

**Clinical Policy: Sofosbuvir (Sovaldi)**

Reference Number: LA.PHAR.281

Effective Date: 09/16

Last Review Date: 05/18

Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

**Description**

Sofosbuvir (Sovaldi®) is a nucleotide analog inhibitor of hepatitis C virus (HCV) NS5B polymerase.

**FDA-Approved Indication**

Sovaldi is indicated for the treatment of:

- Adult patients with genotype 1, 2, 3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen.
- Pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin (RBV).

**Policy/Criteria**

*Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of health plans affiliated with Centene Corporation® that Sovaldi is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria****A. Chronic Hepatitis C Infection (must meet all):**

1. Diagnosis of chronic HCV infection as evidenced by multiple detectable HCV RNA (ribonucleic acid) levels in the last 6 months;
2. Confirmed HCV genotype is one of the following (a or b):
  - a. For adults (>18 years): Genotypes 1, 2, 3, 4, 5, or 6;
  - b. For pediatrics (age ≥ 12 years or body weight > 35kg): Genotypes 2 or 3;
3. Age ≥ 12 years or body weight > 35kg;
4. Life expectancy ≥ 12 months with HCV treatment;
5. Prescriber and patient must attest that the patient is not actively participating in illicit IV drug use and/or alcohol use;
6. Advanced liver disease defined as (a,b or c):
  - a. Advanced fibrosis indicated by i, ii, or iii:
    - i. Liver biopsy showing a METAVIR score of F3 or equivalent (Knodell, Scheuer, Batts-Ludwig – F3; Ishak – F4/5);
    - ii. One serologic test showing an equivalent score to METAVIR F4
    - iii. One radiologic test showing an equivalent score to METAVIR F3 per Appendix C;
  - b. Cirrhosis indicated by i, ii, iii, iv or v:

- i. Hepatocellular carcinoma (HCC) amenable to resection, ablation or transplant;
  - ii. Liver biopsy showing a METAVIR score of F4 or equivalent (Knodell, Scheuer, Batts-Ludwig – F4; Ishak - F5/6);
  - iii. One serologic test showing an equivalent score to METAVIR F4 per Appendix C;
  - iv. One radiologic test showing an equivalent score to METAVIR F4 per Appendix C;
  - v. Other radiologic test showing evidence of cirrhosis (e.g., portal hypertension);
- c. If member is HIV/HCV co-infected, there shall be no METAVIR score requirements.
7. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (*see Section V Dosage and Administration for reference*);
  8. If member is  $\geq 18$  years of age and is without cirrhosis or with compensated cirrhosis (Child-Pugh A): contraindication or intolerance to Mavyret;
  9. Member agrees to participate in a medication adherence program meeting both of the following components:
    - a. Medication adherence monitored by pharmacy claims data or member report;
    - b. Member's risk for non-adherence identified by adherence program or member/prescribing physician follow-up at least every 4 weeks;
  10. Member is hepatitis B virus (HBV) negative, or if positive, documentation that concurrent HBV infection is being treated (e.g., tenofovir alafenamide, adefovir, entecavir), unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);
  11. At the time of request, member has none of the following contraindications if Sovaldi is prescribed with ribavirin:
    - a. Pregnancy;
    - b. For Rebetol: creatinine clearance  $< 50$  mL/min;
  12. Dose does not exceed 400 mg (1 tablet) per day.

**Approval duration for Adults: up to a total of 24 weeks\***

(\*Approved duration should be consistent with a regimen in Section V Dosage and Administration)

**Approval duration for Pediatrics: 12 weeks for genotype 2; 24 weeks for genotype 3**

**B. Other diagnoses/indications**

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. Chronic Hepatitis C Infection (must meet all):**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Sovaldi for chronic HCV infection and has received this medication for at least 30 days;
2. Member is responding positively to therapy (e.g. decreased HCV RNA level, no unacceptable toxicity);

3. Dose does not exceed 400 mg (1 tablet) per day.

**Approval duration for Adults: up to a total of 24 weeks\***

*(\*Approved duration should be consistent with a regimen in Section V Dosage and Administration)*

**Approval duration for Pediatrics: up to 12 weeks for genotype 2; up to 24 weeks for genotype 3**

**B. Other diagnoses/indications**

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.**

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ALT: alanine aminotransferase

