Daiichi-Sankyo | access central™

A single source for support

Turalio® pexidartinib 125 mg capsules

Patient Enrollment Form

Completing this form allows your patient's eligibility for TURALIO support programs to be assessed. If your patient is eligible for a support program, he or she will be informed and may opt in to be automatically enrolled in that particular program. The Physician Attestation on page 3 and Patient Consent on page 4 outline the terms and conditions associated with the completion of this form. Please make sure the patient receives a copy of the Patient Consent and that both the physician and the patient review all of the information provided prior to signing this form. As a reminder, TURALIO is available only through a restricted program called the TURALIO Risk Evaluation and Mitigation Strategy (REMS) Program (www.turalioREMS.com and/or 1-833-887-2546).

TURALIO is only available through Biologics.

How to use this form

- Complete all required fields on page 2
- Please complete both prescriptions in section 4. The QuickStart prescription is optional, but completing it will allow Biologics to automatically ship a 14-day supply in the event of a coverage delay
- Print it
- Obtain physician's signature
- Obtain patient's/representative's signature
- Fax it to Biologics

Upon receiving this form, Biologics will

- Conduct a benefits investigation and assist with the completion of a prior authorization
- Assess patient eligibility for the TURALIO Copay Program
- Assess patient eligibility for the TURALIO Patient Assistance Program
- Fill the prescription upon confirmation of coverage

Biologics Contact Information

Phone
1-800-850-4306

Fax
1-800-823-4506

If you have any questions regarding TURALIO prescriptions or patient support, please call Biologics.

Please submit TURALIO prescriptions to Biologics via your preferred prescribing method. Biologics will ship the medication to your patient.

If you are licensed to practice in the state of New York, you must submit the prescription to Biologics via ePrescribing.

If you feel your patient may be eligible for the Patient Assistance Program (PAP), please fax this form to DSI Access Central at 1-833-471-9988. This form does not need to be sent to Biologics for patients eligible for PAP.

Indication and Important Safety Information

Indication and Usage

TURALIO® (pexidartinib) is indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

WARNING: HEPATOTOXICITY

- **TURALIO can cause serious and potentially fatal liver injury.**
- **Monitor liver tests prior to initiation of TURALIO and at specified intervals during treatment. Withhold and dose reduce or permanently discontinue TURALIO based on severity of hepatotoxicity.**
- **TURALIO is available only through a restricted program called the TURALIO Risk Evaluation and Mitigation Strategy (REMS) Program.**

Please see Important Safety Information on pages 5-6, and accompanying full Prescribing Information, including **Boxed WARNING**, and Medication Guide.

Daiichi-Sankyo | access central

Biologics Contact Information
Phone: 1-800-850-4306 **Fax:** 1-800-823-4506

Turalio® pexidartinib 125 mg capsules

TURALIO Patient Enrollment Form

Upon completion of this form, please fax it to Biologics. Biologics is equipped to answer your questions about the completion of this form or any of the TURALIO support programs.

1 PATIENT INFORMATION

First Name: **Middle Initial:** **Last Name:**
Date of Birth: - - **Sex:** Male Female
Phone: - - **Phone Type:** Home Mobile Work **Email:**
Address: **City:** **State:** **Zip:**
Permission to contact patient? Yes No **Best time to contact patient?** Morning Afternoon Evening
TURALIO REMS Verification Code (optional):

2 PATIENT INSURANCE INFORMATION

Uninsured **Insurance Type:** Commercial/Private Medicare Part D Medicaid Medicare Advantage Veterans Affairs (VA) Other

HEALTH PLAN INFORMATION
Plan Name:
Plan Phone Number: - -
Beneficiary Name:
Beneficiary Date of Birth: - -
Policy ID: **Group No.:**

DRUG PLAN INFORMATION
Plan Name:
Plan Phone Number: - -
Prescription Policy ID:
Prescription Group No.:
RxBIN: **RxPCN:**

If the patient has secondary insurance, please include copies of the front and back of the insurance card when submitting this form.

