



Iowa Department of Human Services

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

Charles M. Palmer
Director

INFORMATIONAL LETTER NO.1398

TO: Iowa Medicaid Physician, Dentist, Advanced Registered Nurse Practitioner, Therapeutically Certified Optometrist, Podiatrist, Pharmacy, Home Health Agency, Rural Health Clinic, Clinic, Skilled Nursing Facility, Intermediate Care Facility, Community Mental Health, Family Planning, Residential Care Facility, ICF MR State and Community Based ICF/MR Providers

FROM: Iowa Department of Human Services, Iowa Medicaid Enterprise (IME)

DATE: June 17, 2014

SUBJECT: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: July 21, 2014

1. **Changes to the Preferred Drug List (PDL) Effective July 21, 2014.** Refer to complete PDL located at www.iowamedicaidpdl.com.

<u>Preferred</u>
Sovaldi ¹

¹Clinical PA Criteria Apply

2. **Changes to Existing Prior Authorization Criteria-** *Changes are italicized.* See complete prior authorization criteria posted at www.iowamedicaidpdl.com under the Prior Authorization Criteria tab.
 - **Antidepressants** (combines existing criteria for vilazodone (Viibryd) and desvenlafaxine (Pristiq) and applies to all non-preferred antidepressants subject to clinical criteria): Prior authorization is required for *non-preferred antidepressants subject to clinical criteria*. Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:
 1. The patient has a diagnosis of Major Depressive Disorder (MDD) and is 18 years of age or older; and
 2. Documentation of a previous trial and therapy failure at a therapeutic dose with *two* preferred generic SSRIs; and
 3. Documentation of a previous trial and therapy failure at a therapeutic dose with one preferred generic SNRI; and
 4. Documentation of a previous trial and therapy failure at a therapeutic dose with one *non-SSRI/SNRI* generic antidepressant.
 5. *If the request is for an isomer, prodrug or metabolite of a medication indicated for MDD, one of the trials must be with the preferred parent drug of the same*

chemical entity that resulted in a partial response with a documented intolerance.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

- **Hepatitis C Antiviral Agents, oral** (replaces Hepatitis C Protease Inhibitors):
Prior authorization is required for *direct-acting oral antiviral agents against the hepatitis C virus. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated.* Payment will be considered under the following conditions:
 1. Patient is 18 years of age or older; and
 2. *Patient's prior treatment history is provided (treatment naïve, prior null responder, partial responder, or relapser); and*
 3. *If patient has a history of failed treatment due to non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and*
 4. *Patient has not previously tried or failed therapy with a hepatitis C protease inhibitor; and*
 5. *Patient is not a pregnant female or a male with a pregnant female partner; and*
 6. *Women of childbearing potential and their male partners must use two forms of effective contraception (non-hormonal contraception for patients taking Incivek and Sovaldi) during treatment and for at least 6 months after treatment has concluded; and*
 7. *Documentation that routine monthly pregnancy tests are performed during this time; and*
 8. *Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and*
 9. *Prescriber is an infectious disease specialist, gastroenterologist, hepatologist or other hepatitis specialist.*
 10. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.*
 11. *Lost or stolen medication replacement requests will not be authorized.*
 12. *The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.*

Incivek

- *Patient has a documented diagnosis of hepatitis C genotype 1; and*
- *Administered in combination with peg-interferon alfa and ribavirin; and*
- *Patient does not have HIV co-infection; and*
- *Patient is not receiving dialysis or does not have a CrCl < 50 mL/min.*
- Additional prior authorization will be considered with documentation of response to treatment, measured by HCV-RNA levels
- A maximum 12 weeks of therapy will be allowed for telaprevir (Incivek)

Victrelis

- *Patient has a documented diagnosis of hepatitis C genotype 1; and*
- *Administered in combination with peg-interferon alfa and ribavirin; and*
- *Patient does not have HIV co-infection; and*
- *Patient does not have decompensated cirrhosis.*
- *HCV-RNA results are required at treatment week 8, 12 and 24 (including lead in period) for boceprevir (Victrelis).*
- *Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels.*
- *Prior authorizations will be approved for a maximum of 24, 32 or 44 weeks of therapy with boceprevir (Victrelis) based on response.*

