



Viral Hepatitis Prevention Board

The Balkan hepatitis meeting

**Elimination of Viral Hepatitis in
The Balkan countries:
Lessons learnt and the way forward**

SKOPJE, NORTH MACEDONIA.

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HBV & HCV: treatment and reimbursement policies

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Disclosure

I have no actual or potential conflict of interest in relation to this presentation



Outline

Differences in the availability of diagnostics and treatment modalities for chronic hepatitis B across Europe

Availability of hepatitis C diagnostics and therapeutics in European and Eurasia countries

Survey of Hepatitis B & C virus treatment and reimbursement policies

Differences in the availability of diagnostics and treatment modalities for chronic hepatitis B across Europe

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2015



ESGVH

European Society of Clinical Microbiology and Infectious Diseases

ESCMID STUDY GROUP
FOR VIRAL HEPATITIS

Methods

- A comprehensive survey was sent to 23 members of the ESGVH
- The survey inquired about
 - The prevalence of HBsAg
 - The availability and reimbursement of diagnostics & antivirals
 - Management of chronic HBV infection and antiviral prophylaxis
 - The duration of treatment in both HBeAg-positive and HBeAg-negative patients
- The study period was June 2013 to June 2014, with updated final corrections in April 2015

HBV diagnostics and drugs

Country	HBV DNA	Liver stiffness measurement	IFN	LAM	TDF	ETV	HBV prophylaxis	WB country group
Albania	A-R	A-R	A-R	A-R	A-R	NA-NR	LAM, TDF	UMI
Romania	A-R	A-R	A-R	A-R	A-R	A-R	TDF, ETV	UMI
Serbia	A-R	A-R	A-R	A-R	A-R	NA-NR	LAM, TDF, ETV	UMI
Turkey	A-R	NR	A-R	A-R	A-R	A-R	LAM, TDF, ETV	UMI
Hungary	A-R	A-R	A-R	A-R	A-R	A-R	LAM, TDF, ETV	UMI
France	A-R	A-R	A-R	A-R	A-R	A-R	LAM, TDF, ETV	HI
Italy	A-R	A-R	A-R	A-R	A-R	A-R	LAM, TDF, ETV	HI
The Netherlands	A-R	NR	A-R	A-R	A-R	A-R	LAM, TDF, ETV	HI
Portugal	A-R	A-R	A-R	A-R	A-R	A-R	LAM, TDF, ETV	HI
Spain	A-R	A-R	A-R	A-R	A-R	A-R	LAM, TDF, ETV	HI
UK	A-R	NR	A-R	A-R	A-R	A-R	LAM, TDF, ETV	

- A-R, available and reimbursed; NA-NR, not available and not reimbursed; NR, not reimbursed
- HI, high-income country; UMI, upper-middle-income country; WB, World Bank

Antiviral drugs

Lamivudine is available and reimbursed

- Albania, France, Hungary, Iran, Italy, The Netherlands, Portugal, Spain, Turkey, and the UK
- with some restrictions (ALT and/or HBV DNA level; degree of liver fibrosis) on initiation in Romania and Serbia

Tenofovir disoproxil fumarate is available and reimbursed

- France, Hungary, Iran, Italy, The Netherlands, Portugal, Spain, Turkey, and UK
- With some restrictions (ALT and/or HBV DNA level; biopsy findings) in Albania and Serbia

Entecavir is available and reimbursed

- France, Hungary, Italy, The Netherlands, Portugal, Spain, Turkey, and UK
- With some restrictions (ALT and/or HBV DNA level; biopsy findings) in Romania
- It is neither available nor reimbursed in Albania, and Serbia

HBV prophylaxis during immunosuppressive therapy

All antivirals are freely reimbursed in France, Hungary, Italy, The Netherlands, Portugal, Spain, Turkey, and the UK

Lamivudine and tenofovir are reimbursed in Albania

In Serbia, lamivudine is reimbursed, tenofovir and entecavir are reimbursed if the HBV DNA level is higher than a certain value

Entecavir and tenofovir are reimbursed in Romania, including for patients who are hepatitis B core antibody-positive and hepatitis B surface antibody (anti-HBs)-negative.