3 HEALTHCARE PROVIDER INFORMATION

Physician Name: **Practice Name:** **UPIN/NPI:**
Office Contact: **Phone:** - - **Fax:** - - **Email:**
Address: **City:** **State:** **Zip:**

4 TURALIO PRESCRIPTION INFORMATION

Patient Name: **Date of Birth:** - - **Diagnosis Code (ICD-10-CM):**
Product Name: TURALIO **DISPENSE AS WRITTEN**

DOSING INSTRUCTIONS: The recommended total daily dose of TURALIO is 500 mg. Please see the Prescribing Information for additional information on dosage recommendations for renal impairment and for use with concomitant medications. Please complete both prescriptions below. *Completing the QuickStart prescription is optional but allows Biologics to ship a 14-day supply, at no cost, to eligible patients with an FDA approved diagnosis, who do not receive a coverage decision within 5 business days.*

Please fill in all blank fields:

Total Daily Dose: mg *Dispense 30-day supply. No refills.*

Instructions: TURALIO 125 mg capsules: Take capsule(s) orally twice daily with a low-fat meal (approximately 11-14 grams of total fat).

Prescriber Signature: _____
Date: - -

QuickStart prescription (optional). Please fill in all blank fields:

Total Daily Dose: mg *Dispense 14-day supply. Up to 1 refill.*

Instructions: TURALIO 125 mg capsules: Take capsule(s) orally twice daily with a low-fat meal (approximately 11-14 grams of total fat).

Prescriber Signature: _____
Date: - -

Prescriber DEA Number: **Collaborating Provider Name:** **UPIN/NPI:**

5 PHYSICIAN ATTESTATION

I confirm that I have read and understood the Physician Attestation on page 3 of this form and agree to the terms explained therein.

Physician Signature: _____ **Date:** - -

6 PATIENT CONSENT

I confirm that I have read and understood the Patient Consent on page 4 of this form and agree to the terms explained therein.

Name:

Patient Signature: _____ **Date:** - -

For Representatives: If a representative for the patient needs to sign this form, please indicate the representative's authority to sign on behalf of the patient (eg, healthcare power of attorney, healthcare proxy, court-appointed legal guardian). Healthcare office staff cannot sign on behalf of the patient.

Representative Name: **Reason for Authority:** **Phone:** - -

Representative Attestation: I confirm that I have the legal right to sign this form (as stated above) on behalf of the patient. I confirm that I have read and understood the Patient Consent on page 4 of this form and agree to the terms explained therein. **Permission to contact representative?** Yes No

Representative Signature: _____ **Date:** - -

Physician Attestation

By providing my signature on page 2 of this form, I attest that I am the prescribing healthcare provider and have determined that prescribing TURALIO (pexidartinib) is medically appropriate and have explained the reasons for doing so to my patient. I also agree to submit requests to Daiichi Sankyo Access Central on behalf of my patient so that his or her eligibility can be evaluated to determine access to various assistance programs.

I certify that I have received the necessary consent from my patient to release the information referenced above and other protected health information (as defined by the Health Insurance Portability and Accountability Act [HIPAA] of 1996) to Daiichi Sankyo Access Central and/or its service providers, including Biologics specialty pharmacy. The patient has confirmed his or her consent by reading page 4 of this form and providing his or her signature on page 2 of this form. I certify that this prescription complies with all applicable state and local laws.

I agree to notify Daiichi Sankyo Access Central or its service providers if I become aware at any time of changes in my patient's circumstances that would affect his or her eligibility for any Daiichi Sankyo Access Central programs, including but not limited to changes in health insurance status or coverage, financial status, residency status in the United States, or the indication for which TURALIO has been prescribed for my patient. I understand that Daiichi Sankyo reserves the right to change or terminate any Daiichi Sankyo Access Central services (including the TURALIO Copay Program or TURALIO Patient Assistance Program) at any time or to refuse to provide TURALIO to any patient under the TURALIO Patient Assistance Program.

