

## APPENDIX C

Healthcare Provider Perception of Boxed Warning Information Survey  
Survey Questionnaire: Chronic Hepatitis C Scenario  
Version: 10/23/20

### Prescriber Survey to Assess Boxed Warnings Perceptions

#### Survey Questionnaire: HCV

(Questions used for pre-testing condition are included at the end)

Introductory Script:

Thank you for your participation in this survey. The first few questions will focus on chronic hepatitis C viral infection, also known as chronic HCV.

**// Note: Where [drug] is indicated, respondents in the chronic HCV condition will be randomly assigned to see Harvoni, Mavyret, or Zepatier.//**

**//HIDDEN FROM PARTICIPANTS, will be used for piping only//**

**//Assign each HCV participant to one drug randomly, balancing the number assigned to each//**

**Question Type: Single Punch**

**Question DAA\_Drug**

Variable Name: *DAA\_Drug*

Variable Label: DAA Drug Assignment

**Question Text:** Random DAA Drug Assignment

Value	Value Label
1	Harvoni
2	Mavyret
3	Zepatier

**//PROGRAMMING NOTES: Display each question on its own separate screen. Do not allow participants to go back on any screen. Include soft prompts for all items. //**

**Question Type:** Single Punch

**Question Q1**

Variable Name: *Q1*

Variable Label: Q1 Familiarity with treating HCV

**Question Text:** How experienced are you with treating chronic HCV?

Value	Value Label
1	Not at all experienced
2	Slightly experienced
3	Somewhat experienced
4	Experienced
5	Very experienced
-99	Refused

**Question Type:** Single Punch

**Question Q2**

Variable Name: Q2

Variable Label: Q2 Number of patients typically seen

**Question Text:** How many patients do you typically see for treatment of chronic HCV?

Value	Value Label
1	One or two patients a week, or fewer
2	Several patients a week
3	Several patients a day
98	Unsure/Don't know
--99	Refused

**Question Type:** Single Punch

**Question 3**

Variable Name: Q3

Variable Label: Q3 Importance of curing HCV

**Question Text:** In general, how important is treating chronic HCV with the goal of a curing it?

Value	Value Label
1	Not at all important
2	Slightly important
3	Somewhat important
4	Important
5	Very important
98	Unsure/Don't know
-99	Refused

**Question Type:** Single Punch

**Question Q4A**

Variable Name: Q4A

Variable Label: Q4A Experience prescribing DAA

**Question Text:** Which of the following is true of your prescribing direct-acting antivirals (DAA) for the treatment of chronic HCV?

Value	Value Label
1	I have written new prescriptions for this product
2	I have only prescribed a refill for this product
3	I have never prescribed this product
98	Unsure/don't know
-99	Refused

**//SKIP 4B if 4A = 2, 3, 4, or 98//**

**Question Type:** Single Punch

**Question Q4B**

Variable Name: Q4B

Variable Label: Q4B Frequency of prescribing DAA

**Question Text:** On average, how often do you prescribe direct-acting antivirals (DAA) for treatment of chronic HCV?

Value	Value Label
1	I prescribe this product one or more times a week
2	I prescribe this product a few times a month
3	I prescribe this product a few times a year
98	Unsure/Don't know
-99	Refused

**Question Type:** Multi-Punch

**Question Q5**

Variable Name: Q5

Variable Label: Q5 Which treatments recommend or prescribe in a month

**Question Text:** Which of the following treatments would you recommend or prescribe in a typical month (Select all that apply)?

Variable Name	Value Text	Variable Label
Q5_1	Direct-acting antivirals (e.g., Harvoni, Epclusa, Mavyret, Vosevi, Zepatier)	Q5_1 Typical treatment: DAA
Q5_2	Multi-pill regimen(s) (e.g., PEG/Riba therapy)	Q5_2 Typical treatment: Multi pills
Q5_3	Interferon	Q5_3 Typical treatment:

		Interferon
Q5_4	Ribavirin	Q5_4 Typical treatment: Ribavirin
Q5_5	Other (specify)	Q5_5 Typical treatment: Other

Value	Value Label
1	Selected
0	Not selected

For the next few questions, we would like you to consider your patients who have been newly diagnosed with chronic HCV or are exhibiting early signs and symptoms of chronic HCV (such as fatigue and mild elevations in liver enzymes).