APRI: AST to platelet ratio

AASLD: American Association for the Study of Liver Diseases

CTP: Child Turcotte Pugh

CrCl: creatinine clearance

DNA: deoxyribonucleic acid

FDA: Food and Drug Administration

FIB-4: Fibrosis-4 index

HBeAg: hepatitis B virus envelope antigen

HBV: hepatitis B virus

HCC: hepatocellular carcinoma

HCV: hepatitis C virus

IDSA: Infectious Diseases Society of America

MRE: magnetic resonance elastography

NS3/4A, NS5A/B: nonstructural protein

Peg-IFN: pegylated interferon

PI: protease inhibitor

PO: by mouth

QD: daily

RBV: ribavirin

RNA: ribonucleic acid

*Appendix B: General Information*

- Hepatitis B Reactivation is a Black Box Warning for all direct-acting antiviral drugs for the treatment of HCV. The provider must provide either:
  - Documentation of absence of concurrent HBV infection as evidenced by laboratory values showing absence of hepatitis B virus envelope antigen (HBeAg) and HBV DNA (deoxyribonucleic acid);
  - Documentation that HBV co-infected patient may not be candidates for therapy as evidenced by one of the following:
    - Absence of HBeAg, HBV DNA less than 2,000 international units/mL, and alanine aminotransferase (ALT) level within 1 to 2 times the upper limit of normal;
    - HBeAg-positive and HBV DNA greater than 1,000,000 international units/mL and ALT level within 1 to 2 times the upper limit of normal;

- Documentation that concurrent HBV infection is being treated (e.g., tenofovir alafenamide, adefovir, entecavir), unless contraindicated or clinically significant adverse effects are experienced.
- The 2016 AASLD/IDSA treatment guideline for HBV consider ALT levels <30 U/L for men and <19 U/L for women as upper limits of normal.
- The 2016 AASLD/IDSA treatment guideline for HBV recommend adults with compensated cirrhosis, even with low levels of viremia (<2,000 IU/mL) be treated with antiviral therapy to reduce the risk of decompensation, regardless of ALT level. The recommendation extends to adults with decompensated cirrhosis be treated with antiviral therapy indefinitely regardless of HBV DNA level, HBeAg status, or ALT level to decrease the risk of worsening liver-related complications.

**Appendix C: Approximate Scoring Equivalencies using METAVIR F3/F4 as Reference**

Fibrosis/ Cirrhosis	Serologic Tests*				Radiologic Tests†		Liver Biopsy‡	
	Fibro Test	FIBRO Spect II	APRI	FI B- 4	FibroScan (kPa)	MRE (kPa)	METAVIR	Ishak
Advanced fibrosis	≥0.59	≥42	>1.5	>3 .25	≥9.5	≥4.11	F3	F4-5
Cirrhosis	≥0.75	≥42	>1.5	>3 .25	≥12.0	≥4.71	F4	F5-6

**\*Serologic tests:**

FibroTest (available through Quest as FibroTest or LabCorp as FibroSure)

FIBROSpect II (available through Prometheus Laboratory)

APRI (AST to platelet ratio index)

FIB-4 (Fibrosis-4 index: includes age, AST level, platelet count)

**†Radiologic tests:**

FibroScan (transient elastography)

MRE (magnetic resonance elastography)

**‡Liver biopsy (histologic scoring systems):**

METAVIR F3/F4 is equivalent to Knodell, Scheuer, and Batts-Ludwig F3/F4 and Ishak F4-5/F5-6

METAVIR fibrosis stages: F0 = no fibrosis; F1 = portal fibrosis without septa; F2 = few septa; F3 = numerous septa without cirrhosis; F4 = cirrhosis

**Appendix D: Direct-Acting Antivirals for Treatment of HCV Infection**

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)	CYP3A Inhibitor
Daklinza	Daclatasvir				
Epclusa*	Velpatasvir	Sofosbuvir			
Harvoni*	Ledipasvir	Sofosbuvir			
Olysio				Simeprevir	
Sovaldi		Sofosbuvir			



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Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)	CYP3A Inhibitor
Technivie*	Ombitasvir			Paritaprevir	Ritonavir
Viekira XR/PAK*	Ombitasvir		Dasabuvir	Paritaprevir	Ritonavir
Zepatier*	Elbasvir			Grazoprevir	

