[INSERT DATE]

Insert Insurance company name

INSERT ADDRESS

Subject: Appealing Reimbursement Denial

Patient Name: [INSERT NAME]

DOB: [INSERT DOB]

ID#: [INSERT HEALTH PLAN ID #]

Group #: [INSERT GROUP #]

Physician Name: [INSERT NAME], MD

Testing Required : Alpha Fetoprotein L3 (AFP-L3) and Des-Gamma-Carboxy Prothrombin (DCP) serum biomarkers

To Whom It May Concern:

As a practicing provider with a major interest in liver disease, I am writing on behalf of my patient to request that \_\_\_\_\_ approve coverage of AFP-L3 and DCP serum biomarkers used for risk assessment for the development of hepatocellular carcinoma (HCC).

My patient has advanced fibrosis or cirrhosis of the liver and is at a high risk of developing HCC. This patient is under a liver surveillance program which can enable earlier detection of liver cancer. If unchecked or detected when only palliative options are left, HCC is ultimately lethal. Currently, liver cancer is the #2 cause of cancer death worldwide, and at this point in time HCC is among the fastest growing causes of cancer death in the United States and has a 5 year survival rate of approximately 15% due to late diagnosis is most patients.1-4

However, diagnosis of HCC at an early stage in the disease progression, allows for a greater variety of potentially curative treatment options when the tumor(s) is relatively small (1-5cm) including liver transplantation.1,2 In Japan, where these biomarkers are routinely employed as part of at risk patient surveillance, 5 year survival rates can be as high as 70%, currently the best in the world. Clinical observations in the United States, have indicated that AFP-L3 and DCP biomarker level elevations can be measured greater than 1 year prior to tumor detection by imaging.5

**Patient Summary**

**Describe patient here: with clinical scenario**

**Device Description Summary**

* AFP-L3 is FDA cleared with the intended use as an in vitro diagnostic aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies and clinical assessment. Patients with elevated AFP-L3% values (>= 10%) have been shown to be associated with a 7-fold (Relative risk=7) increase in the risk of developing HCC within the next 21 months and should be more intensely evaluated for evidence of HCC.
* DCP is FDA cleared with the intended use for in vitro diagnostic aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies, and clinical assessment. Elevated DCP values (>7.5ng/nl) have been shown to be associated with a 5-fold (Relative risk=5) increase of developing HCC.
* Studies show that the biomarkers AFP-L3, AFP, and DCP are complementary and more effective for risk assessment of primary liver cancer when they are measured at the same time in conjunction with imaging modalities.

**Clinical Efficacy**

There are hundreds of peer reviewed publishedarticles validating AFP-L3 and DCP as biomarkers for HCC, their use in surveillance of patients at risk for developing HCC, and the effectiveness of their ability to detect HCC at early treatable stages. The literature has shown that AFP-L3 and DCP are useful in various populations and across all etiologies of liver disease leading to cirrhosis and risk for HCC. AFP-L3 and DCP are also useful across a wide range of body mass index (BMI) where the standard of care, ultrasound, is often problematic, as well as age, gender, and race. Highlights of the published results are summarized below:

* AFP-L3 is elevated in HCC patients and is highly specific for HCC.6-8
* AFP-L3 and DCP has the ability to detect HCC up to 18 months prior to imaging modalities.5
* AFP-L3 is useful in detecting HCC in cirrhotic patients whose AFP is within normal or below normal range.5, 7-13
* AFP-L3 and DCP are able to provide early indication of detect patients and early stage indication in patients at high risk for the development of HCC.14
* AFP-L3 and DCP are integral to the surveillance guidelines in Japan where they lead the world in early detection of HCC and survival is longest.(The Japan Society of Hepatology guidelines).
* Biomarkers AFP-L3, DCP and AFP are most useful when used in conjunction with each other. The trio of biomarkers when used with Liver imaging provides enhanced sensitivity and specificity of detecting HCC. This combination provides for the greatest ability to assess risk to those most probable of developing HCC.5,15,16
* In Vitro serum assay that is technique independent.
  + Safety
    - Besides any normal complications that may be associated with a blood draw there are no safety risks.

**Summary**

I find that AFP-L3 and DCP are FDA cleared tests that are medically necessary tests for this patient’s managment. The role of these biomarkers in surveillance is published in >100 papers to improve clinical outcomes.2 Standard of imaging for surveillance of at risk patients alone is insufficiently sensitive for the early detection of HCC.17,18 AFP, AFP-L3 and DCP, together with imaging, provide the greatest sensitivity and specificity for establishing risk of HCC and enhancing early detection of HCC. This test panel allows me to best provide my patient with the best chances for effecting disease treatment.

If you have any further questions or comments, please feel free to call me at (INSERT PHONE NUMBER) to discuss. Thank you for your immediate attention to this request.

Sincerely,

**[INSERT NAME], MD**

*[INSERT NAME OF PRACTICE]*

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