For this section, also consider the whole class of fixed-dose combination drugs/direct-acting antivirals.

**//[SHOW SCENARIO AT THE TOP OF THE SCREEN FOR QUESTION 6]//**

**Question Type:** Single Punch

**Question Q6**

Variable Name: Q6

Variable Label: Q6 Likelihood of discussing DAA

**Question Text:** How likely are you to discuss direct-acting antivirals as a potential option for these patients?

Value	Value Label
1	Very unlikely
2	Unlikely
3	Somewhat likely
4	Likely
5	Very likely
-99	Refused

**Question Type:** Single Punch

**Question Q7**

Variable Name: Q7

Variable Label: Q7 Risk assessment of DAA

**Question Text:** Which of the following statements describe your assessment of the safety of direct-acting antivirals used to treat HCV?

Value	Value Label
1	Risks are minimal for almost all patients
2	Risks are minimal for most patients, but are significant for some patients
3	Risks are significant for most patients
4	I am not familiar enough with direct-acting antivirals to make an assessment
-99	Refused

**Question Type:** Single Punch

**Question Q8**

Variable Name: Q8

Variable Label: Q8 Benefits/risks of DAA

**Question Text:** Which statement best describes your general perspective on the benefits versus risks of direct-acting antivirals for patients with chronic HCV?

Value	Value Label
1	The benefits of direct-acting antivirals outweigh the risks for most patients
2	The benefits of direct-acting antivirals outweigh the risks for some, but not most, patients
3	The benefits of direct-acting antivirals outweigh the risks for very few patients
4	I am not familiar enough with direct-acting antivirals to make an assessment
-99	Refused

**Question Type:** Multi-Punch

**Question Q9**

Variable Name: Q9

Variable Label: Q9 Factors most important when choosing to prescribe DAA

**Question Text:** Which of the following factors play the most important role when deciding whether or not to prescribe direct-acting antivirals to a patient with chronic HCV? Please choose the three factors that you consider to be most important.

**//PROGRAMMING NOTE: ALLOW PARTICIPANTS TO SELECT UP TO THREE ANSWERS//**

**[RANDOM ORDER EXCEPT FOR OTHER] [//Multi-punch//]**

Variable Name	Variable Text	Variable Label
Q9_1	Considerations of this patient's ability to take the product as prescribed	Q9_1 Factors: Patient ability to use
Q9_2	This patient's understanding and comfort with the risks of this medication	Q9_2 Factors: Understanding and comfort with risks
Q9_3	This patient's previous experience with treatments	Q9_3 Factors: Patient's previous experience
Q9_4	This patient's medical and health context (e.g., medical history, comorbidities)	Q9_4 Factors: Medical and health context
Q9_5	Considerations of this patient's access to the product (e.g., cost, insurance)	Q9_5 Factors: Patient access
Q9_6	Extent, duration, and severity of patient's symptoms	Q9_6 Factors: Symptoms
Q9_7	Patient's preference for a mode of administration	Q9_7 Factors: Patient preference for administration
Q9_8	Potential duration of treatment use/course	Q9_8 Factors: Duration
Q9_9	Other (please specify)	Q9_9 Factors: Other

Value	Value Label
1	Selected
0	Not selected

**Question Type:** Open End Essay

**Question Q9\_ACTIONS**

Variable Name: Q9\_ACTIONS

Variable Label: Q9\_ACTIONS Screening Actions before Starting Treatment

**Question Text:** What screening actions, if any, would you take before starting treatment with a direct-acting antiviral for a patient with chronic HCV?

**Question Type:** Multi-Punch

**Question Q10**

Variable Name: Q10

Variable Label: Q10 Top three questions from patients about using DAA

**Question Text:** What are the top three comments or questions you have heard from patients about using direct-acting antivirals to treat chronic HCV? (Select up to three.)