HBV Highlights

Albania, and Serbia had several restrictions in diagnostics and HBV drugs

The countries in the high-income group were also the ones with no restrictions

The upper-middle-income countries had some restrictions for antiviral prescriptions

The main discrepancy is that countries with higher prevalence rates have limited access to optimal facilities

The economic development status appears to be a factor determining the availability and reimbursement of HBV diagnostics and drugs



Availability of hepatitis C diagnostics and therapeutics in European and Eurasia countries

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2016



ESGVH

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European Society of Clinical Microbiology and Infectious Diseases

Methods

- The survey was conducted between November 1 and December 31, 2015.
- The experts last updated their countries' corresponding data in June 2016.
- It was sent to all members of ESGVH
- A total of 26 countries were included
- The 20-item survey addressed
 - The prevalence of HCV
 - The availability of national guidelines for management of HCV infection
 - Reimbursement policies for diagnostics (HCV-RNA and transient elastography)
 - Availability of anti-HCV drugs including PegIFN, RBV, NS3/NS4A protease inhibitors, NS5B polymerase inhibitors and NS5A inhibitors.

Overview of availability and reimbursement policies

Worldbank definition of country economics ^a	Country	HCV Prevalence (%) (Gower et al., 2014)	Elastography reimbursed	HCV-RNA reimbursed	Reimbursement of acute HCV	At least one DAA reimbursed
Lower-Middle-income	Georgia	6.7	✓	✓	DAA	SOF and SPF/LED
	Kosovo	2 ^b				
Upper-Middle-income	Albania	1 ^b		✓	PegIFN or PegIFN/RBV	
	Azerbaijan	3.1		✓	PegIFN or PegIFN/RBV	
	Bosnia	1 ^b		✓		
	Kazakhstan	3.3	✓	✓		
	Romania	3.2	✓	✓	PegIFN or PegIFN/RBV	✓
	Serbia	1 ^b	✓		PegIFN or PegIFN/RBV	
	Tunisia	1.3	✓			
	Turkey	1.0		✓	PegIFN or PegIFN/RBV	✓
High-Income	Croatia	< 1 ^b	✓	✓	PegIFN or PegIFN/RBV	✓
	Czech Republic	0.7		✓	PegIFN or PegIFN/RBV	✓
	Denmark	0.7	✓	✓	PegIFN or PegIFN/RBV	✓
	France	0.6	✓	✓	PegIFN or PegIFN/RBV	✓
	Germany	0.6		✓	PegIFN or PegIFN/RBV	✓
	Greece	1.9			PegIFN or PegIFN/RBV	✓
	Hungary	0.8	✓		PegIFN or PegIFN/RBV	✓
	Italy	2	✓	✓	PegIFN or PegIFN/RBV	✓
	Portugal	1.8	✓	✓	PegIFN or PegIFN/RBV	✓
	Russian Federation	4.1	✓ (Only in-hospital)			✓
	Slovenia	< 1 ^b	✓	✓	PegIFN or PegIFN/RBV or DAA	✓
	Spain	1.7	✓	✓	PegIFN or PegIFN/RBV or DAA	✓
	Sweden	0.7	✓	✓	PegIFN or PegIFN/RBV	✓
	Switzerland	1.5	✓	✓	PegIFN or PegIFN/RBV	✓
	The Netherlands	0.2		✓	PegIFN or PegIFN/RBV	✓
	United Kingdom	0.6	✓	✓	PegIFN or PegIFN/RBV	✓

Availability and reimbursement policy of DAA use

Economic status	Country	PegIFN +DAA regimen			Sofosbuvir-based regimen			Paritaprevir+ombitasvir+ dasabuvir
		SOF	SMV	DCV	LDV	SMV	DCV	
Lower-Middle-income	Georgia	**			**			
	Kosovo							
Upper-Middle-income	Albania							
	Azerbaijan	*						
	Bosnia							
	Kazakhstan							
	Romania							
	Serbia							
	Tunisia							
	Turkey							

Not available
 Reimbursed with restriction
 Not reimbursed
 Reimbursed

Economic status	Country	PegIFN +DAA regimen			Sofosbuvir-based regimen			Paritaprevir+ombitasvir+ dasabuvir
		SOF	SMV	DCV	LDV	SMV	DCV	
High-Income	Croatia							
	Czech Republic							
	Denmark							
	France							
	Germany							
	Greece							
	Hungary							
	Italy							
	Portugal							
	Russian Federation							
	Slovenia***							
	Spain							
	Sweden							
	Switzerland							
	The Netherlands							
	United Kingdom							

SOF: sofosbuvir, SMV: simeprevir, DCV: daclatasvir, LDV: ledipasvir.