\*Combination drugs

**V. Dosage and Administration**

Drugs	Dosing Regimen	Maximum Dose	Reference
Sovaldi, Olysio	Genotype 1: Treatment-naïve patients without cirrhosis: Sovaldi 400 mg plus Olysio 150 mg by mouth (PO) daily (QD) for 12 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA
Sovaldi, Olysio	Genotype 1: Treatment-naïve patients with compensated cirrhosis: Sovaldi 400 mg PO QD plus Olysio 150 mg PO QD with or without weight-based RBV (1000 mg [<75 kg] to 1200 mg [>75 kg]) for 24 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA
Sovaldi, Olysio	Genotype 1: Liver transplant patients with or without compensated cirrhosis: Sovaldi 400 mg PO QD plus Olysio 150 mg PO QD with or without weight-based RBV for 12 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 1: Treatment-naïve or treatment-experienced without cirrhosis: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD for 12 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA
Sovaldi, Daklinza	Genotype 1: Treatment-naïve or treatment-experienced with compensated cirrhosis: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD with or without weight-based RBV for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 1, 4, 5, or 6: Decompensated cirrhosis (including those with hepatocellular carcinoma):	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA

Drugs	Dosing Regimen	Maximum Dose	Reference
	Daklinza 60 mg PO plus Sovaldi 400 mg PO QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks		
Sovaldi, Daklinza	Genotype 1, 4, 5, or 6: Decompensated cirrhosis (including those with hepatocellular carcinoma) and intolerant to RBV: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 1 or 4: Treatment-naïve or treatment-experienced, post-liver transplantation including those with compensated cirrhosis: Daklinza 60 mg PO QD plus Sovaldi 400 mg PO QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA
Sovaldi, Daklinza	Genotype 1 or 4: Treatment -naïve, post-liver transplantation with compensated liver disease, who are ribavirin ineligible: Daklinza 60 mg PO QD plus Sovaldi 400 mg PO QD for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 2: Treatment-naïve or treatment-experienced without cirrhosis: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD for 12 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 2: Treatment -naïve or treatment-experienced with compensated cirrhosis: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD for 16 to 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 2: In whom previous treatment with Sovaldi/RBV has failed: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD with or without weight-based RBV for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 2 or 3: Decompensated cirrhosis (including those with hepatocellular carcinoma):	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA

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Drugs	Dosing Regimen	Maximum Dose	Reference
	Daklinza 60 mg PO plus Sovaldi 400 mg PO QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks		
Sovaldi, Daklinza	Genotype 2: Treatment-naïve or treatment-experienced, post-liver transplantation, including those with compensated cirrhosis: Daklinza 60 mg PO QD plus Sovaldi 400 mg PO QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 2: Treatment-naïve or treatment-experienced, post-liver transplantation, including those with compensated cirrhosis, who are ribavirin ineligible: Daklinza 60 mg PO QD plus Sovaldi 400 mg PO QD for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 3: Treatment-naïve or treatment-experienced with Peg IFN/RBV without cirrhosis: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD for 12 weeks	Sovaldi: 400 mg/day	1) FDA-approved labeling 2) AASLD-IDSA
Sovaldi, Daklinza	Genotype 3: Treatment-naïve with compensated cirrhosis: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD with or without weight-based RBV for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 3: Treatment-experienced with Peg IFN/RBV or with sofosbuvir-based treatment without prior experience with NS5A inhibitor with compensated cirrhosis: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD with weight-based RBV for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 3: In whom previous treatment with Sovaldi/RBV has failed: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD with weight-based RBV for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA

