**Policy: Post-Liver Transplant Hepatitis C Treatment Protocol for Recurrence**

**Statement: 1. Activation date:** 9/16/04
**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:**

**Protocol:**

**A. Patients**

Patients should be considered for combination therapy of Peg interferon alfa-2a / Ribavirin in the post liver transplant patient with histological findings (Stage 2 or higher) of recurrence of hepatitis C or when clinically indicated. All patients that have histological changes conducive of hepatitis C recurrence will be considered for treatment with Pegylated Interferon and Rribavirin as tolerated by neutrophil count, platelet count, hemoglobin, bilirubin and creatinine.

Medication Dosing Criteria

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | Dose Initiation | Dose Reduction/ Interruption | Permanent Discontinuation |
| Neutrophils | > 1000 | < 750 | < 500 |
| Platelets | > 35,000 | < 35,000 | < 25,000 |
| Hemoglobin | > 10.0 | <10.0 | < 8.5 |
| Creatinine | < 2.5 | > 3.5 | If no reduction in two weeks |

**B. Dosing and Parameters**

Pegylated Interferon will be administered once weekly. Interferon dosing should be done in the evening hours to avoid side effects. Acetaminophen 650mg orally should be taken 30 minutes prior to self-administration of interferon.

1. Initial treatment will begin if ANC is greater than 1000 and platelets are greater than 35,000.
2. Dose reduction and/or interruption, as determined by attending physician, will be based on hematologic factors.

3. Primary goal of therapy is to clear virus and achieve sustained virological response. Secondary goal of therapy is to halt progression of fibrosis.

**C. Patient Inclusion Criteria and Treatment Visits**

Treatment will be indicated for patients having recurrence of HCV following liver transplantation. All patients must be able to self-administer medications. Patients must be able to be evaluated on a frequent basis.

1. **Consider Eye exam clearance prior to initiation of therapy and every 6 months while on therapy.**
2. Mental health exam/clearance should be done and completed prior to initiation of therapy if patient has a significant history of mental illness such as uncontrolled depression, bipolar disorder, or previous suicide attempts.

3. Treatment visits will consist of Day 1(baseline visit), to discuss treatment side effect and management, injection technique, and storage of medication.

2. Treatment visits will occur at Weeks 1, 2, 4, 6, 8 then every 4 weeks until completion of therapy (based on presentation of patient).
3. Clinical evaluations of adverse events as reported by patient and laboratory evaluations (CBC with differential, creatinine, LFT’s & bilirubin) will be performed on each visit.

4. The frequency of visits will also be determined by the escalation/reduction of dosing as well as physical findings during each evaluation.
5. Six months post treatment or as clinically indicated, a liver biopsy will be performed to address the progression of the hepatitis C.

**D. Side effects, Therapy, and Instructions to be given to Patient**

The patients should be monitored for side effects upon each visit. Instructions to the patient should include:

1. Pre-med with acetaminophen 650mg prior to interferon dose.
2. Drink plenty of water to maintain hydration on this regimen.
3. Dosing of interferon should be preformed in the evening hours.

Patients should be evaluated for depression prior to initiation of treatment and during treatment for depression. If applicable, patient should be started on an SSRI for management. If patients have been treated in the past for depression, re-institute anti-depressive therapy. If patients are unresponsive to SSRI anti-depressive therapy, refer for mental health evaluation. If patient becomes suicidal or homicidal, Pegylated Interferon and Ribavirin will be discontinued immediately.

Random drug screens **may** be performed on patients with history of chemical dependence or if there is any concern of illicit drug use.

For patients with ANC < 500, patients will be dosed with GCSF (Neupogen) 480 mcg subcutaneously once weekly until ANC > 750. Discontinuation or drug holiday should be instituted when the patient has an ANC < 500. However, drug holiday should be avoided if at all possible.

Patients should be initiated on erythropoietin 40,000 units or Aranesp **60 - 100** mcg sub q weekly to maintain hemogloblin > 10. With Hgb dropping below 8.5, discontinue ribavirin and continue with erythropoietin or Aranesp therapy.

**F. Immunosuppressive Protocol**

Immunosuppressive protocol will be based on center’s protocol (ref. immunosuppressive protocol).

Approved by: Liver Transplant Leadership Group

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

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