New HCV reimbursement criteria 01-2018

- Chronic hepatitis C with ≥ F2 fibrosis stage

- Chronic hepatitis C regardless of fibrosis stage if:
  - HIV-HCV coinfection
  - HBV-HCV coinfection
  - Listed for or post-solid organ transplantation
  - Listed for or post hematopoietic stem cell/bone marrow transplantation
  - Severe extrahepatic manifestation: diffuse large cell lymphoma B, immunomediated vasculitis, renal disease related to mixed cryoglobulinemia
  - Patient on dialysis
  - Hemophilia or other coagulation disorder
  - Hemoglobinopathy
  - Pregnancy (however contra-indicated in all smpc, and IFN free combinations never tested in pregnant women): BASL recommendation is to never treat a pregnant woman

New HCV reimbursement criteria 01-2018

- Presciption by a Specialist in Gastroenterology or Internal Medicine
  - Attached to an academic centre if 580, 588 or 987
  - Attached to academic **or** non academic hospital if 650, 651 or 659
  - Training in Hepatology (**15 CME/year,** see details on next slide)
  - Agrees to record follow-up data of treated patients
- Trough e-health plateform
- According to international Recommendations

How to obtain 15 CME credits in Hepatology?

- BASL winter meeting: 6 CME credits
- BASL Liver course: 3 CME credits
- Belgian Week (BASL session-specific accreditation): 6 CME credits
- EASL meeting: 27 CME credits
- AASLD meeting: 40.5 CME credits
- EPU journée d'Hépatologie de l'hôpital Beaujon: 6 CME credits
- Erasmus Liver day Rotterdam: 6 CME credits

This is the responsability of each prescriber to be able to demonstrate his/her credits in Hepatology

How to obtain 15 CME credits in Hepatology?

- Paris Hepatitis conference (2 days): 12 CME credits
- Barcelona Liver course (every 2 years, 3 days): 18 CME credits
- Other international or foreign national liver meetings not mentioned above like EASL monothematic conferences, Dutch Liver week, AFEF meeting in France… are also accepted CME credits in Hepatology
- Other national meetings, not mentioned above, and focused on liver diseases are also accepted CME credits in Hepatology

This is the responsability of each prescriber to be able to demonstrate his/her credits in Hepatology

METAVIR F2-F3-F4 criteria consensus

(agreed at RIZIV-INAMI 01.12.2016)

EITHER A LIVER BIOPSY, or

EITHER 1 ELASTOGRAPHY TEST (CUT-OFFS SEE NEXT SLIDE)
+ 1 BIOLOGICAL FIBROSIS SCORE (CUT-OFFS SEE NEXT SLIDE)

MAXIMUM AGE OF ELASTOGRAPHY AND LAB VALUES TO BE USED FOR BIOLOGICAL TESTS = 1 YEAR

RESULTS TO BE KEPT IN FILE OF PATIENT (SCORES & LAB VALUES USED FOR THE TEST)

cut-offs of *ELASTOGRAFY for fibrosis assessment F2-F3-F4 chronic hepatitis C*

(agreed at RIZIV-INAMI 01.12.2016)

1. *FIBROSCAN*[1]

Valid if 10 correct measurements, success rate > 60%, IQR < 30%

F2 ≥ 7.1 kPA
F3 ≥ 9.5 kPA
F4 ≥ 12.5 kPA

2. *SHEAR WAVE ELASTOGRAFIE*[2]

F2 ≥ 7.1 kPA
F3 ≥ 8.7 kPA
F4 ≥ 10.4 kPA

3. *ACOUSTIC RADIATION FORSE IMPULSE (ARFI, SIEMENS TECHNIQUE)*[3,4]

F2 ≥ 1.22 m/s
F3 ≥ 1,55 M/S
F4 ≥ 1,80 M/S

[1]Castera et al. Gasteroenterology 2005
[2]Ferraioli et al Hepatology 2012
[3]Friedrich-Rust et al J Viral Hepat 2012
[4]Ferraioli et al J Ultrasound Med 2014

cut-offs of *BIOLOGICAL FIBROSIS-SCORES for assessment F2-F3-F4 in chronic hepatitis C*

(agreed at RIZIV-INAMI 01.12.2016)

1. *FIBROTEST (BIOPREDICTIVE)*:

Elements : α2 macroglobulin, haptoglobin, apolipoprotein A1, total bilirubin, GGT
F2 : ≥ 0.49
F3: 0.59-0.72
F3-F4: 0.73-0.74
F4: ≥0.75