**//PROGRAMMING NOTE: ALLOW PARTICIPANTS TO SELECT UP TO THREE ANSWERS//**

**[//Multi-punch//]**

Variable Name	Variable Text	Variable Label
Q10_1	Concerns about undergoing treatment if the patient is currently asymptomatic	Q10_1 Comments top 3: Undergoing treatment if asymptomatic
Q10_2	Hearing positive things about how well direct-acting antivirals work	Q10_2 Comments top 3: Hearing positive things
Q10_3	Concerns about specific side effects	Q10_3 Comments top 3: Side effects
Q10_4	Concerns about insurance coverage or cost	Q10_4 Comments top 3: Insurance coverage/cost
Q10_5	Hearing negative things about how well direct-acting antivirals work	Q10_5 Comments top 3: Hearing negative things
Q10_6	Pros about the mode of administration	Q10_6 Comments top 3: Pros mode of administration
Q10_7	Cons about the mode of administration	Q10_7 Comments top 3: Cons mode of administration
Q10_8	Concerns about being able to complete treatment course	Q10_8 Comments top 3: General concerns re: treatment
Q10_9	Other (specify)	Q10_9 Comments top 3: Other

Value	Value Label
1	Selected
0	Not selected

**Question Type:** Multi-Punch

**Question Q11**

Variable Name: *Q11*

Variable Label: Q11 Top three topics talk to patients about DAA

**Question Text:** What are the top three topics that you prioritize when talking to your patients about direct-acting antivirals as a treatment option?

**//PROGRAMMING NOTE: ALLOW PARTICIPANT TO SELECT UP TO THREE ANSWERS//**

**[RANDOM ORDER EXCEPT FOR LAST OPTION] [//Multi-punch//]**

Variable Name	Variable Text	Variable Label
Q11_1	How the product works	Q11_1 Talking top 3: How product works
Q11_2	Expected benefits of the product	Q11_2 Talking top 3: Expected benefits
Q11_3	Common side effects of the product	Q11_3 Talking top 3: Common side effects
Q11_4	Rare but serious side effects of the product	Q11_4 Talking top 3: Rare serious effects
Q11_5	Patient's medical history (e.g., personal history or family history, possible co-morbidities)	Q11_5 Talking top 3: Medical history
Q11_6	The importance of using the product as directed	Q11_6 Talking top 3: Importance of use as directed
Q11_7	Other (Specify)	Q11_7 Talking top 3: Other

Value	Value Label
1	Selected
0	Not selected

**//PROGRAMMING NOTE: If Q11D selected, display Q11\_RISKS. OTHERWISE, PROCEED TO Q12 //**

**Question Type:** Open End Essay

**Question Q11\_RISKS**

Variable Name: *Q11\_RISKS*

Variable Label: Q11\_RISKS Side effects discussed

**Question Text:** You said that you discuss rare but serious side effects of the product. What potential side effects do you discuss?





**Question Type:** Multi-Punch

**Question Q12**

Variable Name: Q12

Variable Label: Q12 How monitor for safety risks and side effects after prescribing DAA

**Question Text:** How do you most commonly monitor your patients for potential safety risks and side effects after prescribing direct-acting antivirals for HCV? Select all that apply.

Variable Name	Variable Text	Variable Label
Q12_1	I schedule routine follow-up appointments with patients.	Q12_1 Monitor: Follow-up appointment
Q12_2	I instruct patients to get bloodwork before follow-up appointment.	Q12_2 Monitor: Bloodwork
Q12_3	I instruct patients to call and schedule an appointment if they experience side effects.	Q12_3 Monitor: Appointment if side effects
Q12_4	I leave it to the patient to follow up if they feel a need to.	Q12_4 Monitor: Leave up to patient
Q12_5	A follow-up appointment is not necessary.	Q12_5 Monitor: Follow-up not necessary
Q12_6	Other (specify)	Q12_6 Monitor: Other

Value	Value Label
1	Selected
0	Not selected

**Question Type:** Grid

**Question Q13**

Variable Name: Q13

Variable Label: Q13 How often look for information on DAA

**Question Text:** How often do you look for information about direct-acting antivirals from the following sources:

**[RANDOM ORDER]**

Variable Name	Variable Text	Variable Label
Q13_1	Medical journals	Q13_1 Info: Medical journals
Q13_2	Medical websites or software (e.g. UpToDate, Epocrates, Medscape)	Q13_2 Info: Medical websites or software
Q13_3	Drug company/pharmaceutical representatives or their website	Q13_3 Info: Drug company rep or website
Q13_4	Go online/use a search engine (e.g., Google)	Q13_4 Info: Online search

