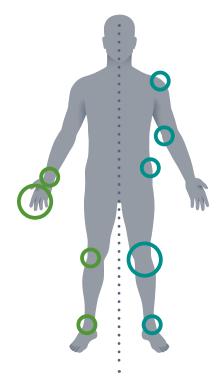
Surgical and non-surgical treatment for patients with TGCT

Both localized and diffuse TGCT may be treated surgically. However, depending on the characteristics of the tumor and your unique circumstances, there may be limited improvement expected with surgery. Another option is systemic therapy (oral medicine). This guide may help you talk with your doctors and loved ones about which treatment approach may be best for you at this time.



Considerations in selecting treatment

Questions to ask your doctor

- What type of tumor is it (localized or diffuse)? Is it widespread? What is its impact on my daily life?
- How does my age, activity level, and general health play into this treatment decision?
- Is the tumor in a location that may be challenging to reach surgically? Or a location where surgical recovery time may have a significant impact on quality of life? What is the size of the tumor?
- What are my goals for treatment?
- How will my treatment results be measured?
- If there have been prior surgeries on the tumor, what is the expectation with a repeat procedure?
- What are the possible drawbacks of surgery or oral medicine? How are those managed?

Treatment decision

- What steps toward treatment of my TGCT will my doctor take next?
- What steps toward treatment of my TGCT will I take next?

Your doctor is your best source of information. Make sure to ask your doctor if TURALIO may be an appropriate option to treat your TGCT.

What is TURALIO?

TURALIO is a prescription medicine used to treat certain adults who have tenosynovial giant cell tumor (TGCT) that is not likely to improve with surgery. TGCT is also known as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS). It is not known if TURALIO is safe and effective in children.

Important Safety Information

What is the most important information I should know about TURALIO® (pexidartinib)? TURALIO can cause serious side effects, including serious liver problems, which may be severe and can lead to death, including liver failure and a liver injury called vanishing bile duct syndrome (VBDS) that can cause the loss of bile ducts in the liver. Severe or life-threatening liver problems can happen with TURALIO even if your healthcare provider monitors liver blood tests during treatment and stops treatment with TURALIO.

Please see Important Safety Information on the reverse and Full Prescribing Information, including Boxed WARNING, and Medication Guide.

Important Safety Information (CONT.)

Your healthcare provider will do blood tests to check for liver problems before starting treatment with TURALIO, every week for the first 8 weeks during treatment, every 2 weeks for the next month, then every 3 months after that.

- If you develop liver problems during treatment with TURALIO, your healthcare provider may do blood tests more often to monitor you or refer you to a liver specialist (hepatologist). It is important to stay under the care of your healthcare provider during treatment with TURALIO. Stop taking TURALIO and call your healthcare provider right away if you develop yellowing of your skin and whites of your eyes or dark urine. Tell your healthcare provider right away if you have any of these symptoms of liver problems during treatment with TURALIO: lack or loss of appetite, right upper stomach-area (abdomen) pain or tenderness, feeling overly tired, nausea, vomiting, fever, rash, or itching.
- Because of the risk of serious liver problems, TURALIO is available only through a restricted program called the TURALIO REMS
 Program. Your healthcare provider must be enrolled in the program in order for you to be prescribed TURALIO. There is a registry that collects information about the effects of taking TURALIO over time. You must complete and sign an enrollment form for the TURALIO REMS Program and the registry. Ask your healthcare provider for more information.

Before you take TURALIO, tell your healthcare provider about all of your medical conditions, including if you have or had liver or kidney problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. TURALIO may harm your baby. Do not breastfeed during treatment with TURALIO and for at least 1 week after your final dose.

• If you are a female who is able to become pregnant, your healthcare provider will do a pregnancy test before you start treatment with TURALIO. You should use an effective non-hormonal method of birth control (contraception) during

- treatment with TURALIO and for 1 month after your final dose of TURALIO. Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective if used during treatment with TURALIO. Talk with your healthcare provider about birth control methods you can use during this time. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with TURALIO.
- If you are a male with a female partner who is able to become pregnant, use effective birth control (contraception) during treatment and for 1 week after your final dose of TURALIO. Tell your healthcare provider right away if your female partner becomes pregnant or thinks she is pregnant during your treatment with TURALIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect the way TURALIO works and TURALIO may affect how other medicines work. Taking TURALIO with certain medicines may increase the amount of TURALIO in your blood. This may make it more likely for you to have side effects and may cause more severe side effects. Avoid taking proton pump inhibitor medicines and St. John's wort because they can affect how TURALIO works. If you take an antacid medicine, take TURALIO either 2 hours before or 2 hours after taking an antacid medicine. If you take an H₂ receptor blocker medicine, take TURALIO at least 2 hours before or **10 hours after** taking an H₂ receptor blocker medicine.

Take TURALIO with a low-fat meal (about 11 to 14 grams of total fat).

See "What should I avoid while taking TURALIO?" TURALIO capsules must be swallowed whole. Do not open, break, or chew TURALIO capsules.

What should I avoid while taking TURALIO?

 Avoid taking TURALIO with a high-fat meal (about 55 to 65 grams of total fat).

- Taking TURALIO with a high-fat meal increases the amount of TURALIO in your blood. This may make it more likely for you to develop side effects and may cause more severe side effects, including serious liver problems.
- Avoid grapefruit or drinking grapefruit juice during treatment with TURALIO. Grapefruit or grapefruit juice can cause you to have too much TURALIO in your blood and may lead to increased side effects and more severe side effects.
- Avoid spending prolonged time in sunlight. TURALIO can make your skin sensitive to the sun (photosensitivity), and you may burn more easily. You should use sunscreen and wear protective clothing that covers your skin to help protect against sunburn if you have to be in the sunlight during treatment with TURALIO.

What are the most common side effects of TURALIO?

The most common side effects of TURALIO include changes in blood liver tests; hair color changes; tiredness; increased cholesterol level in the blood; decreased white blood cells and red blood cells; swelling in or around your eyes; rash, itching, hives, skin redness, and acne; loss of taste or changes in the way things taste; and decreased phosphate in your blood.

TURALIO may affect fertility in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of TURALIO. Call your doctor for medical advice about side effects. You are encouraged to report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see <u>Medication Guide</u>, including Important Warning.