Drugs	Dosing Regimen	Maximum Dose	Reference
Sovaldi, Daklinza	Genotype 3: Treatment-naïve or treatment-experienced, post-liver transplantation, in the allograft, including those with compensated cirrhosis: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD with low initial dose RBV (600mg, increased as tolerated) for 12 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, Daklinza	Genotype 3: Treatment-naïve or treatment-experienced, post-liver transplantation, in the allograft, including those with compensated cirrhosis, who are ribavirin ineligible: Daklinza 60 mg PO plus Sovaldi 400 mg PO QD for 24 weeks	Sovaldi: 400 mg/day	† AASLD-IDSA
Sovaldi, RBV	Genotype 2: Treatment -naïve or treatment-experienced, post-liver transplantation, in the allograft, including those with compensated cirrhosis: Sovaldi 400mg PO QD plus weight-based RBV for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA
Sovaldi, RBV	Genotype 2: Treatment-naïve or treatment-experienced, post-liver transplantation, in the allograft, with decompensated cirrhosis: Sovaldi 400mg PO QD plus RBV (initial dose 600mg/day, increased monthly by 200mg/day as tolerated to weight-based dose) for 24 weeks	Sovaldi: 400 mg/day	AASLD-IDSA

**Indication: Pediatric patients (age ≥ 12 years or weighing at least 35 kg) with chronic HCV infection**

Drugs	Dosing Regimen	Maximum Dose	Reference
Sovaldi, RBV	Pediatric patients (12 years of age and older or weighing at least 35 kg) with chronic HCV infection Genotype 2: Sovaldi 400 mg + RBV for 12 weeks	Sovaldi: 400 mg/day	FDA-approved labeling
Sovaldi, RBV	Pediatric patients (12 years of age and older or weighing at least 35 kg) with	Sovaldi: 400 mg/day	FDA-approved labeling



	chronic HCV infection Genotype 3: Sovaldi 400 mg + RBV for 24 weeks		
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*\*AASLD/IDSA treatment guidelines for chronic hepatitis C infection are updated at irregular intervals; refer to the most updated AASLD/IDSA guideline for most accurate treatment regimen.*

*\*The use of Sovaldi in combination with peginterferon and ribavirin for the treatment of chronic HCV is no longer recommended by the AASLD/IDSA guidelines.*

## VI. Product Availability

Tablet: 400 mg

## VII. References

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13. El-Shabrawi MH, Kamal NM. Burden of pediatric hepatitis C. World J Gastroenterol. 2013 Nov 28;19(44):7880-8. doi: 10.3748/wjg.v19.i44.7880.
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Reviews, Revisions, and Approvals	Date	Approval Date
New policy created, split from CP.PHAR.17. HCV RNA levels over six-month period added to confirm infection is chronic. Life expectancy "≥12 months if HCC and awaiting transplant" is modified to indicate "≥ 12 months with HCV therapy." Testing criteria reorganized by "no cirrhosis"/"cirrhosis" consistent with the regimen tables; HCC population is included under "cirrhosis" and broadened to incorporate HCC amenable to curative measures (resection, ablation, transplant). Methods to diagnose fibrosis/cirrhosis are modified to require presence of HCC, liver biopsy or a combination of one serologic and one radiologic test. Serologic and radiologic tests are updated and correlated with METAVIR per Appendix B. Removed creatinine clearance restriction. Criteria added excluding post-liver transplantation unless regimens specifically designate. Dosing regimens are presented in Appendix D and E. The initial approval is shortened to 8 weeks.	08/16	09/16
Added criteria for Pediatric Chronic Hepatitis C Infection. Updated contraindications, removed hypersensitivity to drug and cardiac disease per PI;	04/17	
Policy converted to new template. Added requirement for prevention of HBV reactivation; expanded genotypes to reflect AASLD/IDSA CHC tx guidelines. Consolidated appendix D and E into dosing and administration in section V, deleted "up to" in initial approval duration; deleted adherence requirement in continued, added documentation of positive response to therapy and continuity of care, and removed CIs in section II, added reference column in section V. Added preferencing information requiring Mavyret for FDA-approved indications. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Exception made to require Hep B screening.	08/17	09/17

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Reviews, Revisions, and Approvals	Date	Approval Date
Removed the following language: "If a lower cost alternative regimen carries an equal or higher AASLD-IDSA rating, a clinical contraindication or intolerance must be present for the alternative regimen prior to approval."	09/17	
Due to State requirements, removed prescriber restrictions regarding who can prescribe Hepatitis C DAA agents; Removed the abstinence period of 6 months and added documentation required that member is not actively participating in alcohol and/or illicit IV drugs use,; Added statement that NO Fibrosis score is required for HIV/HCV co-infected members	5/18	5/18
Changed language to one serologic test OR one radiologic test from one serologic test and one radiologic test	5/18	5/18

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan



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retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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