CLOFAZIMINE TREATMENT PROTOCOL

BACKGROUND:

Clofazimine (CZ) was approved by the Food and Drug Administration in 1986 for the treatment of mycobacterial diseases. CZ is bactericidal for M. tuberculosis (MTb), marinum, and leprae and is bacteriostatic against other mycobacterium such as avium-intracellularare (MAC). Clofazimine is considered to be a second-line drug for MTb and MAC and is used when other preferred agents cannot be used because they are ineffective or because adverse reactions limit their use.

Although CZ has been used for many years in the treatment of mycobacterial diseases, it is no longer available on the US market. It is currently being distributed in the US through a special arrangement with the FDA and the manufacturer on an individual patient approval basis. This arrangement requires that a single patient IND be obtained from FDA for each patient requiring CZ. Upon approval by FDA, the manufacturer (Novartis) will ship the drug directly to the prescribing physician.

TREATMENT:

Patient Eligibility

Patients with a history of culture positive mycobacterial disease whose resistance pattern has indicated resistance to first line agents and sensitivity to clofazimine or in whom an additional drug needs to be added to their regimen because of inadequate response to existing therapy.

Patients with a history of culture positive mycobacterial disease that is sensitive to clofazimine and who have experienced an allergic or adverse reaction to other agents that prevent their use.

Patients with clinical disease that has responded to treatment with anti-mycobacterial drugs but who experienced allergic or adverse reactions to these agents that has prevented their continued use or who have experienced a relapse in their disease that necessitates the addition, or substitution, of second-line agents

Patient has signed an informed consent for the use of clofazimine.

Who should NOT be on clofazimine:

No one to whom any of the following apply should be on this medication:
1. Anyone whose mycobacterial disease can be adequately treated by other available medications.
2. Anyone who is allergic or who has had a severe adverse reaction to clofazimine in the past.
3. Anyone who is unable or unwilling to sign the informed consent.
Dosing:
The dose will usually be 100 mg to 200 mg once a day.

Adverse Effects:
The most common adverse effects include:
- GI disturbances such as loss of appetite, diarrhea, nausea/vomiting or burning abdominal pain
- Discoloration of the skin to a bronze or dark tan color.
- Discoloration of sweat, tears, sputum and feces to a yellow or tan color. The feces can appear dark or tarry.

Less common side effects include:
- Hepatitis or jaundice
- Photosensitivity
- Dizziness, drowsiness, fatigue, headache, and neuralgia.

Monitoring:

The patient should be monitored for elevated LFTs and other signs of hepatitis.
The patient should be monitored for response to therapy.

PATIENT CONSENT;

The patient must sign an informed consent prior to initiation of treatment with CZ. The patient has the right to refuse treatment with CZ or to stop treatment at any time. If the patient refuses treatment with clofazimine, this should in no way compromise his access to treatment or patient status.