MAGELLAN PHARMACY SOLUTIONS | MAGELLAN MEDICAID ADMINISTRATION

Fee-For-Service Pharmacy Provider Notice #173 – September 19, 2013 PTAC PDL Changes

January 6, 2014

11013 W. Broad Street
Glen Allen, VA 23060

Dear Kentucky Medicaid Provider:

Please be advised that the Department for Medicaid Services is making changes to the Kentucky Medicaid Fee-For-Service Pharmacy Preferred Drug List (PDL) based on recommendations from the Kentucky Medicaid Fee-For-Service Pharmacy & Therapeutics Advisory Committee at its September 19, 2013 meeting and as adopted by the Commissioner of the Cabinet for Health and Family Services by order dated November 12, 2013.

On February 11, 2014, the following changes will be effective:

- New Products to Market
  - The following product (s) will become **preferred**:
    - Simbrinza™
  - The following product (s) will require PA:
    - Osphena™
      - Will only be approved for patients meeting ALL of the following criteria:
        - Diagnosis of severe dyspareunia, due to vulvar and vaginal atrophy, in a post-menopausal woman; AND
        - Trial and failure of an over-the-counter vaginal lubricant; AND
        - Trial and failure of a prescription topical estrogen product, unless contraindicated.
    - Invokana™
      - Will only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
  - The following product (s) will become **preferred** and require prior authorization (PA):
    - Kynamro™
      - Approval of mipomersen sodium will be granted as described below.

- For initial treatment, approve for 6 months if ALL of the following are true:
  - Diagnosis of homozygous familial hypercholesterolemia (HoFH) with untreated total cholesterol (TC) >500 mg/dL; **AND**
  - Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; **AND**
  - Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; **AND**
  - Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; **AND**
  - Patient tried and failed at least a 3 month trial of the maximally tolerated dose with two (2) of the following statins: simvastatin 40mg (Zocor®), atorvastatin 80mg (Lipitor®) OR rosuvastatin 40mg (Crestor®), unless contraindicated; **AND**
  - Patient tried and failed at least a 3 month trial of combination therapy with both ezetimibe 10mg (Zetia™) AND atorvastatin 80mg (Lipitor®) OR simvastatin 40mg (Zocor®), unless contraindicated; **AND**
  - Despite the pharmacological treatment with statins and ezetimibe, patient's LDL cholesterol ≥ 300 mg/dL (or non-HDL cholesterol ≥ 330 mg/dL).
- For continuation of treatment, approve for one year if ALL of the following are true:
  - Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) from baseline; **AND**
  - Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); **AND**
  - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevations in transaminases (ALT, AST), hepatic steatosis, serious injection site reactions, and flu-like symptoms.

- Tafinlar® (QL = 4 per day)
  - Tafinlar® will only be approved for a diagnosis of unresectable or metastatic melanoma after confirmation that the BRAF V600E mutation has been detected by an FDA-approved test.
- Mekinist™ (QL = 1 per day)
  - Mekinist™ will only be approved for a diagnosis of unresectable or metastatic melanoma after confirmation that the BRAF V600E or V600K mutation has been detected by an FDA-approved test.
- Oseni® (QL = 1 per day)

- Will be approved for one of the following reasons:
  - Metformin, insulin, a sulfonylurea or a TZD is seen in history within the past 90 days; OR
  - Diagnosis of Chronic Renal Insufficiency/Failure.

- The following product (s) will become **non preferred** and require PA:
  - Juxtapid™
  - Liptruzet™ (QL = 1 per day)
  - Cometriq™ (QL = 1 per day)
  - Rescula® (QL = 5 mL per month)
  - Fulyzaq™ (QL = 2 per day)
    - Approval of crofelemer will be granted as described below.
      - For initial treatment, approve for 6 months if ALL of the following are true:
        - Patient has been diagnosed with human immunodeficiency virus; **AND**
        - Patient is experiencing diarrhea; **AND**
        - Active infection has been ruled out via fecal collection and microbiologic culture; **AND**
        - Patient has tried and failed the preferred antidiarrheals: loperamide, atropine-diphenoxylate.
      - For continuation of treatment, approve for one year if ALL of the following are true:
        - Documented reduction in the frequency and quantity of liquid stool volume for the previous 6 months; AND
        - Documented follow-up with patient that includes re-culture for microbiologic agents if breakthrough diarrhea occurs while on crofelemer therapy.
  - Suclear™ Bowel Prep Kit
  - Diclegis™
  - Tecfidera™ (QL = 2 per day)
  - Breo Ellipta™ (QL = 2 per day)
  - Nesina® (QL = 1 per day)
  - Kazano® (QL = 2 per day)

- Existing Drug Classes
  - DPP-4 Inhibitors
    - Janumet™, Janumet XR™, Januvia™, Kombiglyze XR™ and Onglyza™ will remain **preferred** and require PA.
    - Oseni® will become **preferred** and require PA.
    - Jentadueto™, Juvisync™, Kazano®, Nesina® and Tradjenta™ will become **non preferred** and require PA.
  - DPP-4 Inhibitors Clinical Criteria
    - DPP-4 Inhibitors will be approved for one of the following reasons:

- Metformin, insulin, a sulfonylurea or a TZD is seen in history within the past 90 days; OR
- Diagnosis of Chronic Renal Insufficiency/Failure.