Q13_5	Professional medical societies (e.g., publications, guidelines)	Q13_5 Info: Professional medical societies
Q13_6	Conferences	Q13_6 Info: Conferences
Q13_7	Discussion with colleagues (e.g., in person, email)	Q13_7 Info: Discussion w/ colleagues
Q13_8	FDA website or other FDA sources of information (e.g., email, alerts)	Q13_8 Info: FDA
Q13_9	Other government agencies (e.g., NIH, CDC)	Q13_9 Info: Other government agencies

Value	Value Label
1	Never
2	Rarely
3	Sometimes
4	Often

**//[SHOW QUESTION AT THE TOP OF THE SCREEN FOR QUESTION 14]//**

The next question refers to boxed warnings, commonly referred to as black box warnings, on the product labeling for direct-acting antivirals.

**Question Type:** Multi-Punch

**Question 14**

Variable Name: *Q14*

Variable Label: Q14 Primary role of boxed warning

**Question Text:** In your opinion, what is the primary role of a boxed warning?

*Choose up to three options.*

**//Random Order, except last three//**

**//PROGRAMMING NOTE: ALLOW PARTICIPANT TO UP TO SELECT THREE ANSWERS//**

Variable Name	Variable Text	Variable Label
Q14_1	To highlight if the product has risk of serious or life-threatening adverse effects	Q14_1 BW Primary Role: Highlight most serious risks
Q14_2	To provide information that should be factored into a decision to prescribe the product	Q14_2 BW Primary Role: Provide prescribing information
Q14_3	To provide an overview of the safety profile of the product	Q14_3 BW Primary Role: Provide safety profile overview
Q14_4	To disclose clinical trial and other product safety testing information	Q14_4 BW Primary Role: Clinical trial and safety testing
Q14_5	To provide information that prescribers	Q14_5 BW Primary Role: Info to

	should be communicating to patients	communicate to patients
Q14_6	To provide information on how to safely use the product	Q14_6 BW Primary Role: Info on how to safely use product
Q14_7	I do not see a role for them	Q14_7 BW Primary Role: No role for BW
Q14_8	Other (specify)	Q14_8 BW Primary Role: Other
Q14_9	Unsure/Don't know	Q14_9 BW Primary Role: Unsure/Don't know

Value	Value Label
1	Included
0	Not included

**//PROGRAMMING NOTE: SHOW PARAGRAPH ON ITS OWN PAGE//**

The next set of questions will ask you more specifically about the boxed warning and the prescribing information for direct-acting antivirals to treat chronic HCV. This boxed warning appears on all prescription direct-acting antiviral products.

**//PROGRAMMING NOTE: "NEXT" BUTTON TO PROCEED TO Q15//**

**Question Type:** Single Punch

**Question Q15**

Variable Name: Q15

Variable Label: Q15 Familiarity with BW for DAA

**Question Text:** How would you rate your familiarity with the boxed warning for direct-acting antivirals?

Value	Value Label
1	Not at all familiar
2	Slightly familiar
3	Somewhat familiar
4	Familiar
5	Very familiar
-99	Refused



**Question Type:** Single Select Grid

**Question Q16**

Variable Name: Q16

Variable Label: Q16 Risks recalled from DAA boxed warning

**Question Text:** Which of the following risks do you recall being included in the boxed warning for direct-acting antivirals? Please indicate a response for each risk.

