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## Justification for Approval of FibroScan Examination

FibroScan may help with determining if approval for the new Hepatitis C Treatments is warranted when the FibroScan score shows that the patient's liver is becoming scarred. For example, FibroScan can show that a patient has severe fibrosis (F3) or cirrhosis (F4), and assist the physician and the treatment (e.g. Harvoni, Sovaldi/Sofosbuvir, Olysio/Simeprevir) without the need for biopsy.

- A very low FibroScan score can provide the patient reassurance that the liver can afford to wait for better/less expensive treatment in the future
- In many cases FibroScan can assist the physician to avoid the added risk and complications of liver biopsy
- After successful treatment (e.g. Hepatitis C), annual FibroScan can monitor the liver's recovery
- FibroScan can show the physician how the patient's recovery is advancing
- Recovery from liver fibrosis may lower the long term risk of cancer

### **A FibroScan examination may be needed if the patient has one of the following conditions:**

- Virus infections, such as Hepatitis B or Hepatitis C
- Alcohol related liver disease
- Fatty Liver Disease (NAFLD, NASH)
- Other types of chronic liver disease

### **How FibroScan works:**

FibroScan uses "shear waves" to measure the elasticity of the liver using an improved technique called Vibration-Controlled Transient Elastography (VCTE). As the shear wave passes through the liver, it is affected by the amount of scarring (fibrosis) and this is interpreted to give an accurate global assessment of the stage of the fibrosis (fibrosis staging). The proper use of shear wave velocity analysis requires control of various physical parameters to ensure an accurate, reliable and reproducible assessment of the tissue stiffness, all novel features incorporated into FibroScan 502 Touch device. The stiffer the liver, the more severe the fibrosis.

### **What is liver fibrosis and why detect early?**

Liver fibrosis is a condition of scarring and stiffness of the liver and is caused by a variety of medical conditions. The most advanced and feared form of scarring is called Liver Cirrhosis. Cirrhosis (end stage liver disease) can result from long term liver infections or long term liver toxins (including excessive alcohol and some

medications) in which the healthy liver tissues are slowly replaced by scar tissue. Initially the scar tissue is fine, delicate and hard to detect. Over time it becomes thicker and can start to strangle the liver. This can prevent the liver doing its job: nutrient metabolism and elimination. This can often lead to advanced and often irreversible condition termed “liver failure”.

Patients with liver failure usually need a transplant. Avoidance of cirrhosis by early detection of fibrosis has been a challenge for both patients and physicians, in part because clinical examination and blood tests can easily miss it. In addition, physicians and patients alike prefer to avoid liver biopsies because they are both expensive and can have complications (e.g. pain or bleeding).

However, some patients surprise us and their disease can progress faster than we expected. Others don’t return to the clinic for fear of the biopsy. When this happens, valuable time can be lost.

The FibroScan test of the liver is now routinely used in Europe and elsewhere and has offered a great opportunity to both replace biopsy but also track responses to treatment in a way that biopsy could not be used.

Using FibroScan 502 device, the DAP Hepatitis Center can now routinely provide this test to all patients who have or have had chronic conditions of the liver, including those patients who have previously received treatment.

### **FibroScan for Hepatitis B and Hepatitis C**

Patients who live with viral hepatitis might not have any noticeable health problems for years. However, as the years progress, scarring in the liver can build up and slowly lead to liver failure. Once that stage is reached, the patient will need a liver transplant.

With the new FibroScan technology, it is now easy to measure the health of the liver and see how much scarring the hepatitis virus has caused. Knowing the stage of fibrosis can help the patient/physician decide if they need to start a treatment plan immediately.

### **Monitoring the Progress of Liver Disease**

FibroScan tests can be repeated regularly (e.g. every 6-12 months) without any health risks, which can assist the physician to monitor the progression of a liver disease. For patients who begin treatment (e.g. for Hepatitis C), or are making lifestyle changes to mitigate damage to the liver, the FibroScan can provide information to the physician regarding how successful the treatment/lifestyle change has been.