") cost for prescription drugs calculations.

Patient Signature: _____ **Date:** _____

For full Indication and Important Safety Information, please see page 2. Please see accompanying NINLARO (ixazomib) full [Prescribing Information](#).

Takeda Oncology and are registered trademarks of Takeda Pharmaceutical Company Limited.

NINLARO is a registered trademark of Millennium Pharmaceuticals, Inc.

is a trademark of Millennium Pharmaceuticals, Inc.

Other trademarks are the property of their respective owners.

Copyright © 2017, Millennium Pharmaceuticals, Inc.

All rights reserved. 02/17 USO/IXA/15/0101a(2)