2. *APRI (AST-PLATELET RATIO)*

In a pure HCV cohort
F2: APRI not to use for detection of F2
F3: ≥ 1
F4: ≥ 1.6
Reference: Holmberg, Clin Infect Dis 2013

3. *FIB-4* (age, AST,ALT, platelets)

F2 ≥ 1.45
F3: ≥ 2.1
F3-F4: ≥ 3.25
F4: ≥ 3.85
References: Vallet-Pichard, Hepatology 2007, Holmberg, Clin Infect Dis 2013, Martinez APT 2011

Useful website: www.hepatitisc.uw.edu/page/clinical-calculators

Treatment options for antiviral therapy in Belgium
Update 06-2018

	Genotype 1a	Genotype 1b
Non-cirrhotic	`Sofosbuvir + Daclatasvir 12 wk Glecaprevir/Pibrentasvir 8 wk Ledipasvir/Sofosbuvir 12 wk* Velpatasvir/Sofosbuvir 12 wk Elbasvir/Grazoprevir 12 wk** *consider 8 wk if naïve and HCVRNA < 6.10^6 IU/mL **consider 16 wk + RBV if HCVRNA>800.000 IU/mL or if baseline NS5a RAs	Sofosbuvir + Daclatasvir 12 wk Glecaprevir/Pibrentasvir 8 wk Ledipasvir/Sofosbuvir 12 wk* Velpatasvir/Sofosbuvir 12 wk Elbasvir/Grazoprevir 12 wk *consider 8 wk if naïve and HCVRNA < 6.10^6 IU/mL
Cirrhotic compensated	Sofosbuvir + Daclatasvir + RBV 12 wk* Ledipasvir/Sofosbuvir + RBV 12 wk* Glecaprevir/Pibrentasvir 12 wk Velpatasvir/Sofosbuvir 12 wk Elbasvir/Grazoprevir 12 wk** *In case of poor RBV tolerance, prolong to 24 wk without RBV **consider 16 wk + RBV if HCVRNA>800.000 IU/mL or if baseline NS5a RAs	Sofosbuvir + Daclatasvir +/- RBV 12 wk* Glecaprevir/Pibrentasvir 12 wk Ledipasvir/Sofosbuvir +/- RBV 12 wk* Velpatasvir/Sofosbuvir 12 wk Elbasvir/Grazoprevir 12 wk *In case of poor RBV tolerance, prolong to 24 wk without RBV
PI experienced	Sofosbuvir + Daclatasvir + RBV 12 wk Ledipasvir/Sofosbuvir + RBV 12 wk Velpatasvir/Sofosbuvir + RBV 12 wk Consider 24 wk + RBV in F3-F4 patients	Sofosbuvir + Daclatasvir + RBV 12 wk Ledipasvir/Sofosbuvir + RBV 12 wk Velpatasvir/Sofosbuvir + RBV 12 wk Consider 24 wk + RBV in F3-F4 patients
NS5a experienced	Sofosbuvir/Velpatasvir/Voxilaprévir 12 wk (contraindicated in decompensated cirrhosis)	Sofosbuvir/Velpatasvir/Voxilaprévir 12 wk (contraindicated in decompensated cirrhosis)

No priority in the listing

Treatment options for antiviral therapy in Belgium
Update 06-2018

Cirrhotic decompensated	Sofosbuvir + Daclatasvir + RBV 12 wk* Ledipasvir/Sofosbuvir + RBV 12 wk* Velpatasvir/Sofosbuvir + RBV 12 wk* *In case of poor RBV tolerance, prolong to 24 wk without RBV consider treating after Tx if MELD > 18	Sofosbuvir + Daclatasvir + RBV 12 wk* Ledipasvir/Sofosbuvir + RBV 12 wk* Velpatasvir/Sofosbuvir + RBV 12 wk* *In case of poor RBV tolerance, prolong to 24 wk without RBV consider treating after Tx if MELD > 18
Post-organ transplant	Same recommendations than non transplanted patients RBV should be considered in all patients. However, the need for RBV in non-cirrhotic patients has not been established However, potential drug-drug interactions with immunosuppressant agents requires careful selection of agents	Same recommendations than non transplanted patients RBV should be considered in all patients. However, the need for RBV in non-cirrhotic patients has not been established However, potential drug-drug interactions with immunosuppressant agents requires careful selection of agents
HIV-HCV coinfected	Same recommendations than monoinfected HCV patients However, potential drug-drug interactions in patients receiving antiretroviral agents requires careful selection of agents	Same recommendations than monoinfected HCV patients However, potential drug-drug interactions in patients receiving antiretroviral agents requires careful selection of agents