- Thiazolidinediones
  - Pioglitazone will remain **preferred**.
  - Actos®, ActoPlus Met®, ActoPlus Met® XR, Avandaryl® and Duetact™ will remain **non preferred** and require PA.
  - Avandamet®, Avandia®, pioglitazone/glimepiride and pioglitazone/metformin will become **non preferred** and require PA.
- Oral Steroids
  - Cortisone, dexamethasone solution and tablets, hydrocortisone, methylprednisolone dose pack and tablets, prednisolone solution, prednisolone sodium phosphate, and prednisone dose pack, tablets, and solution will remain **preferred**.
  - Entocort EC® will become **preferred**.
  - Baycadron®, Celestone®, Celestone® Soluspan, Cortef®, DexPak®, DexPak Jr®, Millipred®, Orapred®, Orapred® ODT, Prelone®, Uceris® and Veripred® 20 will remain **non preferred** and require PA.
  - AsmalPred®, budesonide EC, dexamethasone elixir and intensol, Flo-Pred®, Medrol®, methylprednisone 8 mg and 16 mg tablets, prednisone intensol and Rayos® will become **non preferred** and require PA.
- Intranasal Steroids
  - Fluticasone propionate and Nasonex® will remain **preferred**.
  - Beconase AQ®, Dymista®, Flonase®, flunisolide, Nasacort AQ®, Omnaris™, Qnasal™, Rhinocort Aqua®, triamcinolone, Veramyst® and Zetonna™ will remain **non preferred** and require PA.
- Intranasal Antihistamines
  - Astepro® will remain **preferred**.
  - Astelin® and Patanase™ will remain **non preferred** and require PA.
  - Azelastine will become **non preferred** and require PA.
- Topical Steroids
  - Betamethasone dipropionate ointment, cream and lotion, betamethasone valerate cream and ointment, clobetasol propionate ointment, cream, solution and gel, desonide cream and ointment, fluocinolone acetonide, flucinonide, fluocinonide emollient, fluticasone propionate cream and ointment, halobetasol propionate, hydrocortisone cream, gel and ointment, hydrocortisone butyrate ointment and solution, hydrocortisone valerate, mometasone furoate ointment and cream, and triamcinolone acetonide will remain **preferred**.
  - Clobex® shampoo will become **preferred**.
  - Aclovate®, ApexiCon®/ApexiCon E®, Balneol for Her®, Capex® Shampoo, Clobex® lotion and spray, Cloderm®, Cordran® Tape, Cormax®, Cutivate®, Derma-Smoothe®/FS®, Dermatop®, Desowen®, desoximetasone, diflorasone diacetate, Diprolene® AF, Elocon®, Halog®, Halonate®, Kenalog®, Momexin™, Olux®, Olux E®, Olux-Olux E®

Complete Pack, Pandel®, Temovate®, Texacort®, Topicort®, Ultravate®, Vanos™, Verdeso™, and Westcort® will remain **non preferred** and require PA.

- Alclometasone dipropionate, Ala-Cort®, Ala-Scalp®, Aqua Glycolic HC®, amcinonide, betamethasone dipropionate gel, betamethasone dipropionate augmented, betamethasone valerate lotion and foam, Caldecort®, clobetasol emollient, clobetasol propionate foam, lotion and shampoo, Cordran®, Cyclocort®, Desonate®, desonide lotion, fluticasone propionate lotion, Halac® Kit, hydrocortisone-aloe, hydrocortisone lotion, hydrocortisone butyrate cream, hydrocortisone-urea, Lipocream®, Locoid®, Luxiq®, mometasone furoate solution, NuZon™, Pediaderm HC™, Pediaderm TA™, prednicarbate, Scalacort®, Scalacort-DK® Kit, Synalar®, Temovate E®, Topicort® Topical Spray, Triderm®, Trianex®, Ultravate® Pack Kit, and Ultravate® X will become **non preferred** and require PA.

