 Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable

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Description:

Alpha-fetoprotein-L3 (AFP-L3) is a glycoprotein that has been investigated as a biomarker for hepatocellular cancer (HCC). The Wako AFP-L3 laboratory test has received 510K marketing clearance from the Food and Drug Administration.

Criteria:

- Evaluation of AFP-L3 biomarkers for the screening, diagnosis or monitoring of suspected or known hepatocellular cancer is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.
ALPHA-FETOPROTEIN-L3 FOR DETECTION OF HEPATOCELLULAR CANCER
(cont.)

Resources:


ALPHA-FETOPROTEIN-L3 FOR DETECTION OF HEPATOCELLULAR CANCER
(cont.)

Resources: (cont.)


FDA 510K Summary for LBA AFP-L3, AFP-L3 Calibrator Set, AFP-L3 Control:

- FDA-approved indication: As a risk assessment test for the development of hepatocellular carcinoma (HCC) in patients with chronic liver diseases (CLD). Elevated AFP-L3% values (≥ 10%) have been shown to be associated with a seven-fold increase in the risk of developing HCC within the next 21 months. Patients with elevated serum AFP-L3% should be more intensely evaluated for evidence of HCC according to the existing HCC practice guidelines in oncology.