*Available for compassionate use. ** Georgia had sofosbuvir and sofosbuvir/ledipasvir free of charge.

Availability and reimbursement policy of DAA use in Balkans

World bank definition of country economics*	Country	PegIFN +DAA regimen			Sofosbuvir-based regimen			Paritaprevir+ombitasvir+ dasabuvir
		SOF	SMV	DCV	LDV	SMV	DCV	
Lower-Middle-income	Kosovo							
Upper-Middle-income	Albania							
	Bosnia							
	Romania							
	Serbia							
	Turkey							
High-income	Croatia							
	Greece							
	Slovenia*							

*Available for compassionate use.

Availability and reimbursement policy of DAA use

No DAAs were available in four countries: Kazakhstan, Kosovo, Serbia, and Tunisia

In all other countries, at least the combination of sofosbuvir with PegIFN/RBV was available

In Germany and The Netherlands all DAAs were reimbursed without restrictions

Sofosbuvir and sofosbuvir/ledipasvir were free of charge in Georgia

HCV Highlights

Prevalence of HCV is relatively higher in lower-middle than in upper-middle income countries

DAA's are generally not available in European and Eurasia countries for treatment of acute HCV

DAA's are not available or reimbursed in many European and Eurasia countries for treatment of chronic hepatitis C

Patients with fibrosis of F0-1 remain untreated and carry the risk of progression to advanced disease

Survey of Hepatitis B & C virus treatment and reimbursement policies



2022



ESGVH

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FOR VIRAL HEPATITIS

European Society of Clinical Microbiology and Infectious Diseases

Survey of Hepatitis B & C virus treatment and reimbursement policies

- The survey was conducted between October 1 & October 23, 2022.
- It was sent to all members of the ESGVH and participants of VHBP Balkan Hepatitis Meeting
- A total of 20 countries were included
- Survey addressed
 - The prevalence of HBV & HCV
 - The availability of national guidelines for management of HBV & HCV infection
 - Reimbursement policies for diagnostics (HBV DNA, HCV-RNA and transient elastography)
 - Availability of antiviral drugs and reimbursement policies