If my patient obtains TURALIO via the TURALIO Patient Assistance Program, I attest that I understand the following:

- No third party or patient can be charged for TURALIO under such program
- No free product should be sold, traded, or distributed for sale
- Any free drug provided is not contingent upon future purchase or prescribing of TURALIO

By signing page 2 of this form, I certify that a copy of the Patient Consent has been given to the patient named on page 2 or his or her representative.

Patient Consent

Release of Personal Information

By providing my signature on page 2 of this form, I authorize my physician(s), healthcare provider(s), health insurance company, and my pharmacy to disclose information about me (for example, my name, address, and insurance policy number) and my medical condition (for example, my diagnosis or medications) to Daiichi Sankyo and its third-party vendors, suppliers, and other service providers supporting Daiichi Sankyo Access Central, including Biologics Specialty Pharmacy (herein described collectively as "service providers"). I authorize service providers supporting Daiichi Sankyo Access Central to share information about me with each other. I recognize that this type of personally identifiable information (PII) could include spoken or written facts about my health or healthcare or copies of records about my health and insurance benefits provided by my healthcare provider(s) or health plan. My decision to sign this form (or not to sign this form) will not affect the treatment I receive from any healthcare professional or entity involved in my care or coverage.

Use of Personal Information

I understand that the service providers or pharmacy could use or provide my information in one or more of the following ways:

- Assess my eligibility and assist with my enrollment in a Daiichi Sankyo support program, including the TURALIO Copay Program or the TURALIO Patient Assistance Program, and contact me (and/or my legal representative) about my eligibility and enrollment status
- Verify, investigate, and help coordinate my coverage for TURALIO with my health insurance company
- Make referrals to other independent programs or alternate funding sources that may be able to provide me with assistance as allowed under the law, if necessary
- Assist with analyses of the efficiencies and performance of the services provided by service providers
- Provide me (and/or my legal representative) with educational materials, information, and support relating to the Daiichi Sankyo Access Central services
- Provide support to appeal any insurance denials

In some instances, the service providers may de-identify my information and use or disclose the de-identified information (in individual or aggregated form) for any legitimate business purposes. I understand that the service providers will make reasonable efforts to keep my information private; however, I understand that once my information has been disclosed to the service providers, how the service providers further disclose my information may no longer be protected under federal and state privacy laws. I understand that Daiichi Sankyo Access Central is a component of Daiichi Sankyo and that the service providers may be compensated by Daiichi Sankyo. My healthcare providers and my pharmacy may also receive remuneration, or payment, for disclosing my information pursuant to this consent document.

Consent Terms

This consent will last for 3 years from the date on this form or until I am no longer receiving TURALIO or enrolled in any Daiichi Sankyo Access Central services. I recognize that I do not have to sign the consent on page 2, but if I do not, I will not be able to have my insurance coverage verified, be given referrals for alternative funding sources, or have access to other services provided by or on behalf of Daiichi Sankyo Access Central. My decision to sign this form will not affect the treatment I receive from any healthcare professional or entity involved in my care or coverage. I may cancel this consent at any time by contacting Daiichi Sankyo Access Central at 1-866-4-DSI-NOW. By doing so, I revoke my consent for my healthcare provider to disclose my health information to Daiichi Sankyo or its service providers as well as discontinue my participation in the support program. I recognize that revoking my consent will not affect the use or the disclosure of health information that was already disclosed before my cancellation. I confirm that I have received a copy of this consent, and I know I have a right to see or copy the information my healthcare providers or payers have given to the service providers.

Additional Information to Assess Eligibility for the TURALIO Patient Assistance Program

I agree to allow Daiichi Sankyo and its associated service providers to use my demographic information, including but not limited to my name, date of birth, and/or address as needed to access my credit information and information derived from public and other sources. This includes information from a consumer reporting agency (credit bureau) to estimate my income in conjunction with the eligibility determination process performed to determine my eligibility under the TURALIO Patient Assistance Program. Daiichi Sankyo and its associated service providers reserve the right to request additional documents and information at any time. I agree to notify my healthcare providers if I undergo any changes that would, to my knowledge, affect my eligibility, including, but not limited to, changes in health insurance status or coverage, financial status, and my residing status in the United States.

