

CRITERIA FOR PRIOR AUTHORIZATION

Direct Acting Hepatitis C Agents

PROVIDER GROUP	Pharmacy
MANUAL GUIDELINES	The following drug requires prior authorization: Simeprevir (Olysio®)

CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF ONE DIRECT ACTING AGENT: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of 12 weeks of Olysio therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1 hepatitis C
- If patient has subtype 1a they must have a negative test for NS3-Q80k polymorphism
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Olysio must be used in combination with Peginterferon alfa and ribavirin or sofosbuvir
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Olysio
- Patient must not have been on a previous or concurrent direct acting hepatitis C agent
- Dose must not exceed 1 capsule per day
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- The patient must not have advanced and/or decompensated cirrhosis (moderate or severe hepatic impairment)
- Patient must have one of the following:
 - Advanced fibrosis (as defined by a Metavir score of F3)
 - Compensated cirrhosis
 - Organ transplant
 - Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)
 - Proteinuria
 - Nephrotic syndrome
 - Membranoproliferative glomerulonephritis
- For Genotype 1: the PDL preferred drug, which covers Genotype 1, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines

LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT 12 weeks

Ribavirin and peg-interferon alfa are approved when using triple therapy with Olysio, if Olysio criteria are met.

DISCONTINUATION CRITERIA FOR ONE DIRECT ACTING AGENT

- Provider must submit HCV RNA level after treatment week 4, within 7 days, to prevent discontinuation of therapy
- Therapy will be discontinued if the HCV RNA level is greater than or equal to 25IU/mL after treatment week 4

PA Criteria

CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF TWO DIRECT ACTING AGENTS: (must meet all of the following)

- Patient must have a diagnosis of chronic hepatitis C (CHC) genotype 1
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Dose must not exceed 1 capsule per day
- Patient must not be on previous or concurrent therapy with a direct acting hepatitis C agent
- The patient must not have advanced and/or decompensated cirrhosis (moderate or severe hepatic impairment)
- Patient must have one of the following:
 - Advanced fibrosis (Metavir F3)
 - Compensated cirrhosis
 - Organ transplant
 - Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)
 - Proteinuria
 - Nephrotic syndrome
 - Membranoproliferative glomerulonephritis
- For Genotype 1: the PDL preferred drug, which covers Genotype 1, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines

LENGTH OF INITIAL APPROVAL 4 weeks

RENEWAL CRITERIA FOR TWO DIRECT ACTING AGENTS: (must the following)

- Prescriber must document adherence by patient of greater than or equal to 90% for both agents

LENGTH OF RENEWAL APPROVALS 4 weeks for a total of 12 weeks of treatment

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE