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Pharmacy Provider Notice #138 – July 21, 2011 PTAC PDL Changes

September 26, 2011

Dear Kentucky Medicaid Provider:

Please be advised that the Department for Medicaid Services is making changes to the Kentucky Medicaid Preferred Drug List (PDL) based on recommendations from the Kentucky Medicaid Pharmacy & Therapeutics Advisory Committee at its July 21, 2011 meeting and as adopted by the Secretary of the Cabinet for Health and Family Services by order dated August 24, 2011.

On October 26, 2011, the following changes will be effective:

- New Drugs to Market
  - The following product (s) will become **preferred**:
    - vandetanib (QL = 300 mg per day)
  - The following product (s) will become **preferred** and require PA:
    - Viibryd®
      - Viibryd® will only be approved after trial and failure of one SSRI.
    - Zytiga™ (QL = 4 per day)
      - Zytiga™ will only be approved in combination with prednisone for a diagnosis of metastatic castration-resistant prostate cancer (CRPC) after:
        - A trial of chemotherapy with docetaxel or mitoxantrone; OR
        - If the patient has a poor performance status.
    - Daliresp™ (QL = 1 per day)
      - Daliresp™ will only be approved after trial and failure of an inhaled anticholinergic or long-acting bronchodilator.
  - The following product (s) will require PA:
    - Horizant®
      - Horizant® will be approved for a diagnosis of restless legs syndrome (RLS) after trial and failure of ONE of the following:
        - Levodopa/carbidopa, OR
        - Pramipexole, OR
        - Ropinirole.
    - Victrelis™ (QL = 12 per day)
      - Victrelis™ will be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection after the patient has received 4 weeks of ribavirin and peginterferon therapy if they are receiving concurrent therapy with ribavirin and peginterferon. Victrelis™ should have a quantity limit of 12 capsules per day

and be limited to one course of therapy per lifetime. Durations of therapy will be based on the following:

- Cirrhosis or previous treatment with peginterferon / ribavirin with documented lack of achievement of > 2 log reduction at week 12 with previous treatment:
  - Approve for 14 weeks
  - After 14 weeks of therapy:
    - If HCV-RNA level is ≤ 100 IU/mL at week 12 of therapy, approve for 12 more weeks
    - If HCV-RNA results at week 24 of therapy are undetectable, approve for an additional 18 weeks (44 weeks total therapy)
    - If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin).
- If none of the above:
  - Approve for 14 weeks
  - If HCV-RNA level is ≤ 100 IU/mL at week 12 of therapy, approve for 12 more weeks
  - After 26 weeks, continuation of therapy should be approved based on the following:
    - Treatment naïve patients:
      - If HCV-RNA results at week 8 and 24 are both undetectable – 2 more weeks then discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin) – total duration of Victrelis™ therapy = 28 weeks
      - If HCV-RNA results at week 8 are detectable and week 24 are undetectable – 10 more weeks – total duration of Victrelis™ therapy = 36 weeks
      - If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ ribavirin).
    - Previously treated or relapsed patients:
      - If HCV-RNA results at week 8 and 24 are both undetectable – 10 more weeks (then discontinue all 3) – total duration of Victrelis™ therapy = 36 weeks
      - If HCV-RNA results at week 8 are detectable and week 24 results are undetectable 10 more weeks – total duration of Victrelis™ therapy = 36 weeks
      - If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin).

- Incivek™ (QL = 6 per day)
  - Incivek™ will be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection if the patient is receiving concurrent therapy with ribavirin and peginterferon. Incivek™ will have a quantity limit of 6 tablets per day for a total duration of 12 weeks and be limited to one course of therapy per lifetime.
- Sylatron™
  - Sylatron™ will be approved for a diagnosis of melanoma only.

