MAGELLAN PHARMACY SOLUTIONS | MAGELLAN MEDICAID ADMINISTRATION

Fee-For-Service Pharmacy Provider Notice #182 – March 2014 P&T Changes

July 7, 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 March 20, 2014 meeting and as adopted by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services by order dated June 19, 2014.

On August 7, 2014, the following changes will be effective:

- New Products to Market
  - The following product (s) will require prior authorization (PA):
    - Farxiga®
      - Dapagliflozin (Farxiga®) 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):
    - Imbruvica™ (QL = 4 per day)
      - Imbruvica™ will only be approved for a diagnosis of mantel cell lymphoma (MCL) or chronic lymphocytic leukemia (CLL).
    - Olysio™ (QL = 1 per day)
      - Olysio™ will be approved if ALL of the following are true:
        - Age ≥18 years old; AND
        - Patient must be in treatment naïve to simeprevir. Limited to one course of therapy per lifetime; AND
        - Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician; AND
        - Diagnosis of hepatitis C virus (HCV) with genotype 1 showing fibrosis corresponding to a Metavir score of F3 or greater; AND
        - Patient has not actively participated in illicit substance abuse or alcohol abuse for 6 months prior to or during therapy attested by the prescribing physician(s) AND using one of the following confirmation tests:

- Patient has been evaluated for current substance abuse and alcohol with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or National Institute on Drug Abuse's (NIDA's) drug screening tool; OR
  - Acceptable alcohol consumption tests include: Serum gamma-glutamyl transpeptidase (GGT), mean corpuscular volume (MCV), carbohydrate-deficient transferrin (CDT), and urine ethylglucuronide (EtG) tests. Results must be documented in the patient's medical record to include, results of testing, and date tested; AND
  - Urine toxicology screen results for substance abuse are acceptable in lieu of the actual laboratory drug screen report. Results must be documented in the patient's medical record to include substances tested, results of testing, and date tested; AND

- If patient has a prior history of substance or alcohol abuse, the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND
- Patient CANNOT have failed therapy with an oral protease inhibitor indicated for HCV (e.g., Incivek®, Victrelis®, or Olysio™); AND
- Patient has NOT had liver transplant; AND
- Patient is NOT infected with HCV genotype 1a containing the Q80K polymorphism; AND
- Patient is NOT co-infected with HCV/HIV; AND
- Patient is NOT receiving concomitant therapy with sofosbuvir (Sovaldi™); AND
- Baseline HCV-RNA is submitted:
  - Approve [Triple therapy] combination with peginterferon and ribavirin for 8 weeks and request HCV RNA levels at treatment week (TW) 4 for renewal.
  - Renewal (Authorization #2) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW4, approve 4 additional weeks of therapy for a total duration of 12 weeks.

- Sovaldi™ (QL = 1 per day)
  - Sovaldi™ will be approved if ALL of the following are true:
    - Age ≥18 years old; AND
    - Patient must be in treatment naïve to sofosbuvir. Limited to one course of therapy per lifetime; AND
    - Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician; AND

- Patient is not receiving concomitant therapy with a hepatitis protease inhibitor (e.g., telaprevir (Incivek®), boceprevir (Victrelis®), simeprevir (Olysio™); AND
- Patient does *not* have decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); AND
- Patient does *not* have severe renal impairment (eGFR <30 mL/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; AND
- Patient does not have a history of liver transplant; AND
- Patient has not actively participated in illicit substance abuse or alcohol abuse for 6 months prior to or during therapy attested by the prescribing physician(s) AND using one of the following confirmation tests:
  - Patient has been evaluated for current substance abuse and alcohol with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or National Institute on Drug Abuse's (NIDA's) drug screening tool; OR
    - Acceptable alcohol consumption tests include: Serum gamma-glutamyl transpeptidase (GGT), mean corpuscular volume (MCV), carbohydrate-deficient transferrin (CDT), and urine ethylglucuronide (EtG) tests. Results must be documented in the patient's medical record to include, results of testing, and date tested; AND
    - Urine toxicology screen results for substance abuse are acceptable in lieu of the actual laboratory drug screen report. Results must be documented in the patient's medical record to include substances tested, results of testing, and date tested; AND
- If patient has a prior history of substance or alcohol abuse, the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND
- Baseline HCV-RNA is submitted; AND
- One of the following diagnoses:
  - For diagnosis of HCV with genotype 1 showing fibrosis corresponding to a Metavir score of F3 or greater with or without HIV-1 co-infection or with or without compensated cirrhosis, including those with hepatocellular carcinoma:
    - Approve [Triple therapy] combination with peginterferon and ribavirin for 8 weeks and request HCV RNA levels at treatment week (TW) 4 for renewal.
    - Renewal (Authorization #2) approval if all of the following are true:
      - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
      - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and

