



Via Email

Deputy Administrator and Director Dr. Ellen Montz  
Center for Consumer Information and Insurance Oversight  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Baltimore, Maryland 21244

September 6, 2024

Re: Coverage of Biomarker Testing

Dear Director Montz,

In 2024, the Colorado General Assembly passed Senate Bill (SB) 24-124, which requires carriers to cover biomarker testing for diagnosis, treatment, appropriate management, and ongoing monitoring of a covered person's disease or condition to guide treatment decisions when the test is supported by medical and scientific evidence. This includes: (i) labeled indications for an FDA-approved or FDA-cleared test; (ii) indicated tests for an FDA-Approved drug; (iii) warnings and precautions of FDA-approved drug labels; (iv) centers for Medicare and Medicaid services national coverage determinations or Medicare administrative contractor local coverage determinations; or (v) nationally recognized clinical practice guidelines, consensus statements, and peer-reviewed studies.

Pursuant to SB24-124 and 45 C.F.R. § 155.170(a)(3), which provides that states will identify which state-required benefits are in addition to the Essential Health Benefits ("EHBs"), the Division of Insurance ("Division") has determined that biomarker testing coverage set forth in SB24-124 is not a benefit that is in addition to the EHBs and, therefore, Colorado is not required to defray the cost. Additionally, pursuant to SB24-124, the Division is required to submit its determination to the Department of Health & Human Services ("HHS") and request that HHS confirm the Division's determination within sixty (60) days after receiving this submission. Under SB24-124, if HHS fails to respond within 365 days to this submission, the Division is required to consider HHS' unreasonable delay a preclusion from requiring defrayal.

The Division has determined that the biomarker testing coverage requirement in SB24-124 is not a new mandate requiring state defrayal under the Affordable Care Act because

biomarker testing coverage is an EHB that is covered in Colorado's EHB-benchmark plan.<sup>1</sup> In the Notice of Benefit and Payment Parameters for 2025, HHS finalized an amendment to 45 C.F.R. § 155.170(a)(2), which states that "a benefit covered in the State's EHB-benchmark plan is considered an EHB." Further, the released guidance states that "benefits covered in a State's EHB benchmark plan will not be considered in addition to EHB, even if they had been required by State action taking place after December 31, 2011."<sup>2</sup> Additionally, HHS stated "under this policy, there would be no obligation for the State to defray the cost of a State mandate enacted after December 31, 2011, that requires coverage of a benefit if that benefit is included in the State's EHB-benchmark plan."<sup>3</sup>

Biomarker testing coverage is required to be covered by Colorado's EHB-benchmark plan as laboratory and radiology services.<sup>4</sup> Colorado's 2023 EHB-benchmark plan (as have previous benchmark plans) requires individual and small group health benefit plans to cover laboratory and radiology services. In the outpatient setting, diagnostic X-ray and laboratory tests, services and materials, including isotopes, electrocardiograms, electroencephalograms and mammograms are covered. In addition, therapeutic X-ray services and special procedures such as MRI, CT, PET and nuclear medicine are required to be covered in an outpatient setting. In the inpatient setting, during a hospitalization, diagnostic X-ray and laboratory tests, services and materials, including diagnostic and therapeutic X-rays and isotopes, electrocardiograms, electroencephalograms, MRI, CT, PET and nuclear medicine are covered without charge.

To further illustrate that biomarker testing is already included in the EHB-benchmark plan, in December 2023, the Division provided a coverage survey of individual, small group, and large group carriers in Colorado with plans regulated by the Division. The survey defined biomarker testing as an analysis of a patient's tissue, blood, or other biospecimen for the presence of an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. The survey assumed coverage determinations were based on national recognized clinical practice guidelines.<sup>5</sup> The results indicated that carriers are currently covering 100% of biomarker tests.

Finally, the Division notes that SB24-124 expressly states that coverage for biomarker testing is required "to the extent that such coverage is not in addition to the benefits provided pursuant to the benchmark plan." This further demonstrates that SB24-124 simply enacted a

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<sup>1</sup> See 42 U.S.C. § 18022(b)(1)(H) (essential health benefits are required to include "laboratory services."); C.R.S. § 10-16-102(22)(b)(IV) (Colorado definition of essential health benefits aligns with 42 U.S.C. § 18022 to also include "laboratory services.").

<sup>2</sup> Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid, Consumer Operated and Oriented Plan (CO-OP) Program' and Basic Health Program, 89 Fed. Reg. 26218-01, 26225 (April 15, 2024).

<sup>3</sup>*Id.*

<sup>4</sup> Colorado Benchmark Plan, available here [https://drive.google.com/file/d/1uO1hZ\\_-AIZmCGq4Y33YpAoejj9luhHRC/view](https://drive.google.com/file/d/1uO1hZ_-AIZmCGq4Y33YpAoejj9luhHRC/view).

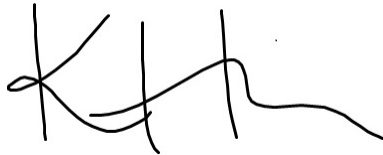
<sup>5</sup> Biomarker Testing Coverage Analysis, Milliman report, available here <https://drive.google.com/file/d/1NxRUaa0HV7me8iUbUzllNGsmhrrnr1ru/view>

mandate that requires coverage of a benefit that is already included in Colorado's EHB-benchmark plan.

Because biomarker testing coverage is a benefit covered in Colorado's EHB-benchmark plan, biomarker testing coverage is an EHB and, therefore, the Division has determined that Colorado is under no obligation to defray the cost.

Please let us know if you have any questions or would like to discuss this matter further with the Division.

Sincerely,

A handwritten signature in black ink, appearing to be 'KH' followed by a stylized flourish.

Kate Harris  
Chief Deputy Commissioner

Cc: Rebecca Bucchieri, CMS