- Topical Acne Agents
  - Benzoyl peroxide OTC, BenzaClin®, clindamycin solution, medicated swab, gel and lotion, Differin® cream and gel, erythromycin solution and gel, sodium sulfacetamide/sulfur cleanser, tretinoin, and tretinoin microspheres will remain **preferred**.
  - Acanya™, Aczone™, adapalene cream and gel, Atralin™, Avar™, Avita®, Azelex®, benzoyl peroxide/clindamycin, BPO®, Cerisa™, Clarifoam EF®, Clindacin Pac™, Clindagel®, Desquam-X®, Differin® lotion, Epiduo™, Evoclin™, Inova™, Klaron®, Pacnex®, Nu-Ox®, Retin-A®, Retin-A Micro®, Sumadan™, Sumaxin®, Tazorac®, Veltin™, and Ziana™ will remain **non preferred** and require PA.
  - Akne-Mycin®, Avar E™, Avar E LS™, Avar LS™, Benzafoam™, Benzafoam Ultra™, Benzamycin Pak®, BenzePro Foam™, benzoyl peroxide cleanser, kit, microspheres and gel, benzoyl peroxide/erythromycin, benzoyl peroxide/sulfur, BP® 10-1, BPO-5®, BPO-10®, BP Wash™, Cleocin-T®, clindamycin foam, Duac®, Effaclar Duo®, erythromycin medicated swab, Inova™ 4/1, Inova™ 8/2, Lavoclen™, Panoxyl®, Persa-Gel®, Prasicon®, OC8®, Ovace®, Ovace Plus®, SE 10-5 SS®, Se BPO®, sodium sulfacetamide, sodium sulfacetamide/sulfur cream, suspension, kit and medicated pad, sodium sulfacetamide/sulfur/urea, SSS 10-4®, SSS 10-5®, Tretin-X™, tretinoin microspheres gel pump, Vanoxide-HC®, and Zencia® will become **non preferred** and require PA.
- Growth Hormones
  - Genotropin® and Norditorpin® will remain **preferred**.
  - Nutropin® and Nutropin AQ® will become **preferred**.
  - Humatrope®, Omnitrope®, Serostim®, Tev-Tropin™ and Zorbtive® will remain **non preferred** and require PA.
  - Saizen® will become **non preferred** and require PA.
- Growth Hormone Clinical Criteria

- Growth Hormones will be approved for one of the following diagnoses:
  - Growth Hormone Deficiency or Pituitary dwarfism
  - Pituitary disease from known causes such as pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, or trauma such as Panhypopituitarism, Iatrogenic pituitary disorders. Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin. Other disorders of the pituitary gland and craniopharyngeal duct.
  - Turner's Syndrome
  - Chronic renal insufficiency & end-stage renal disease (pre transplant)
  - Prader-Willi Syndrome
  - Idiopathic Short Stature (meaning of unknown origin). Also called non-growth hormone deficient short stature
  - Small for gestational age
  - Short Stature Homeobox Gene
  - Noonan Syndrome
  - HIV wasting or cachexia
  - Short bowel syndrome
- Prefilled syringes will be approved in situations of inability to properly/reliable mix/measure dosage.
- Preservative free products will be approved in instances of intolerance/contraindication to preservatives in the preferred products.
- Non-preferred growth hormones require trial and failure of two preferred agents.

- Narcotic Agonists/Antagonists
  - Butorphanol NS and pentazocine/naloxone will remain **preferred**.
  - Pentazocine/APAP will become **non preferred** and require PA.
- Fentanyl Buccal Products
  - Abstral®, Actiq®, fentanyl oral transmucosal, Fentora®, Lazanda®, Onsolis™ and Subsys® will remain **non preferred** and require PA.
- Fentanyl Buccal Products Clinical Criteria
  - Fentanyl Buccal products will be approved if ALL of the following are true:
    - Diagnosis of cancer pain; AND
    - Receiving and tolerant to opioid therapy, as evident by trial of opioid doses equal to, or greater than, morphine 60 mg daily or fentanyl patches 50 mcg/hr for at least one week without adequate pain control; AND
    - Unresponsive to therapy with three other immediate-released unique chemical entities utilized for breakthrough pain.
- GI Antibiotics
  - Alinia® tablets, metronidazole tablets, paromomycin and Vancocin® will remain **preferred**.
  - Xifaxan® will become **preferred**.

