

CRITERIA FOR PRIOR AUTHORIZATION

Daklinza® (daclatasvir)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Daclatasvir (Daklinza®)

CRITERIA FOR INITIAL APPROVAL OF DACLATASVIR: (must meet all of the following):

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

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1 or 3 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Must be used in combination with Sovaldi® (sofosbuvir)
- Patient must not have been on a previous or concurrent direct acting hepatitis C agent (except concurrent therapy with Sovaldi® according to acceptable treatment therapy options)
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 tablet per day
- Patient must have a Metavir score of F3 or greater
- Patient must not be concurrently prescribed a strong CYP3A inducer (e.g. phenytoin, carbamazepine, rifampin, St. John’s wort)
- Patient must not be on concurrent moderate CYP3A inducers (e.g. bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine)
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with daclatasvir combination therapy
- 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

CRITERIA FOR RENEWAL (must meet all of the following):

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

LENGTH OF APPROVAL: 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

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