Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Medication	Quantity Limit
Victrelis (boceprevir)	12 capsules per day

OVERRIDE(S)

Prior Authorization of Benefits

APPROVAL DURATION

Initial Approval Duration: 10 weeks

Additional Approval Duration: based on documentation of HCV-RNA results[ab] and treatment status

HCV Treatment Status	Initial Approval Duration	HCV RNA Results at treatment week 8	Additional Approval Duration
Previously untreated individuals	10 weeks	"Not Detected"	18 weeks
Previously untreated individuals	10 weeks	"Detected"	26 weeks
Previous partial responders[c] or relapsers[d]	10 weeks	"Detected or Not Detected"	26 weeks
Previous null responders[e]	10 weeks	"Detected or Not Detected"	38 weeks

[a]**Treatment Futility (any remaining authorization will be termed):**

- **I.** If the individual has HCV-RNA results greater than or equal to 1000 IU/mL at treatment week 8, then discontinue therapy with Victrelis; **OR**
- **II.** If the individual has HCV-RNA results greater than or equal to 100 IU/mL at treatment week 12 then discontinue therapy with Victrelis; **OR**
- **III.** If the individual has confirmed, detectable HCV-RNA at treatment week 24, then discontinue therapy with Victrelis.

[b]"Not Detected" refers to HCV-RNA assay results reported as "Target Not Detected" or "HCV-RNA Not Detected". In clinical trials, HCV-RNA in plasma was measured using a Roche COBAS® TaqMan® assay with a lower limit of quantification of 25 IU/mL and a limit of detection of 9.3 IU/mL.

[c]Previous Partial Responder: Defined as an individual who failed to achieve SVR after at least 12 weeks (for example, individual had detectable HCV RNA levels at week 12) of previous treatment with peg interferon alfa and ribavirin, but demonstrated a ≥ 2 log10 reduction in HCV RNA by 12 weeks.

[d]Previous Relapser: Individual who had an undetectable HCV RNA by at least 12 weeks of previous treatment with peg interferon alfa and ribavirin, but failed to demonstrate maintenance of SVR (for example, detectable HCV RNA levels) following previous treatment.

[e]Previous Null Responder: Defined as an individual who had a < 2 log10 reduction in HCV RNA at week 12 of previous treatment with peg interferon alfa and ribavirin.

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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APPROVAL CRITERIA

Requests for Victrelis (boceprevir) may be approved if the following criteria are met:

- **I.** Individual will have access to sufficient quantity to complete an entire course of therapy; **AND**
- **II.** Individual is 18 years of age or older; **AND**
- **III.** Documentation is provided for a diagnosis of chronic Hepatitis C virus (HCV) Genotype 1; **AND**
- **IV.** A copy of the baseline quantitative HCV RNA test result is provided to document baseline level of viremia; **AND**
- **V.** Individual is using Victrelis (boceprevir) in combination with peg interferon alfa and ribavirin; **AND**
- **VI.** Individual has compensated liver disease[1] (with or without cirrhosis); **AND**
- **VII.** Individual will receive treatment with peg interferon and ribavirin for 4 weeks (Treatment Weeks 1-4) prior to starting therapy with Victrelis.

Victrelis (boceprevir) may **not** be approved for the following:

- **I.** Individual is using in combination with another serine NS3/4A protease inhibitor, a NS5B polymerase inhibitor, or a NS5A inhibitor; **OR**
- **II.** Individual has received previous treatment for hepatitis C virus (HCV) with one of the following:
  - **a.** An interferon-based triple therapy regimen, which includes ribavirin and an oral direct-acting antiviral [such as but not limited to, Incivek (telaprevir), Victrelis (boceprevir), Olysio (simeprevir), or Sovaldi (sofosbuvir)]; **OR**
  - **b.** A therapy regimen containing a NS5A inhibitor [such as but not limited to, Harvoni (ledipasvir/sofosbuvir) or ombitasvir)]; **OR**
  - **c.** A therapy regimen containing a serine NS3/4A protease inhibitor [such as but not limited to, Incivek (telaprevir), Victrelis (boceprevir), Olysio (simeprevir), or asunaprevir]; **OR**
  - **d.** A therapy regimen containing a NS5B polymerase inhibitor [such as but not limited to Sovaldi (sofosbuvir) or dasabuvir].

***Notes:**

1. Compensated Liver Disease:

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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According to the American Association for the Study of Liver Diseases (AASLD 2009, 2014), the specific criteria for compensated liver disease include all of the following: a total bilirubin; serum albumin; prothrombin time/INR; presence of ascites; and presence of hepatic encephalopathy. However, these criteria do not establish a comprehensive definition of compensated liver disease. In fact, the AASLD guidelines refer to compensated liver disease as Grade A based on the Child Pugh-Turcotte (CPT) classification scoring system.

Child Pugh Classification (AASLD/IDSA 2014)

Parameters			
Points Assigned	1 point	2 points	3 points
Total Bilirubin (µmol/L)	<34	34-50	>50
Serum Albumin (g/L)	>35	28-35	<28
Prothrombin time/INR	INR <1.7	1.71-2.30	>2.30
Ascites	None	Mild	Moderate to Severe
Hepatic Encephalopathy	None	Grade I-II (or suppressed with medication	Grade III-IV (or refractory)

Child Pugh Score Interpretation (AASLD/IDSA 2009, 2014)

Class A	5-6 points	Well compensated liver disease
Class B	7-9 points	Significant functional compromise (moderate hepatic impairment)
Class C	10-15 points	Uncompensated liver disease (severe hepatic impairment)