December 13, 2024

Carmen Heredia
Director
Arizona Health Care Cost Containment System (AHCCCS)
801 E Jefferson Street
Phoenix, AZ 85034

Dear Director Heredia,

The American Cancer Society Cancer Action Network (ACS CAN) and our partners appreciate the opportunity to comment on the AHCCCS Medical Policy 310-KK on Biomarker Testing. Our organizations are working to improve access to comprehensive biomarker testing so that patients can benefit from the most effective treatments for their disease. Data shows that patients receiving targeted treatments, also known as precision medicine, experience better health outcomes, yet patient access to this type of testing has not kept pace with the rate of innovation due to a variety of factors, including lack of coverage or overly restrictive coverage policies by both public and private payers.

We appreciate AHCCCS's continued work to implement the coverage of biomarker testing required under the revised statute according to AZ HB2144 that was signed into law over two years ago. The recent changes in the AHCCCS Medical Policy Manual "approved 10/30/24," however, are extremely concerning as the new 310-KK section will drastically restrict biomarker testing and is in direct conflict with AZ Rev Stat § 20-1406.10 (2023). **We urge you to reject these changes and revert to the previous version of your policy.**

AZ HB2144 and the subsequent revised statute set forth to establish minimum coverage requirements for public and private payers with regard to evidence-based biomarker testing. The legislation provides coverage of testing under specific purposes: *diagnosis, treatment, appropriate management or ongoing monitoring of a disease or condition,* when certain categories of evidence are met: *Labeled indications for tests that are approved or cleared by the United States food and drug administration or indicated tests for a drug that is approved by the United States food and drug administration; Centers for medicare and medicaid services national coverage determinations or medicare administrative contractor local coverage determinations; Nationally recognized clinical practice guidelines and consensus statements*.

The legislation and subsequent law do ***not*** limit biomarker testing to that used for patients with cancer. In fact, the statute is purposefully agnostic to the patient's disease or condition and instead focuses on the application of testing and evidence threshold. Unfortunately, the revised 310-KK explicitly limits testing to certain cancer patients. Specifically, the non-covered section states, "Biomarker testing is **not** covered when: (a.) The member does **not have an active oncology diagnosis**." This interpretation is counter to the statute which never mentions oncology nor any other disease or condition explicitly. The limitation to "active oncology diagnosis" could prevent patients from accessing appropriate monitoring testing after completing active treatment. Biomarker testing has been validated and shown to improve health outcomes for patients with a variety of diseases and conditions like rheumatoid arthritis, major depressive disorder, Alzheimer's

disease, organ transplantation, Parkinson's disease and other rare diseases. The law was meant to require coverage for testing in these areas and more as long as the evidence categories specified in law are met.

The new non-covered section goes on to further limit the type of biomarker testing even for patients with cancer. First, the policy requires tests be performed on tumor tissue. This limitation is narrow and conflicts with the language in 36-2907.03 (D)(2)(b) that is inclusive of all human sample types - "biomarker testing means the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker." This is critically important as technology has been evolving and can now detect biomarkers in blood samples which increases access to testing given the less invasive nature of the sample collection.

Second, sections (c) and (d) limit testing by requiring that tests must be for a *specific* drug rather than a "high-level therapeutic drug class." This requirement is not only counter to FDA-approved labels which seek to harmonize biomarker test labels with entire classes of drugs to ensure broad access[1], but is also counter to the statute which identifies **any** labeled indication approved or cleared by FDA to be evidence of clinical utility (36-2907.03 (A)(1.)). This restriction to tests that function as companion diagnostics also appears earlier in the policy as a limiting factor in section III (A)(2)(a) and is counter to the statute that references "labeled indications for tests that are approved or cleared by the US FDA".

Given the dramatic divergences from the statute displayed in Table 1., **we urge you to revert to the previous version of the biomarker 310-KK policy.** Ensuring appropriate access to biomarker testing as set forth in the statute will enable AHCCCS enrollees to have access to the best precision care tailored to their personal needs. We remain committed to working with you on the implementation of AZ HB2144 as passed. If you have any questions or would like to discuss further, please contact Brian Hummell, Arizona Government Relations Director for ACS CAN at Brian.Hummell@cancer.org.