**[RANDOM ORDER EXCEPT FOR LAST OPTIONS]**

Variable Name	Variable Text	Variable Label
Q16_1	Hepatitis B reactivation in coinfecting patients	Q16_1 Risks: Hepatitis B
Q16_2	Bradycardia	Q16_2 Risks: Bradycardia
Q16_3	Interaction with beta blockers	Q16_3 Risks: Interaction with beta blockers
Q16_4	Asthenia	Q16_4 Risks: Asthenia
Q16_5	Visual abnormalities	Q16_5 Risks: Visual abnormalities
Q16_6	Elevated blood pressure	Q16_6 Risks: Elevated blood pressure
Q16_7	Stroke	Q16_7 Risks: Stroke
Q16_8	Other (specify)	Q16_9 Risks: Other

Value	Value Label
1	Included
2	Not included
98	Don't know

**//PROGRAMMING NOTE: SHOW PARAGRAPH ON ITS OWN PAGE, THEN CLICK NEXT TO VIEW BOXED WARNING//**

We would like to show you some of the boxed warning information for [DAA drug], which is available in the FDA-approved prescribing information. The boxed warning information appears on the labeling for all direct-acting antivirals. Please consider [DAA drug] to serve as an example that represents the direct-acting antiviral drug class as a whole. Please take a few moments to review this information.

**//PROGRAMMING NOTE: SHOW THE BOXED WARNING ON ITS OWN PAGE , CAPTURE TIME SPENT ON BOXED WARNING //**

[View boxed warning information]<sup>123</sup>

**//DISPLAY IF DAA\_DRUG = Harvoni//**

**NDC Code(s):** 61958-1801-1, 61958-1803-1, 61958-1804-1, 61958-1805-1

**Packager:** Gilead Sciences, Inc

**Category:** HUMAN PRESCRIPTION DRUG LABEL

**DEA Schedule:** None

**Marketing Status:** New Drug Application

## DRUG LABEL INFORMATION

Updated November 22, 2019

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### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use HARVONI<sup>®</sup> safely and effectively. See full prescribing information for HARVONI. HARVONI<sup>®</sup> (ledipasvir and sofosbuvir) tablets, for ...

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### BOXED WARNING [\(WHAT IS THIS?\)](#)

#### WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with HARVONI. HBV reactivation has been reported in HCV/HBV coinfecting patients who were undergoing or had completed treatment with HCV direct acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfecting patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated [see [WARNINGS AND PRECAUTIONS \(5.1\)](#)].

[CLOSE](#)

<sup>1</sup> NIH NLM (2019). LABEL: HARVONI- ledipasvir and sofosbuvir tablet, film coated.

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f4ec77e4-bae8-4db0-b3d5-bde09c5fa075>

<sup>2</sup> NIH NLM (2020). LABEL: MAVYRET- glecaprevir and pibrentasvir tablet, film coated. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7bf99777-0401-9095-8645-16c6e907fcc0>

<sup>3</sup> NIH NLM (2018). LABEL: ZEPATIER- elbasvir and grazoprevir tablet, film coated. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=164dc02a-9180-426a-b8b5-04ab39d2bbd4>

**//DISPLAY IF DAA\_DRUG = Mavyret//**

**NDC Code(s):** 0074-2625-01,0074-2625-28,0074-2625-56,0074-2625-80

**Packager:** AbbVie Inc.

**Category:** HUMAN PRESCRIPTION DRUG LABEL

**DEA Schedule:** None

**Marketing Status:** New Drug Application

## DRUG LABEL INFORMATION

Updated January 28, 2020

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### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MAVYRET safely and effectively. See full prescribing information for MAVYRET. MAVYRETTM (glecaprevir and pibrentasvir) tablets ...

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### BOXED WARNING [\(WHAT IS THIS?\)](#)

#### **WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV**

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfecting patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfecting patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated [see *Warnings and Precautions* (5.1)].

[CLOSE](#)



**//DISPLAY IF DAA\_DRUG = Zepatier//**

**NDC Code(s):** 0006-3074-01, 0006-3074-02

**Packager:** Merck Sharp & Dohme Corp.

**Category:** HUMAN PRESCRIPTION DRUG LABEL

**DEA Schedule:** None

**Marketing Status:** New Drug Application

## DRUG LABEL INFORMATION

Updated December 11, 2019

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### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ZEPATIER safely and effectively. See full prescribing information for ZEPATIER. ZEPATIER® (elbasvir and grazoprevir) tablets, for ...

