IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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June 5, 2014

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, June 4, 2014. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Oral Hepatitis C Antiviral Agents, Antidepressants, and Ivacaftor (Kalydeco™). The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to an April 14, 2014 letter that was sent to them detailing the proposed criteria for Oral Hepatitis C Antiviral Agents, Antidepressants, and Ivacaftor (Kalydeco™).

Hepatitis C Antiviral Agents, oral (replacing Hepatitis C Protease Inhibitors)

Changes are italicized:
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.*
- HCV-RNA results are required at treatment week 4 for telaprevir (Incivek™).
- 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 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 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 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 5 cm in diameter for subjects with a single lesion;*
    - *Up to 3 lesions smaller than 3 cm 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 and other autoimmune disorders; a baseline neutrophil count below 1500/µL, a baseline platelet count below 90,000/ µL, or a baseline hemoglobin below 10g/dL; and a history of preexisting unstable cardiac disease.*

Antidepressants (combining existing criteria for Vilazodone (Viibryd™) and Desvenlafaxine (Pristiq®) and applying to all non-preferred antidepressants subject to clinical criteria)

Changes are italicized:
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.

Ivacaftor (Kalydeco™)

Changes are italicized:
Prior authorization is required for Kalydeco™ (ivacaftor). 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, S1251N, 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 abcessus.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Oral Hepatitis C Antiviral Agents, Antidepressants, and Ivacaftor (Kalydeco™).

Sincerely,

Pamela Smith R.Ph.

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Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph., IME
Megan Smith, R.Ph., Pharm.D., IME