HBV: Availability and reimbursement policies in Europe

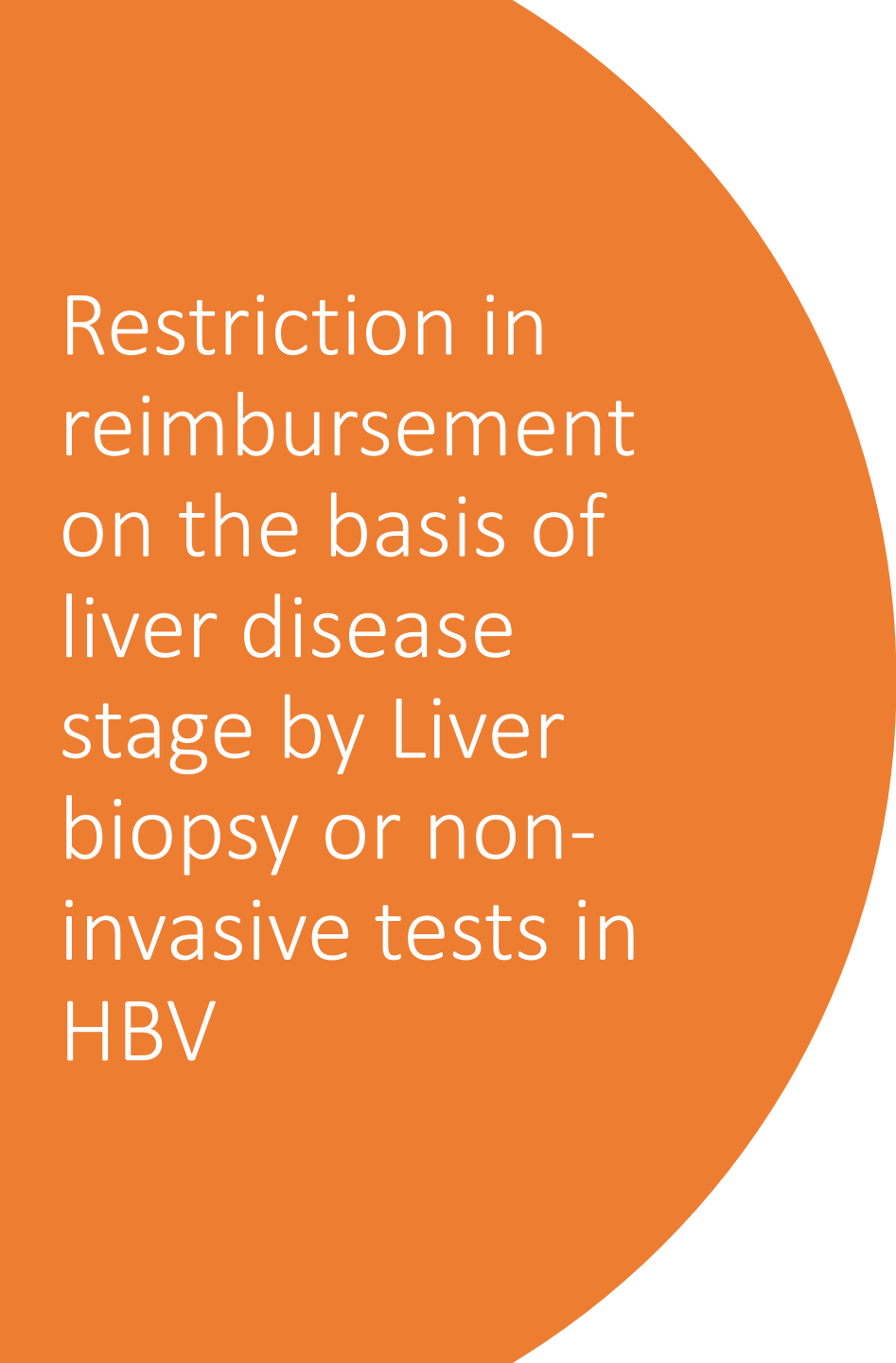
	National guideline	HBV DNA	Antiviral availability	LNB/non-invasive tests	Prophylaxis during immunosuppressive Rx
Czech Republic	Yes	A-reimbursed	Excl. TAF	None	Excl. TAF
England	Yes	A-reimbursed	All	None	Excl. TAF
Germany	Yes	A-reimbursed	All	None	LAM
Italy	Yes	A-reimbursed	Exl. LAM TAF restricted use	None	LAM, ETV
Netherlands	Yes	A-reimbursed	All	Required excl. LAM	Excl. LAM, TAF
Spain	Yes	A-reimbursed	Excl. LAM	None	ETV
Switzerland	No/EASL	A-reimbursed	Excl. LAM	Required	Excl. LAM
Sweeden	Yes	A-reimbursed	All*	None	All*
Russia**	Yes	Not reimbursed	Excl. LAM Others compansate	Required	Excl. LAM

* Rare use of LAM

**National program for elimination of HBV September 2022, DAA are free of charge

HBV: Availability and reimbursement policies in Balkans

	National guideline	HBV DNA	Antiviral	LNB/non-invasive tests	Prophylaxis during immunosuppressive Rx
Albania	Yes	RwRes	LAM, TDF	TDF	TDF
Bosnia & Herzegovina	No/EASL	A-reimbursed	Excl. TAF	None	ETV, TDF
Bulgaria	Yes	A-reimbursed	Excl. TAF LAM, ETV RwRes	All	LAM
Croatia	Yes	A-reimbursed	All TAF restricted use	None	All
Kosovo	No/EASL	Not reimbursed	LAM N-reimbursed ETV RwRes TDF	All	TDF
Montenegro	No/EASL	A-reimbursed	LAM, TDF	None	TDF
N Macedonia	Yes	A-reimbursed	LAM TDF Not reimbursed	None	LAM, TDF
Romania	Yes	RwRes	Excl. TAF	All	ETV, TDF
Serbia	No/EASL	A-reimbursed	All ETV, TAF Not reimbursed	LAM, TDF	TDF
Slovenia	Yes	A-reimbursed	All	None	All
Turkey	Yes	A-reimbursed	All	All	All

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Restriction in
reimbursement
on the basis of
liver disease
stage by Liver
biopsy or non-
invasive tests in
HBV

Bulgaria

Kosovo

Romania

Russia

Switzerland

Serbia

Turkey

Albania (TDF)

The Netherlands (Excl. LAM)