No priority in the listing

Treatment options for antiviral therapy in Belgium
Update 06-2018

	Genotype 2
Non-cirrhotic	Sofosbuvir + Velpatasvir 12 wk Sofosbuvir + Daclatasvir 12 wk Glecaprevir/Pibrentasvir 8 wk If previous failure of Sofosbuvir + Ribavirin: Glecaprevir/Pibrentasvir 8 wk or Sofosbuvir + Velpatasvir or Daclatasvir + Ribavirin 12 weeks
Cirrhotic compensated	Sofosbuvir + Velpatasvir 12 weeks Sofosbuvir + Daclatasvir 12 weeks Glecaprevir/Pibrentasvir 12 wk If previous failure of Sofosbuvir + Ribavirin: Glecaprevor/Pibrentasvir 12 wk or Sofosbuvir + Velpatasvir or Daclatasvir + Ribavirin 24 weeks
PI experienced	Not applicable 1.
NS5a experienced	Sofosbuvir/Velpatasvir/Voxilaprévir 12 wk (contraindicated in decompensated cirrhosis)

No priority in the listing

Treatment options for antiviral therapy in Belgium
Update 06-2018

	Genotype 2
Cirrhotic decompensated	Sofosbuvir + Velpatasvir + Ribavirin 12 weeks Sofosbuvir + Daclatasvir + Ribavirin 12 weeks *In case of poor RBV tolerance, prolong to 24 wk without RBV consider treating after Tx if MELD > 18
Post-organ transplant	Same recommendations than non transplanted patients RBV should be considered in all patients. However, the need for RBV in non-cirrhotic patients has not been established However, potential drug-drug interactions with immunosuppressant agents requires careful selection of agents
HIV-HCV coinfected	Same recommendations than monoinfected HCV patients However, potential drug-drug interactions in patients receiving antiretroviral agents requires careful selection of agents **No priority in the listing**

Treatment options for antiviral therapy in Belgium
Update 06-2018

	Genotype 3
Non-cirrhotic	Sofosbuvir + Daclatasvir 12 wk Velpatasvir/Sofosbuvir 12 wk Glecaprevir/Pibrentasvir 8 wk* both for treatment-experienced (IFN) or -naive patients *16 wk for patients who failed prior therapy with IFN-based therapy+/- SOF or SOF+RBV
Cirrhotic compensated	Sofosbuvir + Daclatasvir + RBV 24 wk* ** Velpatasvir/Sofosbuvir 12 wk* + RBV** Glecaprevir/Pibrentasvir 12-16 wk*** *treatment naive **treatment experienced (IFN) ***16 wk for patients who failed prior therapy with IFN-based therapy+/- SOF or SOF+RBV
PI experienced	Not applicable 1.
NS5A experienced	Sofosbuvir/Velpatasvir/Voxilaprévir 12 wk (contraindicated in decompensated cirrhosis)

No priority in the listing

Treatment options for antiviral therapy in Belgium
Update 06-2018

	Genotype 3
Cirrhotic decompensated	Sofosbuvir + Daclatasvir + RBV 24 wk Velpatasvir/Sofosbuvir + RBV 12 wk consider treating after Tx if MELD > 18
Post-organ transplant	Same recommendations than non transplanted patients RBV should be considered in all patients. However, the need for RBV in non-cirrhotic patients has not been established Potential drug-drug interactions with immunosuppressant agents requires careful selection of agents
HIV-HCV coinfected	Same recommendations than monoinfected HCV patients Potential drug-drug interactions in patients receiving antiretroviral agents requires careful selection of agents

No priority in the listing

Treatment options for antiviral therapy in Belgium
Update 06-2018

	Genotype 4
Non-cirrhotic	Sofosbuvir + Daclatasvir 12 wk Glecaprevir/Pibrentasvir 8 wk Ledipasvir/Sofosbuvir 12 wk Velpatasvir/Sofosbuvir 12 wk Elbasvir/Grazoprevir 12 wk
Cirrhotic compensated	Sofosbuvir + Daclatasvir 12 wk Glecaprevir/Pibrentasvir 12 wk Ledipasvir /Sofosbuvir 12 wk Velpatasvir/Sofosbuvir 12 wk Elbasvir/Grazoprevir 12 wk
PI experienced	Sofosbuvir + Daclatasvir + RBV 12 wk Ledipasvir/Sofosbuvir + RBV 12 wk Velpatasvir/Sofosbuvir + RBV 12 wk Consider 24 wk + RBV in F3-F4 patients
NS5a experienced	Sofosbuvir/Velpatasvir/Voxilaprévir 12 wk (contraindicated in decompensated cirrhosis)