    - HCV RNA levels are < 25 IU/mL at TW4, approve 4 additional weeks of therapy for a total duration of 12 weeks.
- For diagnosis of HCV with genotype 1 showing fibrosis corresponding to a Metavir score of F3 or greater with or without HIV-1 co-infection or with or without compensated cirrhosis, including those with hepatocellular carcinoma:
  - Approve [Dual therapy] combination with ribavirin in patients who are interferon ineligible for 8 weeks and request HCV RNA levels at TW4 and TW12 for renewal.
  - Renewal (Authorization #2) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW4; then approve 8 additional weeks of therapy and request HCV RNA levels at TW12.
  - Renewal (Authorization #3) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW12; then approve 8 additional weeks of therapy for a total duration of 24 weeks.
- For diagnosis of HCV with genotype 2 showing fibrosis corresponding to a Metavir score of F3 or greater with or without HIV-1 co-infection or with or without compensated cirrhosis, including those with hepatocellular carcinoma:
  - Approve [Dual therapy] combination with ribavirin in patients who are interferon ineligible for 8 weeks and request HCV RNA levels at TW4 for renewal.
  - Renewal (Authorization #2) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW4; then approve 4 additional weeks of therapy for a total duration of 12 weeks.

- For diagnosis of HCV with genotype 3 showing fibrosis corresponding to a Metavir score of F3 or greater with or without HIV-1 co-infection or with or without compensated cirrhosis, including those with hepatocellular carcinoma:
  - Approve [Dual therapy] combination with ribavirin in patients who are interferon ineligible for 8 weeks and request HCV RNA levels at TW4 and TW12 for renewal.
  - Renewal (Authorization #2) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW4; then approve 8 additional weeks of therapy and request HCV RNA levels at TW12.
  - Renewal (Authorization #3) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW12; then approve 8 additional weeks of therapy for a total duration of 24 weeks.
- For diagnosis of HCV with genotype 4 showing fibrosis corresponding to a Metavir score of F3 or greater with or without HIV-1 co-infection or with or without compensated cirrhosis, including those with hepatocellular carcinoma:
  - Approve [Triple therapy] combination with peginterferon and ribavirin for 8 weeks and request HCV RNA levels at treatment week (TW) 4 for renewal.
  - Renewal (Authorization #2) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW4; then approve 4 additional weeks of therapy for a total duration of 12 weeks.

- For diagnosis of hepatocellular carcinoma awaiting liver transplantation in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria, and awaiting liver transplantation:
  - Approve [Dual therapy] combination with ribavirin for 8 weeks and request HCV RNA levels at TW4, TW12, TW20, TW28 and TW36 for renewal.
  - Renewal (Authorization #2) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW4; then approve 8 additional weeks of therapy or until scheduled transplant (whichever is sooner) and request HCV RNA levels at TW12, TW20, TW28 and TW36 for renewal.
  - Renewal (Authorization #3) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW12; then approve 8 additional weeks of therapy or until scheduled transplant (whichever is sooner) and request HCV RNA levels at TW20, TW28 and TW36 for renewal.
  - Renewal (Authorization #4) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
    - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
    - HCV RNA levels are < 25 IU/mL at TW20; then approve 8 additional weeks of therapy or until scheduled transplant (whichever is sooner) and request HCV RNA levels at TW28 and TW36 for renewal.
  - Renewal (Authorization #5) approval if all of the following are true:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and

        - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
        - HCV RNA levels are < 25 IU/mL at TW 28; then approve 8 additional weeks of therapy or until scheduled transplant (whichever is sooner) and request HCV RNA levels at TW36 for renewal.
    - Renewal (Authorization #6) approval if all of the following are true:
        - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); and
        - The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; and
        - HCV RNA levels are < 25 IU/mL at TW36; then approve 8 additional weeks of therapy or until scheduled transplant (whichever is sooner) for a total duration of 48 week

- The following product (s) will become **non preferred** and require prior authorization (PA):
    - Brisdelle™
        - Brisdelle™ (paroxetine capsules) will only be approved for patients meeting ALL of the following criteria:
            - Diagnosis of moderate to severe vasomotor symptoms in a post-menopausal woman; AND
            - Trial and failure or contraindication to ONE of the following:
                - Hormonal therapy (Examples: Premarin, Menest, Estrace, Prempro, Premphase, etc.); or
                - Other antidepressants-venlafaxine, other formulations of paroxetine, and other SSRIs.
    - Brintellix™
    - Fetzima™
    - Fycompa™
    - Opsumit®
    - Aerospan™ (QL = 2 inhalers per month)
    - Mirvaso®
        - Mirvaso® will only be approved for a diagnosis of persistent rosacea.