The terms of this document are governed by and interpreted in accordance with the laws of the state of New Jersey, excluding New Jersey conflict of law rules, and applicable federal law.

Indication and Important Safety Information

Indication and Usage

TURALIO® (pexidartinib) is indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

WARNING: HEPATOTOXICITY

- **TURALIO can cause serious and potentially fatal liver injury.**
- **Monitor liver tests prior to initiation of TURALIO and at specified intervals during treatment. Withhold and dose reduce or permanently discontinue TURALIO based on severity of hepatotoxicity.**
- **TURALIO is available only through a restricted program called the TURALIO Risk Evaluation and Mitigation Strategy (REMS) Program.**

Contraindications

None.

Warnings and Precautions

Hepatotoxicity

TURALIO can cause serious and potentially fatal liver injury and is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

Hepatotoxicity with ductopenia and cholestasis occurred in patients treated with TURALIO. Across 768 patients who received TURALIO in clinical trials, there were two irreversible cases of cholestatic liver injury. One patient with advanced cancer and ongoing liver toxicity died and one patient required a liver transplant. The mechanism of cholestatic hepatotoxicity is unknown and its occurrence cannot be predicted. It is unknown whether liver injury occurs in the absence of increased transaminases.

In ENLIVEN, 3 of 61 (5%) patients who received TURALIO developed signs of serious liver injury, defined as ALT or AST ≥3 × upper limit of normal (ULN) with total bilirubin ≥2 × ULN. In these patients, peak ALT ranged from 6 to 9 × ULN, peak total bilirubin ranged from 2.5 to 15 × ULN, and alkaline phosphatase (ALP) was ≥2 ×ULN. ALT, AST and total bilirubin improved to <2 × ULN in these patients 1 to 7 months after discontinuing TURALIO.

Avoid TURALIO in patients with preexisting increased serum transaminases, total bilirubin, or direct bilirubin (>ULN); or active liver or biliary tract disease, including increased ALP. Monitor liver tests, including AST, ALT, total bilirubin, direct bilirubin, ALP, and gamma-glutamyl transferase (GGT), prior to initiation of TURALIO, weekly for the first 8 weeks, every 2 weeks for the next month and every 3 months thereafter. Withhold and dose reduce, or permanently discontinue TURALIO based on the severity of the hepatotoxicity. Rechallenge with a reduced dose of TURALIO may result in a recurrence of increased serum transaminases, bilirubin, or ALP. Monitor liver tests weekly for the first month after rechallenge.

TURALIO REMS

TURALIO is available only through a restricted program under a REMS, because of the risk of hepatotoxicity.

Notable requirements of the TURALIO REMS Program include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- Patients must complete and sign an enrollment form for inclusion in a patient registry.
- Pharmacies must be certified with the program and must dispense only to patients who are authorized (enrolled in the REMS patient registry) to receive TURALIO.

Further information is available at turalioREMS.com or by calling 1-833-887-2546.

Embryo-fetal toxicity

Based on animal studies and its mechanism of action, TURALIO may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use an effective nonhormonal method of contraception, since TURALIO can render hormonal contraceptives ineffective, during treatment with TURALIO and for 1 month after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with TURALIO and for 1 week after the final dose.

Adverse Reactions

The safety of TURALIO was evaluated in ENLIVEN, in which patients received TURALIO without food at a dose of 400 mg in the morning and 600 mg in the evening orally for 2 weeks followed by 400 mg orally twice daily until disease progression or unacceptable toxicity.

Serious adverse reactions were reported in 13% of patients who received TURALIO. The most frequent serious adverse reactions (occurring in >1 patient) included abnormal liver tests (3.3%) and hepatotoxicity (3.3%).

Permanent discontinuation due to adverse reactions occurred in 13% of patients who received TURALIO. The most frequent adverse reactions (occurring in >1 patient) requiring permanent discontinuation included increased ALT (4.9%), increased AST (4.9%), and hepatotoxicity (3.3%).