No priority in the listing

Treatment options for antiviral therapy in Belgium
Update 06-2018

	Genotype 4
Cirrhotic decompensated	Sofosbuvir + Daclatasvir + RBV 12 wk* Ledipasvir/Sofosbuvir + RBV 12 wk* Velpatasvir/Sofosbuvir + RBV 12 wk* *In case of poor RBV tolerance, prolong to 24 wk without RBV consider treating after Tx if MELD > 18
Post-organ transplant	Same recommendations than non transplanted patients RBV should be considered in all patients. However, the need for RBV in non-cirrhotic patients has not been established However, potential drug-drug interactions with immunosuppressant agents requires careful selection of agents
HIV-HCV coinfected	Same recommendations than monoinfected HCV patients However, potential drug-drug interactions in patients receiving antiretroviral agents requires careful selection of agents **No priority in the listing**

Treatment options for antiviral therapy in Belgium
Update 06-2018

	Genotype 5	Genotype 6
Non-cirrhotic	Glecaprevir/Pibrentasvir 8 wk Sofosbuvir+Velpatasvir 12 wk Sofosbuvir+Ledipasvir 12 wk Sofosbuvir+Daclatasvir 12 wk	Glecaprevir/Pibrentasvir 8 wk Sofosbuvir+Velpatasvir 12 wk Sofosbuvir+Ledipasvir 12 wk Sofosbuvir+Daclatasvir 12 wk
Cirrhotic compensated	Glecaprevir/Pibrentasvir 12 wk Sofosbuvir+Velpatasvir 12 wk Sofosbuvir+Ledipasvir 12 wk Sofosbuvir+Daclatasvir 12 wk	Glecaprevir/Pibrentasvir 12 wk Sofosbuvir+Velpatasvir 12 wk Sofosbuvir+Ledipasvir 12 wk Sofosbuvir+Daclatasvir 12 wk
PI experienced	Sofosbuvir+Velpatasvir 12 wk Sofosbuvir+Ledipasvir 12 wk Sofosbuvir+Daclatasvir 12 wk 1.	Sofosbuvir+Velpatasvir 12 wk Sofosbuvir+Ledipasvir 12 wk Sofosbuvir+Daclatasvir 12 wk
NS5a experienced	Sofosbuvir/Velpatasvir/Voxilaprévir 12 wk (contraindicated in decompensated cirrhosis)	Sofosbuvir/Velpatasvir/Voxilaprévir 12 wk (contraindicated in decompensated cirrhosis)

No priority in the listing

Treatment options for antiviral therapy in Belgium
Update 06-2018

	Genotype 5	Genotype 6
Cirrhotic decompensated	Sofosbuvir+Velpatasvir+RBV* 12 wk Sofosbuvir+Ledipasvir+RBV* 12 wk Sofosbuvir+Daclatasvir+RBV*12 wk *In case of poor RBV tolerance, prolong to 24 wk without RBV consider treating after Tx if MELD > 18	Sofosbuvir+Velpatasvir+RBV* 12 wk Sofosbuvir+Ledipasvir+RBV* 12 wk Sofosbuvir+Daclatasvir+RBV*12 wk *In case of poor RBV tolerance, prolong to 24 wk without RBV consider treating after Tx if MELD > 18
Post-organ transplant	Same recommendations than non transplanted patients RBV should be considered in all patients. However, the need for RBV in non-cirrhotic patients has not been established However, potential drug-drug interactions with immunosuppressant agents requires careful selection of agents	Same recommendations than non transplanted patients RBV should be considered in all patients. However, the need for RBV in non-cirrhotic patients has not been established However, potential drug-drug interactions with immunosuppressant agents requires careful selection of agents
HIV-HCV coinfected	Same recommendations than monoinfected HCV patients However, potential drug-drug interactions in patients receiving antiretroviral agents requires careful selection of agents	Same recommendations than monoinfected HCV patients However, potential drug-drug interactions in patients receiving antiretroviral agents requires careful selection of agents

No priority in the listing