Olysio

- *Patient has a documented diagnosis of hepatitis C genotype 1; and*
- *Administered in combination with peg-interferon alfa and ribavirin; and*
- *Patient does not have HIV co-infection; and*
- *Patient does not have the NS3 Q80K polymorphism with hepatitis C genotype 1a; and*
- *The patient is not receiving dialysis or does not have a CrCl < 30 mL/min.*
- *HCV-RNA results are required at treatment week 4 for simeprevir (Olysio).*
- *Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels.*
- *A maximum 12 weeks of therapy will be allowed.*

Sovaldi

- *The patient is not receiving dialysis or does not have a CrCl < 30 mL/min; and*
- *Patient does not have decompensated cirrhosis; and*
- *Documentation the patient has stage 3 or greater fibrosis as confirmed by a liver biopsy.*
- **Genotype 1:** *Patient has a documented diagnosis of hepatitis C genotype 1 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks of therapy will be allowed.*
- **Genotype 2:** *Patient has a documented diagnosis of hepatitis C genotype 2 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks of therapy will be allowed.*
- **Genotype 3:** *Patient has a documented diagnosis of hepatitis C genotype 3 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 24 weeks of therapy will be allowed.*
- **Genotype 4:** *Patient has a documented diagnosis of hepatitis C genotype 4 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks of therapy will be allowed.*

- **Hepatocellular carcinoma:** Patient has a documented diagnosis of hepatitis C genotype 1, 2, 3, 4 with a diagnosis of hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and in combination with ribavirin for up to 48 weeks or until liver transplantation, whichever comes first. Milan criteria are defined as:
 - One lesion smaller than 5cm in diameter for subjects with a single lesion;
 - Up to 3 lesions smaller than 3cm in diameter in subjects with multiple lesions;
 - No extrahepatic manifestations;
 - No vascular invasion.
 - Requests for peg-interferon alfa free regimens will be considered on a case-by-case basis for patients with hepatitis C genotype 1 or 4 where peg-interferon alfa is contraindicated. Contraindications include: documented life-threatening side effects; decompensated hepatic disease; autoimmune hepatitis or other autoimmune disorders; a baseline neutrophil count below 1500/ μ L, a baseline platelet count below 90,000 μ L, or a baseline hemoglobin below 10g/dL; and a history of preexisting unstable cardiac disease.
- **Ivacaftor (Kalydeco™):** Prior authorization is required for ivacaftor (Kalydeco™). Payment will be considered for patients when the following criteria are met:
 1. Patient is 6 years of age or older; and
 2. Has a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1255P, S549N, and S549R as detected by a FDA-cleared CF mutation test; and
 3. Prescriber is a CF specialist or pulmonologist; and
 4. Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus.

3. Point of Sale Billing Issues:

The pharmacy dispensing fee increased to \$10.12 effective July 1, 2013. The increased dispensing fee was implemented beginning with claims with a date of service of October 1, 2013. All claims with a date of service July 1, 2013, through September 30, 2013, were reprocessed with the increased dispensing fee in December 2013. Please contact provider services at 800-338-7909 or 256-4609 locally with any questions regarding these claims.

4. Preferred Brand Name Drugs on the PDL-Pharmacy Clarification

When a status change occurs for a previously preferred brand name drug to non-preferred status, up to a *minimum* of 30 days transition period is given to pharmacies to help utilize existing brand name product in stock in an effort to decrease a pharmacy's remaining brand name drug inventory (see PDL comment section regarding transition periods exceeding 30 days). If additional stock remains beyond this time period, pharmacies may call the POS Helpdesk at 877-463-7671 or 515-256-4608 (local) to request an override for the non-preferred brand name drug with a recent status change.

5. DUR Update: The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website, www.iadur.org under the “Newsletters” link.

We encourage providers to go to the website at www.iowamedicaidpdl.com to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567 or 515-256-4607 (local in Des Moines) or email info@iowamedicaidpdl.com.