Tenofovir alafenamide fumarate (TAF) restricted use

Resistance to antivirals

- Slovenia

Who can not take ETV

- Croatia

Renal insufficiency

- Croatia, England, Germany, Italy, North Macedonia, Slovenia, Sweden, The Netherlands

Osteoporosis

- Bosnia & Herzegovina, Croatia, Italy, North Macedonia, Slovenia, Sweden

DAA

FDA-Approved

Elbasvir-Grazoprevir

Zepatier

[Summary »](#)
[Prescribing Information »](#)
[Clinical Trials »](#)
[References »](#)



Glecaprevir-Pibrentasvir

Mavyret

[Summary »](#)
[Prescribing Information »](#)
[Clinical Trials »](#)
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Ledipasvir-Sofosbuvir

Harvoni

[Summary »](#)
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[Clinical Trials »](#)
[References »](#)



Ribavirin

Copegus, Rebetol, Ribasphere

[Summary »](#)
[Prescribing Information »](#)
[Clinical Trials »](#)
[References »](#)



Sofosbuvir

Sovaldi

[Summary »](#)
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Sofosbuvir-Velpatasvir

Epclusa

[Summary »](#)
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Sofosbuvir-Velpatasvir-Voxilaprevir

Vosevi

[Summary »](#)
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Discontinued

Boceprevir

Victrelis

[Summary »](#)
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[Clinical Trials »](#)
[References »](#)



Daclatasvir

Daklinza

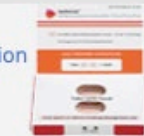
[Summary »](#)
[Prescribing Information »](#)
[Clinical Trials »](#)
[References »](#)



Ombitasvir-Paritaprevir-Ritonavir

Technivie

[Summary »](#)
[Prescribing Information »](#)
[Clinical Trials »](#)
[References »](#)



Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir

Viekira Pak

[Summary »](#)
[Prescribing Information »](#)
[Clinical Trials »](#)
[References »](#)



Simeprevir

Olysio

[Summary »](#)
[Prescribing Information »](#)
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Telaprevir

Incivek

[Summary »](#)
[Prescribing Information »](#)
[Clinical Trials »](#)
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HCV Diagnostics and therapeutics in Europe

	National guideline	HCV RNA	Fibroscan	A HCV
Czech Republic	Yes	Reimbursed	Reimbursed	DAA/ reimbursed
England	Yes	Reimbursed	Reimbursed	DAA/ reimbursed
Germany	Yes	Reimbursed	Not reimbursed	DAA/ N-reimbursed
Italy	Yes	Reimbursed	Not reimbursed	DAA/ reimbursed
The Netherlands	Yes	Reimbursed	Reimbursed	DAA/ reimbursed
Spain	Yes	Reimbursed	Reimbursed	DAA/ reimbursed
Switzerland	No/EASL	Reimbursed	Reimbursed	DAA / N-reimbursed
Sweden	Yes	Reimbursed	Reimbursed	DAA/ reimbursed
Russia	Yes	Not reimbursed	Not reimbursed	DAA/ reimbursed



Not available



Reimbursed with restriction



Not reimbursed



Reimbursed

HCV Diagnostics and therapeutics in Balkans

	National guideline	HCV RNA	Fibroscan	A HCV
Albania	Yes	Reimbursed w Res	Reimbursed	Symptomatic treatment
Bosnia & Herzegovina	No/EASL	Reimbursed	Reimbursed	DAA/ reimbursed
Bulgaria	Yes	Reimbursed w Res	Not reimbursed	DAA/ N-reimbursed
Croatia	Yes	Reimbursed	Reimbursed	DAA/ reimbursed
Kosovo	Yes	Not reimbursed	Not reimbursed	DAA/ reimbursed
Montenegro	No/EASL	Reimbursed	Reimbursed	Symptomatic treatment DAA/ reimbursed
N Macedonia	Yes	Reimbursed	Reimbursed	DAA/ reimbursed
Romania	Yes	Reimbursed w Res	Reimbursed	Symptomatic treatment
Serbia	No/EASL	Reimbursed w Res	Reimbursed	DAA/ reimbursed
Slovenia	Yes	Reimbursed	Reimbursed	DAA/ reimbursed
Turkey	Yes	Reimbursed	Not reimbursed	PEG-IFN /reimbursed

