Annex 3

Guideline for the Drug Use Category จ(2)

etc

Guidelines for the Use of Peginterferon and Ribavirin

Indication for chronic hepatitis from hepatitis C virus (genotype 2, 3)

1. **Authority system to use drug**

   Request for use of Peginterferon and Ribavirin should be pre authorized to a benefit agency which can cover the benefit with registration from both doctors and patientsbefore treatment.

2. **Qualifications for hospitals/ clinics**

   Any hospitals or clinicsthat need to use these drugs must be prepared to do the followings:

   2.1 Be able to test or submit a test of HCV RNA/ HCV Genotype

   2.2 Be able to do liver biopsy or fibroscan

   2.3 Be able to report HAI Score or Metavir Score

   And these hospitals/ clinics must be registered to a benefit agencywhich can cover the benefit or a federal agency that take the responsibility.

3. **Qualifications for clinicians**

   Any doctors who have been working in a hospital or a clinic approved according to (2) and have already registered to an essential-drug-control agency that controls the ordering of the drugs in category จ 2 and must have the following qualifications:

   3.1 Be an expert that has been licensed or certificated from the Medical Council of Thailand in the specialization of gastrointestinal and liver OR

   3.2 Has been *an internal medicine* practitioner for liver disease with not less than 5 years of experience and endorsed by the dean or the chief of the hospital/ clinic.

4. **Criteria of drug permission**[1]

   The permission to use Peginterferon in the term of use of hepatitis C virus (genotype 2 and 3) must have all of the requirements below.

   4.1 Patients who are appropriate to receive the treatment are (all of the following)

   4.1.1 The patient must have chronic hepatitis from hepatitis C virus that has never been treated withPeginterferon and Ribavirin before.

   4.1.2 The patient must comprehend clearly and be prepared to receive the treatment. They also need to sign in a paper stating the instruction on appropriate lifestyles and habits while taking the drugs (both the patient and the spouse).

[1] In case the doctor sees that if it is possible to use different criteria, the permission can be requested to an essential-drug-control agency with the sub steering committee of the national lists of essential medicines by presenting the advantages of the different criteria usage.

4.1.3 The patient must be at the age of 18 – 65

4.1.4 The patient must have ALT higher or equivalent to 1.5 and have no Hepatitis cause from medicines, herbs, alcohol and nonalcoholic steatohepatitis(NASH)

4.1.5 The patient must have HCV genotype 2 and 3 confirmed with RNA positive >/equivalent to 5,000 iu/ml

4.1.6 The result of liver test must have significant fibrosis (F2) (Metavir is higher or equal to 2) or the fibroscan results in pKA>/ equivalent to 7.5

4.1.7 In case of Cirrhosis, it must be on the first phase and well functional with the Child-Pugh score lesser or equal to 6.

4.1.8 The patient must stop drinking any kinds of alcohol at least for 6 months

4.1.9 The patient must follow the standard of care such as the treatment with Peginterferon (alfa 2a or alfa2b) sc injection/ week with Ribavirin 800 – 1400 mg/day for 24 weeks.

There is no restriction for chronic hepatitis treatment from hepatitis C virus as following:

- In a medical history, the patient has an allergy to Interferon and Ribavirin.
- The patient has uncontrollable major depression.
- The patient is pregnant and/or unwilling to use contraception.
- The patient has done liver, heart or lung transplantation.
- It worsens the patient's condition by receiving Interferon, especially immune mediated diseases.
- The patient has not been able to handle their congenital diseases such as high-blood pressure, diabetes, coronary heart disease, emphysema,and thyrotoxicosis.
- The patient has co-diseases that may result in a bad response to treatment or major drug interaction which is considered dangerous for them.
- The patient is alcoholic.
- The patient keeps drinking alcohol during the treatment.

4.2 The patient must not be terminally ill[2].

4.3 Criteria of Discontinuation:

4.3.1 The patient has received the treatment completely for 24 weeks.

4.3.2 The patient must discontinue if they cannot tolerate the side effects of Peginterferon or Ribavarin, which cause them to stop the treatment for more than 4 weeks.

[2] Terminally ill means that a patients who is physically incurable and irreversible, and in medical consideration it may cause the patient's life to death in a shortperiod of time.
Note: in this case, the patient should receive palliative care to mainly reduce pain and suffering.

4.3.3 The patient does not follow the instruction that they have signed on the paper, and the doctor sees as appropriate.

4.4 The form approved by the subcommittee of national lists of essential medicines must be filled every time that the drugs are used to the patient.

5. Suggested dose

- Peginterferonalfa2a : Dose 180 mcg. SC once/week + Ribavirin 800 – 1,400 mg/day
- Peginterferonalfa 2b : Dose 1.5 mcg/kg SC once/week + Ribavirin 800 – 1,400 mg/day

Note:

- No change of drug between Peginterferonalfa 2a and Peginterferonalfa 2b during the treatment of the same patient.
- Do no overdose than the suggested amount.

6. Period of treatment

- 24 – week of treatment

7. Treatment evaluation

- Inject HCV RNA after treatment (ETR)
- Inject HCV RNA after the 24 – week treatment (SVR) (the second times)