By Senator Wright

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A bill to be entitled

An act relating to biomarker testing; amending s. 409.905, F.S.; requiring the Agency for Health Care Administration to pay for biomarker testing under the state Medicaid program for specified purposes; defining terms; specifying tests and circumstances for testing which are deemed covered; requiring certain entities contracted with the program to provide coverage of biomarker testing in the same manner as the program provides to its recipients; requiring the agency to act on a prior authorization request for biomarker testing and notify specified parties within specified timeframes, if the program requires such utilization review procedures; requiring the agency to provide a clear, readily accessible, and convenient process on its website for requesting an exception to the terms of coverage or to appeal certain adverse utilization review determinations; creating ss. 627.64055, 627.6614, and 641.31078, F.S.; defining terms; beginning on a specified date, requiring individual health insurance policies; group, blanket, and franchise health insurance policies; and health maintenance contracts, respectively, to provide coverage for biomarker testing under certain circumstances; specifying tests and circumstances for testing which are deemed covered; requiring coverage to be provided in a manner that limits disruption in care; requiring insurers and health maintenance organizations, as applicable, to act on a prior

authorization request and notify specified parties within specified timeframes if they require such utilization review procedures; requiring insurers and health maintenance organizations, as applicable, to provide a clear, readily accessible, and convenient process on their websites for requesting exceptions to policy or contract terms, as applicable, and for appealing certain adverse utilization review determinations; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (13) is added to section 409.905, Florida Statutes, to read:

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(13) BIOMARKER TESTING SERVICES.—The agency shall pay for biomarker testing for diagnosis, treatment, management, and ongoing monitoring of an insured's disease or condition if use of the test is supported by medical and scientific evidence.

(a) As used in this subsection, the term:

1. "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. The term includes, but is not limited to, gene mutations, characteristics of genes, and protein expression.

2. "Biomarker testing" means the analysis of a patient's tissue, blood, or other biological specimen for the presence of a biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression analysis, and whole exome, whole genome, and whole transcriptome sequencing.

3. "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy. These statements address specific clinical circumstances, and the experts base these statements on the best available evidence to optimize the outcomes of clinical care.

4. "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies

using a transparent methodology and reporting structure and with a conflict of interest policy. These guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(b) For purposes of coverage of biomarker testing, all of the following tests and circumstances for testing are deemed to be supported by medical and scientific evidence:

1. A test approved or cleared by the United States Food and Drug Administration.

2. Indicated tests for a drug approved by the United States Food and Drug Administration.

3. Warnings and precautions on the label for a drug approved by the United States Food and Drug Administration.

4. Tests approved under the Centers for Medicare and Medicaid Services national coverage determination process or the local coverage determination process of a Medicare Administrative Contractor.

5. Nationally recognized clinical practice guidelines and consensus statements.

(c) Risk-bearing entities contracted with the program to deliver services to recipients must provide coverage of biomarker testing in the same manner as the program otherwise provides to recipients.

(d) If utilization review for biomarker testing is required, the program, utilization review entity, or third party acting on behalf of the program must approve or deny a prior authorization request and notify the enrollee, the enrollee's

health care provider, and any entity requesting authorization of the service within 72 hours after a nonurgent request and within 24 hours after an urgent request.

(e) The agency must provide a clear, readily accessible, and convenient process on its website for an enrollee or a provider to request an exception to the terms of coverage or to appeal an adverse utilization review determination relating to biomarker testing services.

Section 2. Section 627.64055, Florida Statutes, is created to read:

627.64055 Coverage of biomarker testing.—

(1) As used in this section, the term:

(a) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. The term includes, but is not limited to, gene mutations, characteristics of genes, and protein expression.

(b) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biological specimen for the presence of a biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression analysis, and whole exome, whole genome, and whole transcriptome sequencing.

(c) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a

conflict of interest policy. These statements address specific clinical circumstances, and the experts base these statements on the best available evidence to optimize the outcomes of clinical care.

(d) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict of interest policy. These guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(2) A health insurance policy issued, delivered, or renewed in this state on or after July 1, 2023, must provide coverage for biomarker testing for diagnosis, treatment, management, or ongoing monitoring of an insured's disease or condition if use of the test is supported by medical and scientific evidence. For purposes of coverage, all of the following tests and circumstances for testing are deemed to be supported by medical and scientific evidence:

(a) A test approved or cleared by the United States Food and Drug Administration.

(b) Indicated tests for a drug approved by the United States Food and Drug Administration.

(c) Warnings and precautions on the label for a drug approved by the United States Food and Drug Administration.

(d) Tests approved under the Centers for Medicare and Medicaid Services national coverage determination process or the

local coverage determination process of a Medicare Administrative Contractor.

(e) Nationally recognized clinical practice guidelines and consensus statements.

