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June 9th, 2015

HEPATITIS C VIRUS (HCV) VIRAL LOAD TESTING AND GENOTYPING

With PharmaCare's approval of Sofosbuvir (Sovaldi) and Ledipasvir-Sofosbuvir (Harvoni) please note these revised HCV viral load testing and genotyping recommendations:

Recommended HCV Viral Load Testing When Treated With (Table 1):

- Sofosbuvir (Sovaldi) with pegylated interferon/Ribavirin
- Sofosbuvir (Sovaldi) with ribavirin
- Ledipasvir-Sofosbuvir (Harvoni)

There is no benefit to performing week 4 or week 12 viral loads to monitor the early course of treatment when using Sofosbuvir (Sovaldi) or Ledipasvir-Sofosbuvir (Harvoni). Most treated patients will rapidly demonstrate undetectable viral loads. However, viral loads obtained during treatment **are not** predictive of whether or not a sustained virological response (SVR) will be achieved.

The following viral load testing approaches are recommended for individuals when treatment with: 1) Sofosbuvir (Sovaldi) in combination with pegylated interferon/ribavirin or; 2) Sofosbuvir (Sovaldi) in combination with ribavirin or, 3) individuals receiving a Ledipasvir-Sofosbuvir (Harvoni):

- Within 6 months prior to the start of treatment, individuals should have a baseline HCV viral load. (Viral load quantifications have become more precise since May 2012.)
- An end of treatment a viral load should be performed to confirm the end of treatment clearance of HCV RNA.
- A viral load at 12 weeks post completion of all treatment should be done to determine if a SVR has been achieved. Viral loads obtained 12 weeks

after treatment have been shown to be essentially equivalent to a 24 week viral load assessment for SVR (Yoshida et al. Hepatology 2015).

- A follow up viral load performed at 24 weeks after completion of all treatment may identify approximately 0.5% of individuals who are late relapsers. Performing both a week 12 and a week 24 post treatment completion viral load assessment to verify SVR is appropriate.

Table 1

RECOMMENDED HCV VIRAL LOAD TESTING WHEN TREATED WITH: • Sofosbuvir (Sovaldi) with pegylated interferon/Ribavirin • Sofosbuvir (Sovaldi) with ribavirin • Ledipasvir-Sofosbuvir (Harvoni)
☐ 6 months prior to the start of treatment ☐ End of treatment ☐ 12 weeks after completion ☐ 24 weeks after completion

RECOMMENDED HCV VIRAL LOAD TESTING WHEN TREATED WITH PEGYLATED INTERFERON AND RIBAVIRIN (Table 2):

The following viral load testing approaches continue to be recommended for individuals when treatment with pegylated interferon and ribavirin:

- Within 6 months prior to the start of treatment, individuals should have a baseline HCV viral load.

- Week 4 and 12 viral load monitoring will be performed as required for individuals receiving pegylated interferon and ribavirin (genotype 2 [week 4 only] and genotype 3 [week 4 and week 12]).

- Patients receiving interferon-based therapy should also be assessed at week 12 after treatment completion to confirm if they have achieved a SVR.

- A follow up viral load performed at 24 weeks after completion of all treatment may identify approximately 0.5% of individuals who are late relapsers. Performing both a week 12 and a week 24 post treatment completion viral load assessment to verify SVR is appropriate.

Table 2

RECOMMENDED HCV VIRAL LOAD TESTING WHEN TREATED WITH: PEGYLATED INTERFERON AND RIBAVIRIN
☐ 6 months prior to the start of treatment ☐ Week 4 viral load monitoring (Genotype 2) ☐ Week 4 and 12 viral load monitoring (Genotype 3) ☐ 12 weeks after completion ☐ 24 weeks after completion

HCV Genotyping

- For treatment naïve patients infected with genotypes 2, 3, 4, 5, 6 prior genotyping results are considered valid.
- For treatment naïve genotype 1 patients, genotyping performed prior to May 2012 did not discriminate between genotypes 1a and 1b sufficiently. Therefore if the genotype result was performed prior to May 2012, the HCV genotyping should be repeated prior to Ledipasvir-Sofosbuvir treatment.
- When Simeprevir treatment is being considered Q80K resistance testing is required.
- **For all treatment experienced patients, whether they are considered a non-responder or they relapsed post-therapy, or, if re-infection is a consideration**, the HCV genotyping should be repeated prior to retreatment.