STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DACLATASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DACLATASVIR DIHYDROCHLORIDE	DAKLINZA	41377		GPI-10 (1235302510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hepatitis C, genotype 1 or genotype 3 infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - There is evidence of current HCV infection and chronic HCV infection documented by at least ONE detectable HCV RNA level within the past 6 months
   - The patient is 1) without cirrhosis or 2) has decompensated cirrhosis or 3) post-liver transplant patient (with or without cirrhosis)
   - The request is for Daklinza in combination with Sovaldi

   CLINICAL PHARMACIST: Patient must also meet all criteria in Sovaldi guideline to be approvable for both agents. Review hepatitis C MRF and Sovaldi request to ensure patient meets criteria for both agents.

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
   - The patient is concurrently taking the following medications:
     - For Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin **OR**
     - For Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following?
   - The patient is decompensated cirrhosis (moderate or severe hepatitis impairment (Child-Pugh B or C))
   - The patient is post-liver transplant (with or without cirrhosis)

   If yes, continue to #4.
   If no, continue to #6.

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GUIDELINES FOR USE (CONTINUED)

4. Is the request for triple therapy using Daklinza/Sovaldi **WITH** ribavirin?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria for the patient type? [**NOTE:** An individual who has completed a full course of therapy with Mavyret, Harvoni or Epclusa that did not achieve SVR will not be approved]
   - Genotype 1, decompensated cirrhosis: short trial of Harvoni or Epclusa OR contraindication to Harvoni and Epclusa
   - Genotype 1, post-liver transplant: short trial of Harvoni or Mavyret OR contraindication to Harvoni and Mavyret
   - Genotype 3, decompensated cirrhosis short trial of or contraindication to Epclusa
   - Genotype 3, post-liver transplant WITHOUT cirrhosis: short trial of or contraindication to Mavyret
   - Genotype 3, post-liver transplant with compensated cirrhosis: short trial of Epclusa or Mavyret OR contraindication to Epclusa and Mavyret

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria? [**NOTE:** An individual who has completed a full course of therapy with Mavyret, Harvoni or Epclusa that did not achieve SVR will not be approved]
   - Genotype 1, without cirrhosis: treatment naïve or treatment experienced with a peginterferon and ribavirin regimen AND a short trial of Epclusa, Harvoni or Mavyret OR a contraindication Epclusa, Harvoni and Mavyret
   - Genotype 3, without cirrhosis: treatment naïve or treatment experienced with a peginterferon and ribavirin regimen AND a short trial of Epclusa or Mavyret OR a contraindication to Epclusa and Mavyret

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

7. Is the patient using any of the following moderate CYP3A inducers while taking Daklinza in combination with Sovaldi: rifapentine, bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, or nevirapine?
   CLINICAL PHARMACIST: Patient is on combination therapy with Sovaldi; please also review Sovaldi prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Sovaldi.

   If yes, **approve Daklinza 90mg strength for 12 weeks by GPID or GPI-14 with a quantity limit of #1 tablet per day. (NOTE: 90mg tablet used for drug interactions listed above)**

   If no, continue to #8.

8. Is the patient concurrently using any of the following with Daklinza?
   - HIV protease inhibitors (atazanavir with ritonavir, indinavir, nelfinavir, saquinavir)
   - A cobicistat-containing regimen (exception: darunavir/cobicistat does not require Daklinza 30mg dose), such as atazanavir/cobicistat, elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, or other cobicistat-containing regimen
   - Strong CYP3A inhibitors, such as clarithromycin, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, or voriconazole

   If yes, **approve Daklinza 30mg strength for 12 weeks by GPID or GPI-14 with a quantity limit of #1 tablet per day. (NOTE: 30mg tablet used for drug interactions listed above)**

   If no, **approve Daklinza 60mg strength for 12 weeks by GPID or GPI-14 with a quantity limit of #1 tablet per day.**

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DACLATASVIR (Daklinza)** requires the following rule(s) be met for approval:
   A. You have hepatitis C, with genotype 1 or genotype 3 infection
   B. You are 18 years of age or older
   C. You have documentation showing at least ONE detectable HCV (hepatitis C virus) RNA level (amount of virus in your blood) within the past 6 months as evidence of a current and chronic HCV infection.
   D. You must be taking Daklinza in combination with Sovaldi, and must meet all required criteria for Sovaldi
   (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

E. **For Genotype 1 infection approval also requires:**
   1. *Patients without cirrhosis (liver scarring):*
      a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
      b. You have previously tried Epclusa, Harvoni or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa, Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
   2. *Patients with decompensated cirrhosis (you have symptoms related to liver scarring):*
      a. You have previously tried Epclusa or Harvoni and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required
   3. *Patients status post liver transplant:*
      a. You have previously tried Harvoni or Mavyret and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required

F. **For Genotype 3 infection approval also requires:**
   1. *Patients without cirrhosis:*
      a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
      b. You have previously tried Epclusa or Mavyret and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
   2. *Patients with decompensated cirrhosis (Child-Pugh B or C; you have symptoms related to liver scarring):*
      a. You have previously tried Epclusa and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required

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GUIDELINES FOR USE (CONTINUED)

3. *Post-liver transplant, without cirrhosis:*
   a. Previous trial of Mavyret required and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
   b. Concurrent (used at the same time with) ribavirin use required
4. *Post-liver transplant, with compensated cirrhosis*
   a. Previous trial of Epclusa or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
   b. Concurrent (used at the same time with) ribavirin use required

Daklinza will not be approved if you meet ANY of the following:

A. You are using any of the following medications at the same time while on Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin
B. You are using any of the following medications at the same time while on Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir
C. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
D. You have compensated cirrhosis (Child-Pugh A; you have no symptoms related to liver damage) and are not status post liver transplant (you have not had a liver transplant)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daklinza.

REFERENCES

- Daklinza [Prescribing Information]. Princeton, NJ: Bristol Myers Squibb; February 2017.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 26, 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 08/15
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P&T Approval: 10/17