- The following product (s) will become **non-preferred** and require PA:
  - Tradjenta™ (QL = 1 per day)
  - Natroba™

On November 2, 2011, the following changes will be effective:

- New Drug Classes
  - 5-ASA Derivatives, Rectal Preparations
    - Canasa®, mesalamine enemas and Rowasa® will become **preferred**.
    - Rowasa® will become **non-preferred** and require PA.

- Existing Drug Classes
  - 5-ASA Derivatives, Oral Preparations
    - Apriso™, Asacol®, balsalazide, sulfasalazine and sulfasalazine EC will remain **preferred**.
    - Asacol® HD, Azulfidine®, Azulfidine EN-tabs®, Dipentum® and Lialda™ will remain **non-preferred** and require PA.
    - Pentasa® will become **non-preferred** and require PA.
  - 5-HT1 receptor Agonists
    - Sumatriptan (QL = 9 tabs, 8 nasal sprays, 4 mL injection, 8 pens/cartridges per month) will remain **preferred**.
    - Amerge® (QL = 9 per month), Axert® (QL = 8 per month), Frova™ (QL = 12 per month), Imitrex® (QL = 9 tabs, 8 nasal sprays, 4 mL injection, 8 pens/cartridges per month), naratriptan (QL = 9 per month), Relpax™ (QL = 6 per month), Sumavel™ Dosepro (QL = 8 per month) and Zomig® (QL = 6 per month) will remain **non-preferred** and require PA.
    - Cambia™ (QL = 9 per month), Maxalt® (QL = 12 per month) and Treximet™ (QL = 9 per month) will become **non-preferred** and require PA.
  - Multiple Sclerosis Agents
    - Avonex® (QL = 4 per month), Betaseron® (QL = 15 per month), Copaxone® (QL = 1 per month) and Rebif® (QL = 12 per month) will remain **preferred**.
    - Extavia® (QL = 15 per month) will remain **non-preferred** and require PA.
    - Ampyra™ (QL = 2 per day) and Gilenya™ (QL = 1 per day) will become **non-preferred** and require PA.
      - After 12 weeks of therapy (84 days), Ampyra™ therapy will be allowed to continue if the diagnosis is multiple sclerosis and Ampyra™ has shown clinical efficacy.
  - Hematopoietic Agents
    - Aranesp®, Epogen® and Procrit® will remain **preferred**.
    - Erythropoiesis stimulating agents will be approved for recipients meeting the following criteria:
      - The patient has a hemoglobin of less than 12 g/dL AND one of the following diagnoses:
        - Anemia associated with chronic renal failure OR anemia associated with kidney transplantation; OR
        - Treatment of chemotherapy induced anemia for non-myeloid malignancies; OR
        - Drug-induced anemia (examples, not all inclusive: Retrovir® or Combivir® or ribavirin); OR

- Autologous blood donations by patients scheduled to undergo nonvascular surgery.

On November 9, 2011, the following changes will be effective:

- Oral Antiemetics: Anticholinergics
  - Meclizine, prochlorperazine, promethazine and trimethobenzamide will remain **preferred**.
  - Antivert®, Phenergan® and Univert® will remain **non-preferred** and require PA.
  - Tigan® will become **non-preferred** and require PA.
- Oral Antiemetics: 5-HT_3 Antagonists
  - Ondansetron will remain **preferred**.
  - Aloxi®, Anzemet®, granisetron, Granisol™, Kytril®, Sancuso® and Zofran® will remain **non-preferred** and require PA.
    - Sancuso® will be approved if the patient is currently undergoing cancer chemotherapy and one of the following is true:
      - The provider wishes to use this product to avoid the need for IV anti-emetics; OR
      - There has been a trial/failure on one preferred product.
- NK-1 Antagonists
  - Emend® (QL = 12 per month) will remain **preferred**.
- Oral Antiemetics: Δ-9-THC Derivatives
  - Dronabinol (QL = 20 mg per day) will remain **preferred** and require PA.
  - Cesamet® (QL = 6 mg per day) will remain **non-preferred** and require PA.
  - Marinol® (QL = 20 mg per day) will become **non-preferred** and require PA.
  - Cannabinoids will be approved if one of the following is true:
    - Nausea and vomiting associated with cancer chemotherapy AFTER failure to respond adequately to at least ONE other anti-emetic therapy; OR
    - Anorexia associated with weight loss in patients with AIDS or cancer (dronabinol ONLY).
- H_2 Receptor Antagonists
  - Cimetidine, famotidine and ranitidine will remain **preferred**.
  - Axid®, Pepcid® and Zantac® will remain **non-preferred** and require PA.
  - Nizatidine will become **non-preferred** and require PA.
- Anti –Ulcer Protectants
  - Misoprostol and sucralfate will remain **preferred**.
  - Carafate® and Cytotec® will remain **non-preferred** and require PA.
- Combination Products for H. pylori
  - Helidac® (QL = 4 per day) and Prevpac® (QL = 1 per day) will remain **preferred**.
  - Pylera® (QL = 12 per day) will remain **non-preferred** and require PA.
- Antispasmodics/Anticholinergics
  - Atropine sulfate, dicyclomine, hyoscyamine, glycopyrrolate, methscopolamine, propantheline and Transderm-Scop® will remain **preferred**.
  - Anaspaz®, Bentyl®, Cantil®, chlordiazepoxide/clidinium, Cuvposa®, Librax®, Pamine®, Pamine Forte®, PB-Hyos®, Quadrapax®, Robinul®, Robinul Forte® and Sal-Tropine® will remain **non-preferred** and require PA.
- Antidiarrheals
  - Diphenoxylate with atropine and loperamide will remain **preferred**.
  - Lomotil® will remain **non-preferred** and require PA.

- Motofen® and paregoric will become **non-preferred** and require PA.

- Laxatives and Cathartics
  - Amitiza®, lactulose, Moviprep®, Osmoprep®, PEG 3350/Electrolyte, PEG 3350/Na Sulf, Bicarb. Cl/KCl, polyethylene glycol, Sod Chloride /NAHCO3/KCl/PEGS and Visicol® will remain **preferred**.
    - Amitiza® will be approved for the following diagnoses:
      - Irritable Bowel Syndrome with constipation; OR
      - Chronic Idiopathic Constipation after failure of one laxative.
  - Colyte® with flavoring, Gavilyte-C®, Gavilyte-G®, Gavilyte-N®, Glycolax®, Golytely®, Miralax®, Nulytely® with Flavor Packs, OCL®, Relistor®, Suprep® and Trilyte® with Flavor Packets will remain **non-preferred** and require PA.
    - Relistor® will be approved if all of the following criteria are met:
      - Diagnosis of opioid-induced constipation; AND
      - Patient has advanced illness, which is defined as a terminal disease (incurable cancer or other end-stage disease); AND
      - Trial and failure (unless contraindicated or intolerant to) of an agent in each of the following drug classes:
        - Stool softening agent; AND
        - Peristalsis-inducing agent.
  - Halflytely-Bisacodyl Bowel Kit® and Kristalose® will become **non-preferred** and require PA.

Please note that for future prior authorization requests, Magellan Medicaid Administration now offers real time service! Please contact the Clinical Support Center at (800) 477-3071 to speak with a live agent. The only drugs that are now required to be submitted via fax are Brand Medically Necessary, Suboxone®/Subutex®, Synagis®, and Zyvox®.

Prior authorization forms are located at https://kentucky.fhsc.com. Please fax all requests to Magellan Medicaid Administration at the following numbers:

- Non-Urgent: (800) 365-8835
- Urgent: (800) 421-9064
- Mental Health Providers: (800) 453-2273
- Long Term Care: (800) 453-2273

Thank you for helping Kentucky Medicaid members to maintain access to prescription coverage by selecting drugs on the preferred drug list whenever possible.

* Please note the dates that are associated with the above changes are subject to change.

Sincerely,

Kasie Purvis
Provider Relations Manager