        - Alinia® suspension, Dificid®, Flagyl®, Flagyl ER®, metronidazole capsules, neomycin, Tindamax®, tinidazole, and vancomycin will remain **non preferred** and require PA.
    - 1st Generation Cephalosporins
        - Cefadroxil capsules and cephalexin will remain **preferred**.
        - Duricef® and Keflex® will remain **non preferred** and require PA.
        - Cefadroxil tablets and suspension will become **non preferred** and require PA.
    - 2nd Generation Cephalosporins
        - Cefuroxime will remain **preferred**.
        - Ceclor®, Ceclor CD®, cefaclor CD, Ceftin® and Cefzil® will remain **non preferred** and require PA.
        - Cefaclor and cefprozil will become **non preferred** and require PA.
    - 3rd Generation Cephalosporins
        - Cefdinir, cefpodoxime, and Suprax® suspension and tablets will remain **preferred**.
        - Cedax®, Omnicef®, Spectracef®, Suprax® capsules and chewable tablets, and Vantin® will remain **non preferred** and require PA.
        - Cefditoren pivoxil will become **non preferred** and require PA.
    - Penicillins
        - Amoxicillin, amoxicillin/clavulanate tablets and suspension, ampicillin, dicloxacillin, and penicillin V will remain **preferred**.
        - All branded products and amoxicillin/clavulanate ER will remain **non preferred** and require PA.
        - Amoxicillin/clavulanate chewable tablets will become **non preferred** and require PA.
    - Tetracyclines
        - Demeclocycline, doxycycline hyclate, doxycycline monohydrate 50 mg, 100 mg capsules, tablets and suspension, minocycline capsules and tetracycline will remain **preferred**.
        - Doxycycline monohydrate suspension and 75 mg capsules and tablets will become **preferred**.
        - All branded products and doxycycline hyclate DR tablets, doxycycline monohydrate 150 mg capsules, minocycline tablets, and minocycline ER will remain **non preferred** and require PA.
    - Ketolides
        - Ketek® will remain **preferred**.
    - Ketek® Clinical Criteria
        - Telithromycin (Ketek®) will be approved for a diagnosis of community-acquired pneumonia (CAP) IF:
            - There has been previous use (within the past 28 days) of ONE of the following:
                - Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam); OR

        - 2nd or 3rd generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone); OR
        - Macrolide (e.g., azithromycin, clarithromycin, erythromycin); OR
        - Fluoroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin); OR
        - Tetracycline (e.g., doxycycline); OR
        - Trimethoprim/sulfamethoxazole (e.g., Bactrim); AND
      - Request is NOT for more than a 10-day supply
      - If Ketek was initiated in the hospital, approve to complete the course of antibiotic therapy
  - Macrolides
    - Azithromycin, clarithromycin, and erythromycin base tablets will remain **preferred**.
    - Erythromycin base capsules DR will become **preferred**.
    - All branded products and clarithromycin ER will remain **non preferred** and require PA.
  - Oxazolidinones
    - Zyvox® will remain **preferred**.
  - Zyvox® Clinical Criteria
    - Diagnoses to approve:
      - Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing for Enterococcus faecium or Enterococcus faecalis
      - Methicillin-Resistant S. aureus Infections (MRSA) via current culture and sensitivity testing
      - Empiric management of suspected MRSA infection without culture confirmation if any of the following are true:
        - Previously documented MRSA infection; OR
        - Previous cellulitis caused by documented MRSA; OR
        - Skin and soft tissue infection with abscess; OR
        - Patient has:
          - Failed antibiotic therapy within the past month with any of the following:
            - Tetracycline, or
            - Sulfamethoxazole/trimethoprim, or
            - Fluoroquinolone, or
            - Clindamycin; AND
          - Presents with any of the following risk factors:
            - Health facility stay/visit (current or within the past month); or
            - Surgery in the past month; or
            - Participation in team sports (current or past month); or
            - Jail/Prison (current or in past month); or
            - Military (current or in past month); or
            - History of "spider bite" within the past month; or

- Pediatrics enrolled in daycare or school (current or in past month); or
- Multiple areas of induration; or
- HIV; or
- Permanent indwelling catheters; or
- Percutaneous implanted device; or
- Previously colonized with multi-drug resistant pathogens including MRSA; or
- Diabetic foot ulcer; or
- End stage renal disease.

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: All dates are subject to change.

Sincerely,

Kristina Hawkins, PharmD
Director, Clinical Services

Kentucky Medicaid Fee-For-Service Pharmacy Program's Contact Information		
Clinical Support Center	(800) 477-3071 Sunday – Saturday 24 hours a day	Please contact the Clinical Support Center to request a prior authorization (PA) or to check the status of a request. **NOTE: The only drugs that are now required to be submitted via fax are Brand Medically Necessary, Suboxone®/Subutex®, Synagis®, and Zyvox®.**
Pharmacy Support Center	(800) 432-7005 Sunday – Saturday 24 hours a day	Please contact the Pharmacy Support Center when claims assistance is required. Timely filing, lock-in, and early refill (ER) overrides can be obtained through this call center.
Provider Services	(877) 838 – 5085 Monday – Friday 8:00 am – 4:30 pm	Please contact Provider Services if you have questions about enrollment or when updating your license or bank information.
Member Services	(800) 635 – 2570	Please contact Member Services if you are a member or if you as the provider have questions regarding the member's benefits or eligibility coverage dates.