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### BOXED WARNING [\(WHAT IS THIS?\)](#)

#### WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with ZEPATIER. HBV reactivation has been reported in HCV/HBV coinfecting patients who were undergoing or had completed treatment with HCV direct acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfecting patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated [see [WARNINGS AND PRECAUTIONS \(5.1\)](#)].

[CLOSE](#)

**//PROGRAMMING NOTE: HAVE A “NEXT” BUTTON AT THE BOTTOM OF THE BOXED WARNING PAGE TO PROCEED TO QUESTION 17//**

**Question Type:** Single Punch

**Question 17**

Variable Name: Q17

Variable Label: Q17 Usefulness of BW for DAA

**Question Text:** How useful is the information in the boxed warning for [DAA drug]?

Value	Value Label
1	Not at all useful
2	Slightly useful
3	Somewhat useful
4	Useful
5	Very useful
-99	Refused

**Question Type:** Single Punch

**Question Q18**

Variable Name: Q18

Variable Label: Q18 Assessment of risk framing in DAA BW

**Question Text:** What is your assessment of the way the risks of [DAA drug] are framed in the boxed warning?

Value	Value Label
1	Strongly understates risk
2	Somewhat understates risk
3	Provides appropriate assessment of risk information
4	Somewhat overstates risk
5	Strongly overstates risk
6	Other (specify)
-99	Refused

**Question Type:** Single Punch

**Question Q19**

Variable Name: Q19

Variable Label: Q19 Assessment of benefits versus risks Post-BW

**Question Text:** Which statement best reflects your opinion on the relative benefits versus risks of direct-acting antivirals for patients with chronic HCV?

Value	Value Label
1	The benefits of direct-acting antivirals outweigh the risks for most patients
2	The benefits of direct-acting antivirals outweigh the risks for some, but not most, patients
3	The benefits of direct-acting antivirals outweigh the risks for very few patients
4	I am not familiar enough with direct-acting antivirals to make an assessment
-99	Refused

**//[SHOW SCENARIO AT THE TOP OF THE SCREEN FOR QUESTION 19\_HBV]//**

Imagine this scenario when answering the following question:

In prescreening, you determine that your patient with HCV has previously received treatment for an HBV infection. The patient tests positive for HBV antibodies, but has no signs of currently active infection.

**Question Type:** Single Punch

**Question Q19\_HBV**

Variable Name: Q19\_HBV

Variable Label: Q19\_HBV Treating patient using DAA

**Question Text:** Which of the following best describes your course of action for treating this patient?

Value	Value Label
1	I would not prescribe [DAA drug] to this patient
2	I might still prescribe [DAA drug] to this patient, but would consider other options first
3	I would prescribe [DAA drug] to this patient but monitor her more carefully than other patients
4	I would refer this patient to someone else for treatment
5	Other (specify)
98	Unsure/Don't know
-99	Refused



[PIPE ALL RESPONSES TO Q19\_HBV\_OTH]

**Question Type: Open End Essay**

**Question Q19\_HBV\_OE**

Variable Name: *Q19\_HBV\_OE*

Variable Label: Q19\_HBV\_OE Reason for treatment option

**Question Text:** You said you would take the following course of action for treating this patient:

**PIPE SELECTED RESPONSE FROM Q19\_HBV]**

**//BOLD PIPED SELECTED RESPONSE//**

Please briefly elaborate on the reason(s) for your response.

[SOFT PROMPT]

**Question Type:** Multi-Punch

**Question 20**

Variable Name: Q20

Variable Label: Q20 How improve DAA boxed warning

**Question Text:** What would improve the boxed warning for [DAA drug] in your opinion? (Select all that apply.)

Variable Name	Variable Text	Variable Label
Q20_1	Nothing, the warning is fine the way it is	Q20_1 Improve BW: Nothing
Q20_2	Better evidence to support risk information	Q20_2 Improve BW: Better risk info evidence
Q20_3	Decrease the amount of information given/fewer words	Q20_3 Improve BW: Decrease amount of info/shorten
Q20_4	Simpler language	Q20_4 Improve BW: Simpler language
Q20_5	Formatting improvements (e.g., use of boldface)	Q20_5 Improve BW: Formatting
Q20_6	Increase the amount of information (e.g., statistics, more details)	Q20_6 Improve BW: Increase amount of info
Q20_7	Other (Specify)	Q20_7 Improve BW: Other (specify)
Q20_8	Unsure/Don't know	Q20_8 Improve BW: Unsure/Don't know