(3) Insurers must ensure that coverage of biomarker testing is provided in a manner that limits disruptions in care, including, but not limited to, coverage of biomarker testing for multiple biopsies or biological specimen samples if needed.

(4) If utilization review for biomarker testing is required, the insurer, utilization review entity, or third party acting on behalf of the insurer must approve or deny a prior authorization request and notify the insured, the insured's health care provider, and any entity requesting authorization of the service within 72 hours after a nonurgent request and within 24 hours after an urgent request.

(5) Insurers must provide a clear, readily accessible, and convenient process on their websites for requesting an exception to the terms of a policy or for appealing an adverse utilization review determination relating to biomarker testing services.

Section 3. Section 627.6614, Florida Statutes, is created to read:

627.6614 Coverage of biomarker testing.—

(1) As used in this section, the term:

(a) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. The term includes, but is not limited to,

gene mutations, characteristics of genes, and protein expression.

(b) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biological specimen for the presence of a biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression analysis, and whole exome, whole genome, and whole transcriptome sequencing.

(c) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy. These statements address specific clinical circumstances, and the experts base these statements on the best available evidence to optimize the outcomes of clinical care.

(d) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict of interest policy. These guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(2) A group, blanket, or franchise health insurance policy issued, delivered, or renewed in this state on or after July 1, 2023, must provide coverage for biomarker testing for diagnosis, treatment, management, or ongoing monitoring of an insured's disease or condition if use of the test is supported by medical

and scientific evidence. For purposes of coverage, all of the following tests and circumstances for testing are deemed to be supported by medical and scientific evidence:

(a) A test approved or cleared by the United States Food and Drug Administration.

(b) Indicated tests for a drug approved by the United States Food and Drug Administration.

(c) Warnings and precautions on the label for a drug approved by the United States Food and Drug Administration.

(d) Tests approved under the Centers for Medicare and Medicaid Services' national coverage determination process or the local coverage determination process of a Medicare Administrative Contractor.

(e) Nationally recognized clinical practice guidelines and consensus statements.

(3) Insurers must ensure that coverage of biomarker testing is provided in a manner that limits disruptions in care, including, but not limited to, coverage of biomarker testing for multiple biopsies or biological specimen samples if needed.

(4) If utilization review for biomarker testing is required, the insurer, utilization review entity, or third party acting on behalf of the insurer must approve or deny a prior authorization request and notify the insured, the insured's health care provider, and any entity requesting authorization of the service within 72 hours after a nonurgent request and within 24 hours after an urgent request.

(5) Insurers must provide a clear, readily accessible, and convenient process on their websites for requesting an exception to the terms of a policy or for appealing an adverse utilization

review determination relating to biomarker testing services.

Section 4. Section 641.31078, Florida Statutes, is created to read:

641.31078 Coverage of biomarker testing.—

(1) As used in this section, the term:

(a) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. The term includes, but is not limited to, gene mutations, characteristics of genes, and protein expression.

(b) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biological specimen for the presence of a biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression analysis, and whole exome, whole genome, and whole transcriptome sequencing.

(c) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy. These statements address specific clinical circumstances, and the experts base these statements on the best available evidence to optimize the outcomes of clinical care.

(d) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies

using a transparent methodology and reporting structure and with a conflict of interest policy. These guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(2) A health maintenance contract issued, delivered, or renewed in this state on or after July 1, 2023, must provide coverage for biomarker testing for diagnosis, treatment, management, or ongoing monitoring of a subscriber's disease or condition if use of the test is supported by medical and scientific evidence. For purposes of coverage, all of the following tests and circumstances for testing are deemed to be supported by medical and scientific evidence:

(a) A test approved or cleared by the United States Food and Drug Administration.

(b) Indicated tests for a drug approved by the United States Food and Drug Administration.

(c) Warnings and precautions on the label for a drug approved by the United States Food and Drug Administration.

(d) Tests approved under the Centers for Medicare and Medicaid Services national coverage determination process or the local coverage determination process of a Medicare Administrative Contractor.

(e) Nationally recognized clinical practice guidelines and consensus statements.

(3) Health maintenance organizations must ensure that coverage of biomarker testing is provided in a manner that limits disruptions in care, including, but not limited to,

coverage of biomarker testing for multiple biopsies or biological specimen samples if needed.

(4) If utilization review for biomarker testing is required, the health maintenance organization, utilization review entity, or third party acting on behalf of the health maintenance organization must approve or deny a prior authorization request and notify the subscriber, the subscriber's health care provider, and any entity requesting authorization of the service within 72 hours after a nonurgent request and within 24 hours after an urgent request.

(5) Health maintenance organizations must provide a clear, readily accessible, and convenient process on their websites for requesting an exception to the terms of a health maintenance contract or for appealing an adverse utilization review determination relating to biomarker testing services.

Section 5. This act shall take effect July 1, 2023.