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.

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

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

  - Is the cancer type “On Label”?
    - **Yes**
      - Administer
    - **No**
      - Do clinical pathways, compendia, or published literature support clinical use and reimbursement?
        - **Yes**
          - Discuss, consent, and enroll
        - **No**
          - Obtain payer authorization to prescribe.

  - Is a clinical trial available?
    - **Yes**
      - Is there sufficient data to proceed with off-label use?
        - **Yes**
          - Examine options for financial assistance
        - **No**
          - No, therapy not appropriate
    - **No**
      - Is a clinical trial available?
        - **Yes**
          - Discuss, consent, and enroll
        - **No**
          - No, therapy not appropriate

- **NO**
  - There is no actionable target and/or no therapies for the target

  - Is a clinical trial available?
    - **Yes**
      - Discuss, consent, and enroll
    - **No**
      - Does drug manufacturer make the investigational therapy available?
        - **Yes**
          - In Right to Try program
        - **No**
          - Manufacturer does not provide access for this patient

  - Will FDA approve use through Expanded Access Program?
    - **Yes**
      - Administer
    - **No**
      - No, therapy not approved

**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.