//Q20\_8: Make exclusive//

Value	Value Label
1	Included
0	Not included

**Question Type:** Open End Essay

**Question Q21**

Variable Name: Q21

Variable Label: Q21 Specific feedback on DAA BW information

**Question Text:** Please provide any specific feedback on the boxed warning information for [DAA drug].

**//PROGRAMMING NOTE: SHOW SENTENCE ON ITS OWN PAGE, THEN CLICK NEXT TO VIEW Q22//**

Please now consider boxed warnings in general, not only the one you saw for [DAA drug].

**Question Type:** Grid

**Question Q22**

Variable Name: Q22

Variable Label: Q22 Degree agree or disagree with BW statements

**Question Text:** To what degree do you agree or disagree with the following statements about boxed warnings in general (in other words, across all classes of prescription drugs)?

**[RANDOM ORDER for 1-6]**

Variable Name	Variable Text	Variable Label
Q22_1	Boxed warnings are very common on the products that I prescribe	Q22_1 Agree/Disagree: BW are very common on products I prescribe
Q22_2	Boxed warnings do not generally factor heavily into my decisions on whether to prescribe a product	Q22_2 Agree/Disagree: BW do not generally factor heavily
Q22_3	I think carefully before prescribing a product with a boxed warning if other treatments are available	Q22_3 Agree/Disagree: I think carefully before prescribing BW product if others available
Q22_4	I counsel my patients differently when prescribing a product with a boxed warning	Q22_4 Agree/Disagree: Counsel patients differently with BW
Q22_5	My patients rarely know whether a product would have a boxed warning or not	Q22_5 Agree/Disagree: Patients rarely know if product has BW
Q22_6	My patients are worried or scared when they see boxed warnings	Q22_6 Agree/Disagree: Patients worried/scared when they see BW

Value	Value Label
1	Strongly disagree
2	Disagree
3	Neither agree nor disagree
4	Agree
5	Strongly agree
98	Unsure/Don't know





**Question Type:** Single Punch

**Question 23**

Variable Name: Q23

Variable Label: Q23 General favorability of BW

**Question Text:** How favorable is your opinion of boxed warnings *in general* (across all classes of prescription drugs)?

Value	Value Label
1	Very unfavorable
2	Somewhat unfavorable
3	Neither unfavorable nor favorable
4	Somewhat favorable
5	Very favorable
98	Unsure/Don't know
-99	Refused

**Question Type:** Open End Essay

**Question Q24**

Variable Name: Q24

Variable Label: Q24 Suggestions for better using BW to highlight safety info

**Question Text:** In general, what suggestions do you have on how to better use boxed warnings as a tool to highlight important safety information?

**//PRETEST ONLY//**

**//DISPLAY TEXT//**

**We would like your feedback on the survey that you completed. This will help FDA improve the survey for future use with healthcare providers.**

**Question Type:** Single Punch

**Question P1**

Variable Name: *P1*

Variable Label: P1 One session completion

**Question Text:** Were you able to complete the survey in one session?

Value	Value Label
1	Yes
0	No

**Question Type:** Single Punch

**Question P2**

Variable Name: *P2*

Variable Label: P2 Participant Experience with Survey

**Question Text:** How would you rate your experience taking the survey?

Value	Value Label
1	Poor
2	Fair
3	Good
4	Very good
5	Excellent
-99	Refused

**Question Type:** Open End Essay

**Question P3**

Variable Name: *P3*

Variable Label: P3 Difficulty answering question

**Question Text:** Were there any questions you had difficulty answering? If yes, please explain.

**Question Type:** Open End Essay

**Question P4**

Variable Name: *P4*

Variable Label: P4 Other feedback

**Question Text:** What other suggestions of feedback about this survey would you like to share?

**//DISPLAY FOR BOTH PRETEST AND MAIN STUDY//**

Thank you for taking this survey. Your time is greatly appreciated.