Dose reductions or interruptions occurred in 38% of patients who received TURALIO. The most frequent adverse reactions (occurring in >1 patient) requiring a dosage reduction or interruption were increased ALT (13%), increased AST (13%), nausea (8%), increased ALP (7%), vomiting (4.9%), increased bilirubin (3.3%), increased GGT (3.3%), dizziness (3.3%), and abdominal pain (3.3%).

The most common adverse reactions for all grades (>20%) were increased lactate dehydrogenase (92%), increased AST (88%), hair color changes (67%), fatigue (64%), increased ALT (64%), decreased neutrophils (44%), increased cholesterol (44%), increased ALP (39%), decreased lymphocytes (38%), eye edema (30%), decreased hemoglobin (30%), rash (28%), dysgeusia (26%), and decreased phosphate (25%).

Indication and Important Safety Information (*cont'd*)

Adverse Reactions (*cont'd*)

Clinically relevant adverse reactions occurring in <10% of patients were blurred vision, photophobia, diplopia, reduced visual acuity, dry mouth, stomatitis, mouth ulceration, pyrexia, cholangitis, hepatotoxicity, liver disorder, cognitive disorders (memory impairment, amnesia, confusional state, disturbance in attention, and attention deficit/hyperactivity disorder), alopecia, and skin pigment changes (hypopigmentation, depigmentation, discoloration, and hyperpigmentation).

Drug Interactions

- Use with hepatotoxic products: TURALIO can cause hepatotoxicity. In patients with increased serum transaminases, total bilirubin, or direct bilirubin (>ULN) or active liver or biliary tract disease, avoid coadministration of TURALIO with other products known to cause hepatotoxicity.
- Moderate or strong CYP3A inhibitors: Concomitant use of a moderate or strong CYP3A inhibitor may increase pexidartinib concentrations. Reduce TURALIO dosage if concomitant use of moderate or strong CYP3A inhibitors cannot be avoided.
- Strong CYP3A inducers: Concomitant use of a strong CYP3A inducer decreases pexidartinib concentrations. Avoid concomitant use of strong CYP3A inducers.
- Uridine diphosphate glucuronosyltransferase (UGT) inhibitors: Concomitant use of a UGT inhibitor increases pexidartinib concentrations. Reduce TURALIO dosage if concomitant use of UGT inhibitors cannot be avoided.
- Acid-reducing agents: Concomitant use of a proton pump inhibitor (PPI) decreases pexidartinib concentrations. Avoid concomitant use of PPIs. Use histamine-2 receptor antagonists or antacids if needed.
- CYP3A substrates: TURALIO is a moderate CYP3A inducer. Concomitant use of TURALIO decreases concentrations of CYP3A substrates. Avoid coadministration of TURALIO with hormonal contraceptives and other CYP3A substrates where minimal concentration changes may lead to serious therapeutic failure. Increase the CYP3A substrate dosage in accordance with approved product labeling if concomitant use is unavoidable.

Use in Specific Populations

- **Pregnancy:** TURALIO may cause embryo-fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to a fetus.
- **Lactation:** Because of the potential for serious adverse reactions in the breastfed child, advise women to not breastfeed during treatment with TURALIO and for at least 1 week after the final dose.
- **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to the initiation of TURALIO. Advise females of reproductive potential to use an effective nonhormonal method of contraception, since TURALIO can render hormonal contraceptives ineffective, during treatment with TURALIO and for 1 month after the final dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TURALIO and for 1 week after the final dose.
- **Renal impairment:** Reduce the dose when administering TURALIO to patients with mild to severe renal impairment (CLcr 15 to 89 mL/min, estimated by Cockcroft-Gault [C-G] using actual body weight).
- **Hepatic impairment:** Reduce the dosage of TURALIO for patients with moderate hepatic impairment (total bilirubin greater than 1.5 and up to 3 times ULN, not due to Gilbert's syndrome, with any AST). TURALIO has not been studied in patients with severe hepatic impairment (total bilirubin greater than 3 to 10 times ULN and any AST).

To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc, at 1-877-437-7763 or FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please see accompanying full Prescribing Information, including **Boxed WARNING**, and Medication Guide.

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