**Policy: Pre and Post-Liver Transplant Hepatitis C Patient Protocol**

**Statement: 1. Activation date:**
**2. Affected Department:** LiverTransplant Program

**3. Vision Strategy:** Patient Care

**4. Policy Statement:** The Emory Transplant Center will comply with all applicable federal, state and local laws, regulations and policies regarding the management of prescribing medications and refills.

**5. Basis**: This policy is necessary for the protection of patients, physicians and staff.

**6. Administrative Responsibility:** Section heads, physicians, practitioners, and staff are responsible for compliance with this policy.

**Scope/Procedure:**

**A. Evaluation Process**

Patients undergoing evaluation for liver transplantation should have Hepatitis A, B, and C Virus serologies: HAV IgM, HAV IgG, HBsAg, HBcAb, HBsAb, and HCV Ab. If patient is known or suspected to have hepatitis C virus or is found to have a positive HCV Ab, then the laboratory studies should include HCV RNA Quantitation and HCV Genotype.

1. Patients should have HCV RNA level repeated at time of transplant & according to the Hepatitis C Pathway Protocol.

2. Patients preparing for Liver Transplantation should be considered for HCV treatment by the transplant hepatologist. The newly FDA-approved direct acting anti-viral agents (DAA’s) are much more efficacious and tolerated medications that can be tolerated in even carefully selected decompensated cirrhotics. There may be a small rate of “hepatic recompensation” with successful viral clearance obviating the need for transplantation. Importantly, successful treatment can eradicate the virus prior to liver transplantation and thus prevent viral recurrence post-transplantation, which has historically been a major cause of hepatic allograft loss and patient mortality. Recent studies indicate that the strongest predictor of post-transplantation virologic response (pTVR) is the number of consecutive days with undetectable HCV-RNA before transplant. According to Currey et al, patients with 30 or more days of HCV RNA undetectability have a 95% chance of achieving pTVR-12. On the other hand, patients who had HCV RNA undetectability for < 30 days had 64% post-LT HCV recurrence. Therefore, if transplantation is considered to be immediate in a patient with high-MELD score, deferring treatment until after transplantation may be advised.

**B. Treatment process**

The antiviral regimen is rapidly changing with the widespread use of recently FDA-approved DAA’s. The most current updated recommendations for treating Hepatitis C Virus by the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) may be found at online at [**http://www.hcvguidelines.org/**](http://www.hcvguidelines.org/)**.** For patients who are listed for transplant or have received a liver transplant, an effort should be made to avoiding starting the co-packaged antiviral regimen consisting of ombitasvir, paritaprevir, ritonavir, and dasabuvir (“Viekira Pak”) due to significant drug-drug interactions with immunosuppression medications.

In general once a patient’s viral load and genotype have been determined, the treating hepatologist may order the prescribed antiviral regimen and communicate the plan and timeline with our staff in the Center for Viral Hepatitis to coordinate labs and clinic follow up. In general, patients should have labs including a viral load drawn routinely and be seen at least once during their antiviral regimen in clinic. The viral load will be checked at the end of treatment (EOT) and 3 and 6 months after EOT to determine the sustained virologic response (SVR).

For patients who are actively listed for liver transplantation, the viral load should be **checked every two weeks** as this determines rate of recurrence after transplantation which is important data for the patient’s management.

Many patients with active hepatitis C virus are listed to accept a hepatitis C virus-positive donor as a means to increase the donor organ pool. Unless the treating team or the patient wishes otherwise, for the first 4 weeks of treatment, patients listed for HCV-positive donors will be marked to accept a HCV-positive organ. After **4 weeks of anti-viral treatment** this should be changed by the coordinator to “not accepting” HCV donor organs. This status should be reviewed routinely by both the transplant hepatologist and pre-transplant coordinator and monthly audits should be conducted.

For patients that are currently undergoing antiviral treatment when they undergo liver transplantation, antiviral therapy should only be terminated at the time of transplant if the patient has had undetectable viral load for over 30 days. Otherwise, treatment should be resumed as soon as the patient is able to take oral pills.

**B. Immunosuppression for the HCV Patient**

Similar to recipients due to other disease etiologies, patients with active hepatitis C virus will receive the same immunosuppression regimen including intra-operative steroid bolus and will also undergo a 3 month prednisone taper.

For patients with aggressive rejection requiring high-doses of immunosuppression, consideration of prompt antiviral regimen should be considered.

**C. Role of biopsy in post-transplant patients**

Historically, annual liver biopsies were performed in all patients with active hepatitis C virus to determine antiviral treatment. With the recently approved DAA’s, the threshold for treatment should be much lower and thus annual liver biopsy is no longer required and can be determined by the treating transplant hepatologist. Treatment can be initiated by the current guidelines at <http://www.hcvguidelines.org/> or as part of a clinical research trial if available and appropriate.

In lieu of liver biopsies, it can be very helpful to have data regarding individual transplant recipients allograft fibrosis. When Fibroscan becomes available, protocol measurements should be performed at 1, 3, and 5 years after transplantation.

Approved by: Liver Transplant Leadership Group

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Approval Dates: 9/14/04**,** 6/8/2009, 1/24/2011

Revised: 04/28/2008, 6/8/2009, 1/24/2011

REFERENCES

1. Curry, M et al. “Sofosbuvir and ribavirin prevent recurrence of HCV infection after liver transplantation: An open-label study.” Gastro 2015 148(1):100-107.

2. <http://www.hcvguidelines.org/>

3. Pungpapong, S et al. “Multicenter experience using simeprevir and sofosbuvir with or without ribavirin to treat hepatitis C genotype 1 after liver transplant.” Hepatology 2015 (Epub ahead of print, doi: 10.1002/hep.27770.)

4. Forns, X et al. “Sofosbuvir compassionate use program for patients with severe recurrent hepatitis C following liver transplantation.” Hepatology 2014 (Epub ahead of print. PMID 25557906).

5. Reddy, KR et al. “Ledipasvir-Sofosbuvir and ribavirin in HCV genotypes 1 and 4: the SOLAR-1 Trial”. Abstract, AASLD 2014.

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| **Regulatory References:** |  |

**Related Policies/Procedures:**