- Existing Drug Classes

Drug Class	The following products will remain **preferred products**:	The following products will become **preferred products**:	The following products will become **non-preferred products** and require prior authorization (PA):	The following products will remain **non-preferred products** and require prior authorization (PA):
Injectable Insulins	Humalog® Vial Humalog® Mix Vial/Pen Humulin® Vial Humulin® 70/30 Vial Lantus® Vial Levemir® Vial/Pen Novolog® Vial/Pen/ Cartridge Novolog® Mix Vial/ Pen		Humalog® Pen/Cartridge Humulin® 500 Vial Novolin® Vial Novolin® 70/30 Vial Non-Preferred Insulin Pens/Cartridges will be approved after trial and failure of one preferred insulin pen/cartridge belonging to the same insulin class (bolus, basal, premixed, rapid-acting, biphasic, and long-acting) if any one of the following is true: • Patient is 15 years of age and under; OR • Patient or active care-giver is unable to manipulate vials/syringes due to issues related to poor eyesight, dexterity, or comprehension.	Apdira™ Vial/Pen Humulin® Pen Humulin® 70/30 Pen Lantus® Solostar Pen
Amylin Analogue				Symlin® Pramlintide (Symlin®) will be approved if insulin is seen in history within the past 90 days.
GLP-1 Receptor Agonists	Byetta™ GLP-1 Receptor Agonists will be approved if metformin, a sulfonylurea, insulin, a DPP-4 Inhibitor, or a TZD is seen in history within the past 90 days.			Bydureon® Victoza®

Drug Class	The following products will remain **preferred products**:	The following products will become **preferred products**:	The following products will become **non-preferred products** and require prior authorization (PA):	The following products will remain **non-preferred products** and require prior authorization (PA):
Alpha-Glucose Inhibitors	acarbose Glyset®			Precose®
Meglitinides	Prandin® Starlix®			nateglinide PrandiMet™ repaglinide
Sulfonylureas	chlorpropamide glimepiride glipizide glipizide extended-release glyburide glyburide micronized tolazamide tolbutamide			Amaryl® Diabeta® Glucotrol® Glucotrol XL® Glynase PresTab® Micronase®
Androgenic Agents	Androderm® Androgel®			Axiron® Fortesta® Testim®
Erythropoiesis Stimulating Proteins	Aranesp® Epogen® Procrit® Erythropoiesis stimulating agents will be approved for recipients meeting one of the following criteria: • The patient has a hemoglobin of less than 12 g/dL **AND one** of the following diagnoses: o Anemia associated with chronic renal failure **OR** anemia associated with kidney transplantation; **OR** o Treatment of chemotherapy induced anemia for non-myeloid malignancies; **OR** o Drug-induced			

Drug Class	The following products will remain **preferred products**:	The following products will become **preferred products**:	The following products will become **non-preferred products** and require prior authorization (PA):	The following products will remain **non-preferred products** and require prior authorization (PA):
	anemia (examples, not all inclusive: Retrovir® **or** Combivir® **or** ribavirin); **OR** ○ Autologous blood donations by patients scheduled to undergo nonvascular surgery.			
Thrombopoiesis Stimulating Proteins	Neumega® Promacta® • Neumega® will be approved for a diagnosis of severe thrombocytopenia following myelosuppressive chemotherapy. • Promacta® will be approved for a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) OR for the treatment of thrombocytopenia in patients with chronic hepatitis C.			Nplate™ • Nplate™ will be approved for a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP).

Drug Class	The following products will remain **preferred products**:	The following products will become **preferred products**:	The following products will become **non-preferred products** and require prior authorization (PA):	The following products will remain **non-preferred products** and require prior authorization (PA):
Antihyperuricemics	allopurinol probenecid probenecid/colchicine			Colcrys® Uloric® Zyloprim® Febuxostat (Uloric®) will be approved after an adequate trial (at least 3 months) of allopurinol without achievement of serum urate level below 6mg/dL OR intolerance OR contraindication to allopurinol. Colchicine (Colcrys®) will be approved if any one of the following is true: • Diagnosis of Familial Mediterranean Fever; OR • Diagnosis of pericarditis; OR • Trial and failure of one of the following: o NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen) or o Corticosteroid
Phosphate Binders	calcium acetate Fosrenol® Renagel®	MagneBind® 400 RX		Eliphos™ PhosLo® Phoslyra™ Renvela™
Ophthalmic Antivirals	trifluridine		Viroptic® Vitrasert® intraocular implant Zirgan®	
Ophthalmic Antifungals	Natacyn®			
Ophthalmic Quinolones	ciprofloxacin solution Moxeza™			Besivance™ Ciloxan®

