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A blood test that can detect cancer?
Liquid biopsy: A potential diagnostic to watch closely

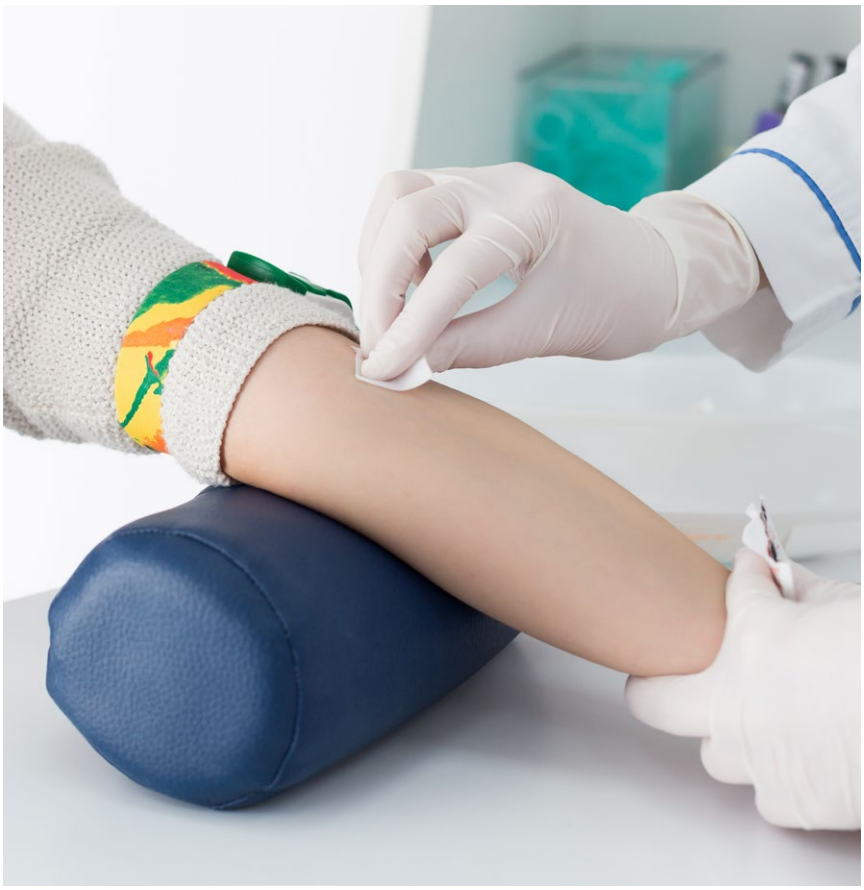
"Liquid biopsy" is a new molecular technology being explored for its use in helping to treat – and detect – cancer. While the new test could ultimately benefit cancer patients and improve survival outcomes, it also creates new risks and exposures for life and health insurers, particularly for critical illness and cancer products.

A liquid biopsy is not really a "biopsy" but rather a molecular cancer test that uses body fluids.

Traditional tumour biopsies remain the standard for diagnosis and should be used for underwriting and claims assessment.

Key facts

- Liquid biopsy is a minimally invasive technique that can identify genetic material from tumour cells shed into the blood from a primary tumour or metastatic site.
- Liquid biopsy is being tested for its use to monitor a patient's response to treatment, to identify actionable genetic markers for targeted therapy, to support disease prognosis and to detect disease recurrence.
- Only one liquid biopsy test has obtained US FDA approval for use as a companion diagnostic in clinical practice to identify lung cancer patients eligible for a targeted therapy.
- For the foreseeable future, histopathology will remain the standard for cancer diagnosis and staging.
- Far more research and clinical trials are needed to establish liquid biopsy as an acceptable screening tool and as a substitute or adjunct for conventional cancer diagnosis.
- A "negative" liquid biopsy test does not rule out the presence of cancer.
- A "positive" liquid biopsy test does not meet today's clinical standard for cancer diagnosis, and therefore any critical illness claims should continue to require histopathological proof.



Risk considerations for insurers

Liquid biopsy is less invasive than extracting tissue, easier to obtain and holds the potential to transform clinical practice, if it should become an accepted and routine alternative to help diagnose, define and treat cancer. However, it raises the stakes for insurers and requires careful consideration to manage issues like anti-selection, over-diagnosis and to ensure our products remain sustainable and able to cover the people who need them the most.

An overview of the insurance risks for liquid biopsy

Underwriting

If a positive test result is submitted, it's best to postpone cover until the client can discuss the results and next steps with a doctor, and ideally to receive histopathological confirmation with clear cancer staging and diagnosis.

Anti-selection may also be a factor for someone who is seeking a liquid biopsy test. If market regulations allow, it's good to assess medical history and identify other red flags that could suggest a possible cancer pre-disposition or diagnosis.

Claims

Just as when other new diagnostic tools have been introduced, like mammograms or breast MRI, liquid biopsy will likely increase cancer incidence rates and the number of cancer-related claims for critical illness (CI) or standalone cancer cover products. As cancer is a leading form of CI, this new development could significantly impact the experience of a CI portfolio. The financial impact of this will multiply where long-term guarantees are in place.

Cancer definitions for critical illness

Cancer definitions vary by market. Although most definitions explicitly require histopathological proof, some products only require cytology, rely on ICD coding or accept clinical diagnosis and would be less protected against a new wave of liquid biopsy diagnosis. Using explicit liquid biopsy exclusions in definitions could act as a safeguard.

Pricing and long-term guarantees

Since pricing assumptions are usually based on historical experience, advances in diagnostic techniques and their potential impact on cancer incidence rates are not accounted for during pricing. Tightening definitions to exclude liquid biopsy and/or reducing the duration of long-term CI guarantees are important measures to consider.

Product design

The clinical TNM cancer staging system requires histopathology and/or imaging to identify the severity of cancer and would not be possible based on liquid biopsy alone. Routine use of liquid biopsy in clinical practice could potentially alter how we identify and measure the severity of cancer and could lead to implications for cancer products that are based on severity levels. It could eventually warrant a different type severity criteria to by-pass the problem.

Anti-selection

As more people access liquid biopsy tests, anti-selection risk may also increase. Those with a negative test could deter or delay the purchase of insurance, leaving only those with higher risk to buy cancer cover.

Over-diagnosis

Should in the future liquid biopsy become a screening tool, it would likely increase over-diagnosis rates similar to what we've seen with PSA testing for prostate cancer and recently with ultrasound screening for thyroid cancer. Over-diagnosis detects a hidden disease that would not have caused symptoms or death and may subject patients to new risks including unnecessary treatment.

Going forward

We will continue to closely monitor this topic as we do with others that have the potential to change the life and health risk landscape. We'll also continually review CI cancer definitions to ensure they consider the latest clinical diagnostic standards. As it stands, liquid biopsy tests should not be accepted as evidence of a valid CI claim.