

## Summary of amendment(s) to K.A.R. 129-5-1 temporary – December 30, 2014

This Medicaid regulation covers prior authorization, generally. Subsection (b) of the regulation contains a list of pharmaceuticals requiring prior authorization from the Kansas Medical Assistance Program. Prior authorization (pre-approval before dispensing) would be a requirement for a compensable Medicaid claim.

The proposed amendment adds a new anti-hepatitis C drug, ledipasvir-sofosbuvir, to the PA drug list. See p. 12. The primary reason is cost. This new drug (Harvoni) from Gilead costs approximately \$1,125 per pill with an 8 week treatment cost of approximately \$63,000. The Kansas Drug Utilization Board has reviewed this new drug and recommended its addition to the PA list. It is estimated that the addition of this new drug to the PA list will reduce Kansas Medicaid expenditures by \$1,194,794.93 SGF and \$1,560,093.04 FFP. The cost of reviewing this addition to the PA list will be borne by the DHCF and the contracted KanCare Managed Care Organizations.

There were, also, minor editing changes to the regulation involving the placement of “and” in a string listing (see page 12) and a clarification of the inconsistent use of “beta 2 agonists” between (b) (17) & (b) (71).

129-5-1. Prior authorization. (a) Any medical service may be placed by the Kansas department of health and environment, division of health care finance on the published list of services requiring prior authorization or precertification for any of the following reasons:

- (1) To ensure that provision of the service is medically necessary;
- (2) to ensure that services that could be subject to overuse are monitored for appropriateness in each case; and
- (3) to ensure that services are delivered in a cost-effective manner.

(b) Administration of covered pharmaceuticals in the following classes shall require prior authorization. A cross-reference of generic and brand names shall be made available upon request:

- (1) Ace inhibitors:
  - (A) Quinapril;
  - (B) moexipril;
  - (C) perindopril;
  - (D) ramipril; and
  - (E) trandolopril;
- (2) retinoids:
  - (A) Tretinoin;
  - (B) alitretinoin; and
  - (C) bexarotene;
- (3) adjunct antiepileptic drugs:
  - (A) Gabitril;

- (B) zonegran;
  - (C) clobazam;
  - (D) lacosamide;
  - (E) rufinamide;
  - (F) eslicarbazepine;
  - (G) perampanel;
  - (H) ezogabine; and
  - (I) oxcarbazepine;
- (4) angiotensin II receptor antagonists:
- (A) Candesartan;
  - (B) candesartan-HCTZ;
  - (C) eprosartan;
  - (D) eprosartan-HCTZ;
  - (E) olmesartan;
  - (F) olmesartan-HCTZ; and
  - (G) azilsartan;
- (5) antibiotics:
- (A) Telithromycin; and
  - (B) rifaximin;
- (6) anticholinergic urinary incontinence drugs:
- (A) Flavoxate;
  - (B) oxybutynin XL;
  - (C) oxybutynin patches;

- (D) trospium chloride;
- (E) darifenacin; and
- (F) oxybutynin, topical;
- (7) antiemetics:
  - (A) Nabilone; and
  - (B) doxylamine succinate-pyridoxine hydrochloride;
- (8) antipsoriatics:
  - (A) Alefacept; and
  - (B) ustekinumab;
- (9) antiretroviral drugs:
  - (A) Enfuvirtide; and
  - (B) maraviroc;
- (10) antirheumatics:
  - (A) Leflunomide;
  - (B) infliximab;
  - (C) anakinra;
  - (D) adalimumab;
  - (E) etanercept;
  - (F) abatacept;
  - (G) rituximab;
  - (H) golimumab;
  - (I) certolizumab;
  - (J) tocilizumab; and

- (K) tofacitinib;
- (11) cervical dystonias:
  - (A) Onabotulinum toxin A;
  - (B) abobotulinum toxin A;
  - (C) rimabotulinum toxin B; and
  - (D) incobotulinum toxin A;
- (12) drugs for the treatment of osteoporosis: teriparatide;
- (13) antituberculosis products:
  - (A) Aminosalicylate sodium;
  - (B) capreomycin;
  - (C) ethambutol;
  - (D) ethionamide;
  - (E) isoniazid;
  - (F) pyrazinamide; and
  - (G) rifampin and rifampin-isoniazid combinations;
- (14) all decubitus and wound care products;
- (15) all intravenous and oral dietary and nutritional products, including the following:
  - (A) Amino acids, injectable;
  - (B) 1-cysteine;
  - (C) lipids, injectable; and
  - (D) sodium phenylbutyrate;
- (16) beta-blockers:

- (A) Betaxolol;
  - (B) bisoprolol;
  - (C) carteolol;
  - (D) penbutolol;
  - (E) propranolol XL; and
  - (F) nebivolol;
- (17) short-acting, inhaled beta 2 agonists:
- (A) Metaproterenol inhaler;
  - (B) levalbuterol solution;
  - (C) albuterol solutions: 0.021% and 0.042%;
  - (D) levalbuterol inhaler; and
  - (E) pirbuterol inhaler;
- (18) calcium channel blockers:
- (A) Diltiazem extended release, with the following brand names:
    - (i) Cardizen SR<sup>®</sup>;
    - (ii) Cardizem CD<sup>®</sup>;
    - (iii) Cartia XT<sup>®</sup>;
    - (iv) Dilacor XR<sup>®</sup>;
    - (v) Taztia XT<sup>®</sup>; and
    - (vi) Cardizem LA<sup>®</sup>;
  - (B) verapamil sustained release, with the following brand names:
    - (i) Covera HS<sup>®</sup>; and
    - (ii) Verelan PM<sup>®</sup>;

- (C) nifedipine sustained release, with the following brand names:
  - (i) Nifedical XL<sup>®</sup>; and
  - (ii) Procardia XL<sup>®</sup> and all generic equivalents;
- (D) nisoldipine;
- (E) felodipine;
- (F) isradipine;
- (G) nicardipine SR; and
- (H) nifedipine immediate release, with the following brand names:
  - (i) Adalat<sup>®</sup> and all generic equivalents; and
  - (ii) Procardia<sup>®</sup> and all generic equivalents;
- (19) fibric acid derivatives:
  - (A) Antara<sup>®</sup>; and
  - (B) Lofibra<sup>®</sup>;
- (20) all growth hormones and growth hormone stimulating factor, including the following:
  - (A) Somatrem;
  - (B) somatropin;
  - (C) sermorelin; and
  - (D) mecasermin rinfabate;
- (21) intranasal corticosteroids:
  - (A) Flunisolide;
  - (B) beclomethasone; and
  - (C) ciclesonide;

- (22) inhaled corticosteroids:
  - (A) Flunisolide-menthol;
  - (B) flunisolide; and
  - (C) budesonide inhaled suspension;
- (23) proton pump inhibitors:
  - (A) Esomeprazole;
  - (B) omeprazole;
  - (C) omeprazole OTC;
  - (D) lansoprazole;
  - (E) pantoprazole;
  - (F) rabeprazole;
  - (G) omeprazole NaHCO<sub>3</sub>; and
  - (H) dexlansoprazole;
- (24) monoclonal antibody for respiratory syncytial virus (RSV), including palivizumab;
- (25) muscle relaxants:
  - (A) Tizanidine;
  - (B) orphenadrine;
  - (C) carisoprodol;
  - (D) carisoprodol-aspirin;
  - (E) carisoprodol-aspirin-caffeine;
  - (F) cyclobenzaprine;
  - (G) metaxolone;

- (H) dantrolene; and
- (I) orphenadrine-aspirin-caffeine;
- (26) narcotics:
  - (A) Buprenorphine-naloxone; and
  - (B) buprenorphine;
- (27) nonsteroidal, anti-inflammatory drugs:
  - (A) Nabumetone;
  - (B) diclofenac patches;
  - (C) diclofenac, topical; and
  - (D) ketorolac, intranasal;
- (28) drugs for the treatment of obesity:
  - (A) Orlistat;
  - (B) phentermine;
  - (C) lorcaserin; and
  - (D) phentermine-topirimate ER;
- (29) oxazolidinones, including linezolid;
- (30) HMG-CoA reductase inhibitors:
  - (A) Pravastatin;
  - (B) fluvastatin;
  - (C) lovastatin; and
  - (D) pitavastatin;
- (31) nonsedating antihistamines:
  - (A) Desloratidine;