DAA use in Europe

	Sovaldi	Harvoni	Epclusa	Vosevi	Zepatier	Mavyret	Epclusa + ribavirin	Harvoni + ribavirin
Czech Republic	NA	NA	A-NotRes	AwRes	A-NotRes	A-NotRes	AwRes	NA
England	A-NotRes	A-NotRes	A-NotRes	AwRes	A-NotRes	A-NotRes	A-NotRes	A-NotRes
Germany	A-NotRes	A-NotRes	A-NotRes	AwRes	A-NotRes	A-NotRes	A-NotRes	A-NotRes
Italy	NA	NA	A-NotRes	AwRes	A-NotRes	A-NotRes	C	NA
Nederland	A-NotRes	A-NotRes	A-NotRes	AwRes	A-NotRes	A-NotRes	A-NotRes	A-NotRes
Russia*	C	C	C	NA	C	C	C	C
Spain	AwRes	NA	A-NotRes	AwRes	NA	A-NotRes	NA	NA
Sweedan	AwRes	A-NotRes	A-NotRes	A-NotRes	A-NotRes	AwRes	NA	NA
Switzerland	AwRes	NA	A-NotRes	AwRes	A-NotRes	A-NotRes	AwRes	NA



Not available



Available with restriction



Compensate use



Available w no restriction

*National program for elimination of HCV September 2022
DAA are free of charge

DAA use in Balkans

	Sovaldi	Harvoni	Epclusa	Vosevi	Zepatier	Mavyret	Epclusa + ribavirin	Harvoni + ribavirin
Albania	NA	AwRes	AwRes	NA	AwRes	AwRes	NA	NA
Bosnia & Herzegovina	NA	NA	A-NotRes	NA	NA	AwRes	NotReimbursed	NA
Bulgaria	AwRes	AwRes	A-NotRes	AwRes	AwRes	A-NotRes	AwRes	AwRes
Croatia	NA	A-NotRes	A-NotRes	AwRes	A-NotRes	A-NotRes	A-NotRes	A-NotRes
Kosovo	NA	NA	A-NotRes	NA	NA	NA	AwRes	NA
Montenegro	NA	NA	A-NotRes	NA	A-NotRes	A-NotRes	A-NotRes	NA
N Macedonia	NA	A-NotRes	A-NotRes	NA	A-NotRes	A-NotRes	A-NotRes	A-NotRes
Romania	NA	AwRes	AwRes	AwRes	NotReimbursed	AwRes	AwRes	AwRes
Serbia	AwRes	AwRes	AwRes	NA	AwRes	AwRes	NA	NA
Slovenia	NA	NA	A-NotRes	A-NotRes	NA	A-NotRes	NA	NA
Turkey	NA	NA	NA	A-NotRes	NA	A-NotRes	NA	AwRes



Not available



Not reimbursed

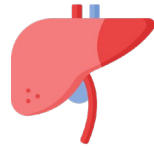


Reimbursed with restriction



Reimbursed

DAA reimbursed with restrictions



Liver disease stage (liver biopsy or non-invasive tests)



Relapse to previous treatment



Decompensated cirrhosis



Liver transplantation

Restriction in
reimbursement
on the basis of
liver disease
stage by Liver
biopsy or non-
invasive tests in
HCV

Albania

Bosnia & Herzegovina

Bulgaria

Romania

Russia

Serbia

Switzerland

Czech Republic (Epclusa + ribavirin)

Kosovo (Epclusa + ribavirin)

The Netherlands (Sovaldi)

Highlights HBV

The stage of disease assessed by liver biopsy or by using a variety of non-invasive methods is compulsory before treatment in some countries

HBV-DNA is available in all countries but reimbursed with some restrictions in Albania and Romania

Tenofovir alafenamide fumarate (TAF) is not available or not reimbursed in most Balkan countries

TAF appears to have limited, if any, bone toxicity and/or renal insufficiency in most countries

TAF is not indicated for prophylaxis during immunosuppressive treatment in most countries

Highlights HCV

The stage of disease assessed by liver biopsy or by using a variety of non-invasive methods is compulsory before treatment in some countries

PCR HCV RNA is available in all countries but reimbursed with some restrictions in Albania, Bulgaria, Romania and Serbia

There is still problem in treatment of acute HCV: DAA in not indicated or symptomatic treatment is common

At least one pan-genotypic DAA is available in all countries

Substantial progress has been made in accessing DAA HCV treatment

Thank you

