

514C.36 Biomarker testing — coverage.

1. As used in [this section](#), unless the context otherwise requires:

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 but not limited to genetic mutations or protein expression.

b. “Biomarker testing” means the analysis of an individual’s tissue, blood, or other biospecimen for the presence of a biomarker, including but not limited to single-analyte tests, multiplex panel tests, or whole genome sequencing.

c. “Clinical utility” means sufficient medical and scientific evidence indicating that the use of a biomarker test will provide meaningful information that affects treatment decisions and guides improvement of net health outcomes, including an improved quality of life or longer survival.

d. “Consensus statement” means a statement developed by an independent, multidisciplinary panel of experts, none of whom have a conflict of interest, who utilize a transparent methodology and reporting structure. A consensus statement concerns specific clinical circumstances and is based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

e. “Covered person” means a policyholder, subscriber, or other person participating in a policy, contract, or plan that provides for third-party payment or prepayment of health or medical expenses.

f. “Health care professional” means the same as defined in [section 514J.102](#).

g. “Local coverage determinations” means the same as defined in section 1869(f)(2)(B) of the federal Social Security Act.

h. “National coverage determinations” means the same as defined in section 1869(f)(1)(B) of the federal Social Security Act.

i. “Nationally recognized clinical practice guidelines” means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies, none of which have a conflict of interest, that utilize a transparent methodology and reporting structure. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and assessment of the costs and benefits of alternative care options and include recommendations intended to optimize patient care.

2. Notwithstanding the uniformity of treatment requirements of [section 514C.6](#), a policy, contract, or plan providing for third-party payment or prepayment of medical expenses shall provide coverage for biomarker testing for the purposes of diagnosing, treating, appropriately managing, or monitoring a disease or condition in a covered person when the biomarker testing has demonstrated clinical utility, including but not limited to any of the following:

a. Labeled indications for a test approved or cleared by the United States food and drug administration or indicated tests for a drug approved by the United States food and drug administration.

b. Centers for Medicare and Medicaid services of the United States department of health and human services national coverage determinations or Medicare administrative contractor local coverage determinations.

c. Nationally recognized clinical practice guidelines and consensus statements.

3. Coverage required under [this section](#) shall limit disruptions in care, including mitigating the need for a covered person to undergo multiple biopsies or to provide multiple biospecimen samples.

4. A covered person and the covered person’s health care professional shall have access to a clear and convenient process available on the health carrier’s internet site to request an exception to coverage provided under [this section](#).

5. a. [This section](#) applies to the following classes of third-party payment provider policies, contracts, or plans delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2025:

(1) Individual or group accident and sickness insurance providing coverage on an expense-incurred basis.

(2) An individual or group hospital or medical service contract issued pursuant to [chapter 509](#), [514](#), or [514A](#).

(3) An individual or group health maintenance organization contract regulated under [chapter 514B](#).

(4) A plan established pursuant to [chapter 509A](#) for public employees.

b. [This section](#) shall apply to all of the following:

(1) The medical assistance program under [chapter 249A](#).

(2) The healthy and well kids in Iowa (Hawki) program under [chapter 514I](#).

(3) A managed care organization acting pursuant to a contract with the department of health and human services under [chapter 249A](#), or with the healthy and well kids in Iowa (Hawki) program under [chapter 514I](#).

c. [This section](#) shall not apply to accident-only, specified disease, short-term hospital or medical, hospital confinement indemnity, credit, dental, vision, Medicare supplement, long-term care, basic hospital and medical-surgical expense coverage as defined by the commissioner, disability income insurance coverage, coverage issued as a supplement to liability insurance, workers' compensation or similar insurance, or automobile medical payment insurance.

6. The commissioner of insurance may adopt rules pursuant to [chapter 17A](#) to administer [this section](#).

[2024 Acts, ch 1129, §1](#)