 Draft New Policy: Do Not Implement

Next-generation sequencing for the assessment of measurable residual disease

DESCRIPTION

Measurable residual disease or minimal residual disease (MRD) refers to residual clonal cells that are still in the blood or bone marrow after treatment for hematologic malignancies. It is typically assessed using flow cytometry (FC) or polymerase chain reaction that can detect 1 clonal cell in 100,000 cells. Next-generation sequencing (NGS) is being proposed to improve the health outcomes in individuals who have been treated for hematological malignancies (e.g., acute lymphoblastic leukemia (ALL), chronic lymphoblastic leukemia (CLL), multiple myeloma (MM), diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL)) as it can detect 1 leukemic cell out of 1,000,000 cells.

The clonoSEQ® minimal residual disease test is offered by Adaptive Biotechnologies, previously marketed as clonoSIGHT™ (Sequenta) in 2015. In 2018, clonoSEQ®, received de novo clearance from the Food and drug administration (FDA) for individuals with ALL. In 2020 it received marketing clearance for CLL.

POLICY

- Next-generation sequencing to detect measurable residual disease is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Next-generation sequencing to detect measurable residual disease, including, but not limited to, the following is considered ***investigational*****:**
  - Diffuse large B-cell lymphoma
  - Mantle Cell Lymphoma

MEDICAL APPROPRIATENESS

- Next-generation sequencing (e.g., clonoSEQ) to detect measurable residual disease is considered **medically appropriate** if **ANY ONE** of the following are met:
  - Individual has a threshold of 10^{-4} and **ANY ONE** of the following:
    - Acute lymphoblastic leukemia
    - Chronic lymphocytic leukemia
  - Individual has a threshold of 10^{-5} with multiple myeloma

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g., statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

ADDITIONAL INFORMATION

The evidence available on NGS for detection of MRD in diffuse large B-Cell lymphoma and mantle cell lymphoma are lacking clinical validity or utility.

SOURCES

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EFFECTIVE DATE

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