Precision medicine treatments (also known as targeted therapies) have the potential to improve outcomes for patients with advanced cancer. However, it can be challenging for oncologists to navigate the options available for each patient. This illustration provides a guide that clinicians can use to determine whether a targeted therapy is a viable treatment option. The first step is ordering and evaluating a genomic test.

1. **DOES THE TUMOR GENOMIC TEST REVEAL AN ACTIONABLE ALTERATION?**

   - **YES**
     - There is an actionable target AND an FDA approved drug for the target
     - Administer

   - **NO**
     - There is no actionable target and/or no therapies for the target
     - Discuss, consent, and enroll

   Is the cancer type “On Label”?

   - **Yes**
     - Do clinical pathways, compendia, or published literature support clinical use and reimbursement?
     - Yes
     - Obtain payer authorization to prescribe.
     - Yes
     - Discuss, consent, and enroll
     - Yes
     - Examine options for financial assistance
   
   - **No**
     - Administer

   - **No**
     - Is a clinical trial available?
     - Yes
     - Does drug manufacturer make the investigational therapy available?
     - Yes
     - Will FDA approve use through Expanded Access Program?
     - Yes
     - Administer

   - **No**
     - Manufacturer does not provide access for this patient

   - **No**
     - Is there sufficient data to proceed with off-label use?
     - Yes
     - Discuss, consent, administer.
     - No
     - therapy not appropriate

**REFERENCE:** Bruinooge SS, Sherwood S, Grubbs S, Schilsky RL. Determining if a Somatic Tumor Mutation is Targetable and Options for Accessing Targeted Therapies. J Oncol Pract 2019

1. The extent to which a clinician can take clinical action depends on 1) evidence related to role of the genomic biomarker in the patient’s cancer and 2) the ability of a therapy to target the genomic alteration.
2. Dependent on eligibility criteria, location of trial, and whether patient is willing and able to travel.
3. FDA approves 99% of Expanded Access requests.

**Over the past 5 years**

- **20%** of all Food and Drug Administration (FDA) drug approvals have been for precision medicine treatments.
- **FDA approved** 20 companion diagnostics

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