

# Pexidartinib (TURALIO) in Tenosynovial Giant Cell Tumor (TGCT)

## Criteria for Use

### December 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

## Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive pexidartinib.

- Baseline ALT, AST, total bilirubin, or direct bilirubin > ULN (local laboratory reference values)
- Active liver or biliary tract disease, including increased alkaline phosphatase (ALP)
- Active or chronic hepatitis B viral infection
- Active or chronic hepatitis C viral infection
- Known active or chronic HIV infection
- Concomitant use of strong CYP3A inDUCers
- Concomitant use of proton pump inhibitors
- Concomitant use of hormonal contraceptives (CYP3A substrate), unless another highly effective nonhormonal contraception<sup>1</sup> is used in combination
- Concomitant use of other CYP3A substrates when minimal decreases in drug concentration can result in serious therapeutic failures
- Unwilling or unable to comply with recommended laboratory monitoring
- Breastfeeding

## Inclusion Criteria

All criteria must be met<sup>2</sup>:

- Care is provided by a VA / VA Community Care oncologist or locally designated expert
- Histologically confirmed, symptomatic, nonmetastatic TGCT, including pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS)
- TGCT is associated with severe morbidity or functional limitations
- TGCT is not amenable to improvement with surgery, or surgical resection is likely to be associated with potentially worse functional limitation or severe morbidity
- No improvement after 12 weeks of **imatinib**, disease progression despite **imatinib**, or **imatinib** is medically inadvisable (e.g., contraindication, unmanageable toxicity, etc.)<sup>3</sup>

- Pexidartinib is prescribed at the FDA-approved dose for TGCT, modified as recommended for moderate or strong CYP3A inhibitors and UGT inhibitors (if these agents are unavoidable), and for mild to severe renal impairment (CrCl 15–89 mL/min)
- For women of childbearing potential and men who partner with women of childbearing potential: Pregnancy is excluded in the previous 14 days, and patient is counseled on use of highly effective contraception<sup>1</sup> and on risks and benefits of treatment

- 1 **Highly effective methods of contraception** include intrauterine device (nonhormonal or hormonal), bilateral tubal occlusion, vasectomy, sexual abstinence, or barrier methods (e.g., condom, diaphragm) used in combination with hormonal methods that inhibit ovulation.
- 2 Prescriber should submit a completed [TURALIO \(pexidartinib\) Prescription Form for VA](#) to the VA Pharmacy. Refer to the [TURALIO VA Ordering Summary](#) at [PBM INTRAnet](#) under [Special Handling Drugs](#). Prescriber must be certified, and the patient enrolled in the TURALIO REMS program (1-833-TURALIO or 1-833-887-2546. Enrollment forms are available at [www.turaliorems.com](http://www.turaliorems.com) ).
- 3 Use of pexidartinib without a prior trial of imatinib should be requested on a case-by-case basis after a risk-benefit discussion between the patient and provider.

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