Drug Class	The following products will remain **preferred products**:	The following products will become **preferred products**:	The following products will become **non-preferred products** and require prior authorization (PA):	The following products will remain **non-preferred products** and require prior authorization (PA):
	ofloxacin Vigamox™			gatifloxacin Iquix® levofloxacin 0.5% Ocuflox® Quixin® Zymar™ Zymaxid™
Ophthalmic Macrolides	erythromycin			AzaSite™ Ilotycin® Romycin®
Ophthalmic Antibiotics, Non-Quinolones	bacitracin bacitracin/polymyxin B gentamicin solution/ointment neomycin/polymyxin B/gramicidin polymyxin B/trimethoprim sulfacetamide solution tobramycin solution		neomycin/polymyxin B/bacitracin sulfacetamide ointment	Bleph®-10 Garamycin® Neocidin® Neosporin® Polytrim® Tobrex®
Ophthalmic Antibiotic-Steroid Combinations	Blephamide® dexamethasone/ neomycin sulfate/ polymyxin B sulfate hydrocortisone/ bacitracin zinc/ neomycin sulfate/ polymyxin B sulfates Pred-G® Tobradex®	Blephamide® S.O.P Pred-G® S.O.P	hydrocortisone/ neomycin sulfate/polymyxin B sulfate Zylet™	dexamethasone/ tobramycin Maxitrol® prednisolone acetate/ sulfacetamide sodium prednisolone sodium phosphate/ sulfacetamide sodium Tobradex® ST
Ophthalmic Vasoconstrictors	phenylephrine	naphazoline	Altafrin® Neofrin®	Mydfrin®
Ophthalmic Antihistamines	Pataday™			azelastine Bepreve™ Elestat™ Emadine® epinastine Lastacaft™ Optivar® Patanol®
Ophthalmic Mast Cell Stabilizers	cromolyn			Alamast® Alocril® Alomide®
Ophthalmic Anti-Inflammatory Steroids	dexamethasone sodium phosphate Flarex® fluorometholone		Lotemax™ Maxidex® Ozurdex™ Vexol®	Alrex® Durezol™ FML® FML Forte®

Drug Class	The following products will remain **preferred products**:	The following products will become **preferred products**:	The following products will become **non-preferred products** and require prior authorization (PA):	The following products will remain **non-preferred products** and require prior authorization (PA):
	prednisolone acetate prednisolone sodium phosphate			FML S.O.P.® Omnipred™ Pred Forte® Pred Mild® Retisert™ Triesence®
Ophthalmic NSAIDs	Bromday™ diclofenac flurbiprofen ketorolac			Acular® Acular LS® Acuvail® bromfenac Ilevro™ Nevanac™ Ocufen® Prolensa™ Voltaren®
Ophthalmic Carbonic Anhydrase Inhibitors	Azopt® dorzolamide			Trusopt®
Ophthalmic Prostaglandin Analogs	latanoprost			Lumigan® Rescula® Travatan Z® travoprost Xalatan® Zioptan®
Ophthalmic Glaucoma Direct Acting Miotics	pilocarpine			Isopto Carpine® Pilopine HS® 4%
Ophthalmic Sympathomimetics	apraclonidine Alphagan P® 0.15% brimonidine 0.2%			Alphagan P® 0.1% brimonidine 0.15% Iopidine®
Ophthalmic Combinations for Glaucoma	Combigan™ dorzolamide/timolol Simbrinza™			Cosopt® Cosopt PF®
Ophthalmic Immunomodulator	Restasis® Cyclosporine ophthalmic 0.05% emulsion (Restasis®) will be approved if one of the following is true: • Patient is status-post corneal transplant; **OR** • Patient has tried/failed polyvinyl alcohol (Artificial Tears) in the past 90 days.			

Drug Class	The following products will remain **preferred products**:	The following products will become **preferred products**:	The following products will become **non-preferred products** and require prior authorization (PA):	The following products will remain **non-preferred products** and require prior authorization (PA):
Ophthalmic Mydriatics & Mydriatic Combinations	atropine sulfate cyclopentolate tropicamide		Homatropaire® homatropine Isopto Hyoscine®	Cyclogyl® Cyclomydril® Isopto Atropine® Isopto Homatropine® Mydriacyl® Paremyd®

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

* Please note: All dates are subject to change.

Sincerely,
Michael Price
Provider Relations Manager

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, Buprenorphine Products, 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.