Not Recommended Regimens In HCV Treatment

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Regimens Not Recommended

NOT RECOMMENDED	RATING
Daily sofosbuvir (400 mg) and weight-based ribavirin for 24 weeks.[f]	IIb, A
PEG-IFN/ribavirin with or without sofosbuvir, simeprevir, telaprevir, or boceprevir.	IIb, A
Monotherapy with PEG-IFN, ribavirin, or a direct-acting antiviral.	III, A

[f] Due to fewer options in the posttransplant population, sofosbuvir and ribavirin for 24 weeks is recommended in patients with genotype 2 infection.

Although regimens of sofosbuvir and ribavirin or PEG-IFN/ribavirin plus sofosbuvir, simeprevir, telaprevir, or boceprevir are FDA-approved for particular genotypes, they are inferior to the current recommended regimens. The efficacy of sofosbuvir plus ribavirin for 24 weeks is well demonstrated to be inferior to combination DAA therapy for genotype 1 and 3. For genotype 4, it has not been compared head-to-head with DAA combination therapy, but shorter, well-tolerated DAA combination regimens are now available. The IFN-containing regimens are associated with higher rates of serious adverse events (eg, anemia and rash), longer treatment duration in some cases, high pill burden, numerous drug-drug interactions, more frequent dosing, and higher intensity of monitoring for safety or treatment response.

Regimens Not Recommended:

With Regard to Pregnancy-Related Issues

NOT RECOMMENDED	RATING
Treatment with ribavirin is Not Recommended during pregnancy or for women who are unable or unwilling to adhere to use of adequate contraception, including those who are receiving ribavirin themselves or are sexual partners of male patients who are receiving ribavirin.	III, C
Female patients who have received ribavirin and sexual partners of male patients who have received ribavirin should NOT become pregnant for at least 6 months after stopping ribavirin.	III, B

Regimens Not Recommended for:

Patients with Decompensated Cirrhosis (Moderate or Severe Hepatic Impairment; Child Turcotte Pugh Class B or C)

NOT RECOMMENDED	RATING
Simeprevir-based regimens	III, B
Paritaprevir-based regimens	III, B
Elbasvir/grazoprevir-based regimens	III, C

IFN should not be given to patients with decompensated cirrhosis (moderate or severe hepatic impairment; CTP class B or C) because of the potential for worsening hepatic decompensation. Minimal data exist for the use of simeprevir in patients with decompensated cirrhosis (Modi, 2016). Until additional data become available, simeprevir should not be used in patients with decompensated cirrhosis. No data exist for the use of currently approved doses of elbasvir and grazoprevir for patients with decompensated cirrhosis, and this combination should not be used in this population until additional data become available.

Recent data reported by the US FDA have demonstrated that some patients with compensated HCV genotype 1 cirrhosis treated with paritaprevir, ombitasvir, and dasabuvir may develop rapid onset of direct hyperbilirubinemia within 1 to 4 weeks of starting treatment without ALT elevations that can lead to rapidly progressive liver failure and death. A multicenter cohort study from Israel reported 7 patients who received PrOD and also developed decompensation within 1 to 8 weeks of starting therapy, including 1 patient who died (Zuckerman, 2016). Therefore, this antiviral treatment regimen is CONTRAINDICATED in all patients with decompensated HCV cirrhosis due to concerns of hepatotoxicity. In addition, all patients with cirrhosis receiving this regimen should be monitored for clinical signs and symptoms of hepatic decompensation and undergo hepatic laboratory testing at baseline and at least every 4 weeks on therapy.

Regimens Not Recommended for:

Patients with HCV Infection in the Allograft, Including Those with Compensated Cirrhosis

NOT RECOMMENDED	RATING
Elbasvir/grazoprevir-based regimens	III, C

Regimens Not Recommended for:

Patients with Decompensated Cirrhosis, Who Have HCV Infection in the Allograft

NOT RECOMMENDED	RATING
Regimens containing simeprevir	III, B
Fixed-dose combination of paritaprevir, ritonavir, and ombitasvir with or without dasabuvir or ribavirin	III, B
Elbasvir/grazoprevir-based regimens	III, C

Last update: July 6, 2016