Sincerely,

AiArthritis: International Foundation for Autoimmune & Autoinflammatory Arthritis
ALS Arizona
ALS Association
American Cancer Society Cancer Action Network
American Lung Association
American Society of Pharmacovigilance
Arizona Chronic Care Together Coalition
American Kidney Fund
Arizona Pharmacy Association
Arthritis Foundation
Association for the Chronically Mentally Ill (ACMI)
Biomarker Collaborative
Brain Injury Association of Arizona
CancerCare
Cancer Support Community
CLL Society
Colon Cancer Coalition
Colorectal Cancer Alliance
Crohn's & Colitis Foundation
Debbie's Dream Foundation: Curing Stomach Cancer
End Preeclampsia
Exon 20 Group

[1] Table "Device Indication for a Specific Group of Oncology Therapeutic Products" https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools

Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
GI Cancers Alliance
Global Colon Cancer Association
Global Liver Institute
GO2 for Lung Cancer
Honor the Gift
ICAN, International Cancer Advocacy Network
KRAS Kickers
Lung Cancer Research Foundation
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
MET Crusaders
Michael J. Fox Foundation
National Organization for Rare Diseases (NORD)
National Ovarian Cancer Coalition
Neuropathy Action Foundation
No Stomach for Cancer
Oncology Nursing Society
One Cancer Place
Ovarian Cancer Research Alliance
Patient Empowerment Network
Patients Rising
PD-L1 Amplifieds
Raymond Foundation
Sharsheret
Stupid Cancer
Susan G. Komen
Test Your Biomarkers
Tigerlily Foundation
Triage Cancer
VHL Alliance
ZERO Prostate Cancer

Table 1. Statute vs Policy Manual (emphasis added)

ARS 36-2097.03
A. The administration and its contractors shall provide biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a member's disease or condition to guide treatment decisions when the test provides clinical utility as demonstrated by medical and scientific evidence, including any of the following: 1. **Labeled indications for tests that are approved or cleared by the United States food and drug administration** or indicated tests for a drug that is approved by the United States food and drug administration. 2. Centers for medicare and medicaid services national coverage determinations or medicare administrative contractor local coverage determinations. 3. Nationally recognized clinical practice guidelines and consensus statements. B. The administration and its contractors shall provide biomarker testing with the same scope, duration and frequency as the system otherwise provides to members pursuant to this article. C. The member and prescribing practitioner must have access to a clear, readily accessible and convenient online process to request an exception to a coverage policy of the system. This subsection does not require a separate process if the administration's and its contractor's existing process complies with this subsection. Any request for a coverage exception shall be submitted electronically by the prescribing practitioner.

310-KK Biomarker Testing

C. NON-COVERED INDICATIONS

1. Biomarker testing is not covered when:
    a. The member does not have an **active oncology** diagnosis,
    b. The member does not have an **active oncology** diagnosis and the test is a screening tool or exploratory,
    c. The requested test is not:
        i. For a **specific drug**,
        ii. Being performed **on an excised tumor/biopsy**, or
        iii. An FDA Companion Test or a gene mutation test for a specific drug with treatment and consensus guidelines available to guide drug therapy.
    d. **The testing is to provide high-level therapeutic drug class information and is not for a specific drug,**
    e. The level(s) of evidence do not support the requested test, for example, the NCCN guidelines has identified the test as a Category 3 and is defined as based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate, or the test has a Hayes Rating System of less than A, or a.
    f. The testing is performed on patients for the purposes of screening members or their relatives.

2. Pharmacogenomic and Pharmacogenetics Testing including but not limited to:
    a. Genotyping for cytochrome P450 polymorphisms, diagnostic tests to identify specific genetic variations including but not limited to, CYP2C9, CYP2C19, CYP2D6, CYP3A4 or CYP3A5, that may be linked to reduced/enhanced effects or severe side effects of drugs metabolized by the cytochrome P450 system is not covered,
    b. Multigene pharmacogenetics panels, for example, diagnostic tests to identify specific genetic variations that may be linked to reduced/enhanced metabolism and/or severe side effects of multiple classes of drugs is not covered,
    c. Pharmacogenetic testing, for example, genotyping or a mutation analysis may be covered for major depressive and generalized anxiety disorders when medically necessary and the criteria below are met.
        i. For Major Depressive Disorder (MDD):
            1) The member has been diagnosed with MDD, and
            2) The member has been treated with a sufficient trial at maximum tolerated doses of the following:
                a) A Selective Serotonin Reuptake Inhibitor (SSRI),
                b) A Serotonin and Norepinephrine Reuptake Inhibitor (NSRI),
                c) An atypical antidepressant (e.g., bupropion, mirtazapine), or
                d) An atypical antipsychotic as augmentation or monotherapy.
        ii. For Generalized Anxiety Disorders (GAD)
            1) The member has been diagnosed with GAD, and
            2) The member has been treated with a sufficient trial at maximum tolerated doses of the following:
                a) A Selective Serotonin Reuptake Inhibitor (SSRI),
                b) A Serotonin and Norepinephrine Reuptake Inhibitor (NSRI), or
                c) A Benzodiazepine, or
            3) Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.