## ENGROSSED SUBSTITUTE HOUSE BILL 1689

## State of Washington 67th Legislature 2022 Regular Session

 $\mathbf{B}\mathbf{v}$ Health Care & Wellness (originally sponsored Harris, Leavitt, Graham, Representatives Walen, Duerr, Slatter, and Tharinger)

READ FIRST TIME 01/27/22.

- AN ACT Relating to exempting biomarker testing from prior 1 2 authorization for patients with late stage cancer; adding a new 3 section to chapter 48.43 RCW; and adding a new section to chapter
- 74.09 RCW. 4

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- BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON: 5
- 6 NEW SECTION. Sec. 1. A new section is added to chapter 48.43 7 RCW to read as follows:
- 8 (1) Health plans issued or renewed on or after January 1, 2023, 9 shall exempt an enrollee from prior authorization requirements for coverage of biomarker testing for either of the following: 10
  - (a) Stage 3 or 4 cancer; or
- (b) Recurrent, relapsed, refractory, or metastatic cancer. 12
- (2) For purposes of this section, "biomarker test" means a single 13 14 or multigene diagnostic test of the cancer patient's biospecimen, 15 such as tissue, blood, or other bodily fluids, for DNA, RNA, or 16 protein alterations, including phenotypic characteristics of a 17 malignancy, to identify an individual with a subtype of cancer, in order to quide patient treatment. 18
- 19 (3) For purposes of this section, biomarker testing must be:

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- (a) Recommended in the latest version of nationally recognized guidelines or biomarker compendia, such as those published by the national comprehensive cancer network;
  - (b) Approved by the United States food and drug administration or a validated clinical laboratory test performed in a clinical laboratory certified under the clinical laboratory improvement amendments or in an alternative laboratory program approved by the centers for medicare and medicaid services;
    - (c) A covered service; and

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- (d) Prescribed by an in-network provider.
- 11 (4) This section does not limit, prohibit, or modify an 12 enrollee's rights to biomarker testing as part of an approved 13 clinical trial under chapter 69.77 RCW.
- 14 (5) Nothing in this section may be construed to mandate coverage 15 of a health care service.
- 16 (6) Nothing in this section prohibits a health plan from 17 requiring a biomarker test prior to approving a drug or treatment.
- 18 (7) This section does not limit an enrollee's rights to access 19 individual gene tests.
- NEW SECTION. Sec. 2. A new section is added to chapter 74.09
  RCW to read as follows:
  - (1) Upon initiation or renewal of a contract with the authority to administer a medicaid managed care plan, a managed care organization shall exempt an enrollee from prior authorization requirements for coverage of biomarker testing for either of the following:
    - (a) Stage 3 or 4 cancer; or
- 28 (b) Recurrent, relapsed, refractory, or metastatic cancer.
  - (2) For purposes of this section, "biomarker test" means a single or multigene diagnostic test of the cancer patient's biospecimen, such as tissue, blood, or other bodily fluids, for DNA, RNA, or protein alterations, including phenotypic characteristics of a malignancy, to identify an individual with a subtype of cancer, in order to guide patient treatment.
    - (3) For purposes of this section, biomarker testing must be:
- 36 (a) Recommended in the latest version of nationally recognized 37 guidelines or biomarker compendia, such as those published by the 38 national comprehensive cancer network;

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- (b) Approved by the United States food and drug administration or a validated clinical laboratory test performed in a clinical laboratory certified under the clinical laboratory improvement amendments or in an alternative laboratory program approved by the centers for medicare and medicaid services;
  - (c) A covered service; and

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- (d) Prescribed by an in-network provider.
- 8 (4) This section does not limit, prohibit, or modify an 9 enrollee's rights to biomarker testing as part of an approved 10 clinical trial under chapter 69.77 RCW.
- 11 (5) Nothing in this section may be construed to mandate coverage 12 of a health care service.
- 13 (6) Nothing in this section prohibits a managed care plan from 14 requiring a biomarker test prior to approving a drug or treatment.
- 15 (7) This section does not limit an enrollee's rights to access 16 individual gene tests.

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