- (B) fexofenadine; and
- (C) levocetirizine;
- (32) H<sub>2</sub> antagonists: nizatidine;
- (33) triptans:
  - (A) Zolmitriptan;
  - (B) frovatriptan;
  - (C) almotriptan;
  - (D) Alsuma<sup>®</sup>;
  - (E) Sumavel<sup>®</sup>;
  - (F) rizatriptan; and
  - (G) sumatriptan pens, vials, cartridges, and nasal sprays;
- (34) antidiabetic drugs:
  - (A) Glipizide XL;
  - (B) glipizide-metformin;
  - (C) repaglinide;
  - (D) acarbose;
  - (E) Glucophage XR<sup>®</sup>;
  - (F) Fortamet<sup>®</sup>;
  - (G) Glumetza<sup>®</sup>;
  - (H) exenatide;
  - (I) pramlintide acetate; and
  - (J) liraglutide;
- (35) the following types of syringes, penfills, and cartridges of insulin:

- (A) Humalog<sup>®</sup>;
  - (B) Humalog Mix<sup>®</sup>;
  - (C) Humulin R<sup>®</sup>;
  - (D) Humulin N<sup>®</sup>;
  - (E) Humulin 70/30<sup>®</sup>;
  - (F) Novolog<sup>®</sup>;
  - (G) Novolog Mix<sup>®</sup>;
  - (H) Novolin R<sup>®</sup>;
  - (I) Novolin N<sup>®</sup>;
  - (J) Novolin 70/30<sup>®</sup>;
  - (K) Velosulin BR<sup>®</sup>; and
  - (L) insulin detemir;
- (36) hypnotics:
- (A) Zaleplon;
  - (B) zolpidem;
  - (C) zolpidem CR; and
  - (D) eszopiclone;
- (37) serotonin 5-HT<sub>3</sub> receptor antagonist antiemetics:
- (A) Granisetron;
  - (B) dolasetron; and
  - (C) ondansetron film;
- (38) influenza vaccines: Flumist<sup>®</sup>;
- (39) monoclonal antibody for asthma: omalizumab;

- (40) bisphosphonates:
  - (A) Risedronate; and
  - (B) risedronate-calcium;
- (41) combination products for hypertension:
  - (A) Enalapriol maleate-felodipine;
  - (B) trandolapril-verapamil; and
  - (C) telmisartan-amlodipine;
- (42) ophthalmic prostaglandin analogues:
  - (A) Bimatoprost; and
  - (B) unoprostone;
- (43) topical immunomodulators:
  - (A) Protpic<sup>®</sup> (topical formulation); and
  - (B) Elidel<sup>®</sup>;
- (44) narcotic analgesics: any transmucosal form of fentanyl;
- (45) tramadol and all opioids, opioid combinations, and skeletal muscle relaxants, at any dose greater than the maximum recommended dose in a 31-day period;
- (46) progestin for preterm labor: Makena<sup>®</sup>;
- (47) aromatase inhibitors:
  - (A) Letrozole;
  - (B) anastrozole; and
  - (C) exemestane;
- (48) long-acting, inhaled beta 2 agonists:
  - (A) Salmeterol;

- (B) formoterol;
- (C) arformoterol; and
- (D) indacaterol;
- (49) miscellaneous biologic agents:
  - (A) Canakinumab;
  - (B) natalizumab;
  - (C) denosumab; and
  - (D) riloncept;
- (50) stem cell mobilizers: plerixafor;
- (51) antidotes: methylnaltrexone;
- (52) complement inhibitors:
  - (A) C1 esterase inhibitor;
  - (B) ecallantide;
  - (C) icatibant; and
  - (D) eculizumab;
- (53) anti-hepatitis C virus agents:
  - (A) Boceprevir;
  - (B) telaprevir;
  - (C) simeprevir; ~~and~~
  - (D) sofosbuvir; and
  - (E) ledipasvir-sofosbuvir;
- (54) cystic fibrosis agents: ivacaftor;
- (55) agents for gout:

- (A) Febuxostat; and
- (B) pegloticase;
- (56) phenylketonurics: sapropterin;
- (57) topical anesthetics: lidocaine;
- (58) antithrombin agents: eltrombopag;
- (59) anti-malarials: quinine;
- (60) hormone analog for precocious puberty: histrelin acetate;
- (61) agents for chorea associated with Huntington's disease: tetrabenazine;
- (62) enzyme preparations: collagenase clostridium histolyticum;
- (63) agents for cataplexy: sodium oxybate;
- (64) topical acne agents:
  - (A) Adapalene;
  - (B) adapalene-benzyl peroxide;
  - (C) azelaic acid;
  - (D) dapsona;
  - (E) tazarotene; and
  - (F) tretinoin-clindamycin;
- (65) interferons:
  - (A) Interferon alfacon-1;
  - (B) interferon alfa-2b;
  - (C) interferon beta-1a;
  - (D) interferon beta-1b;
  - (E) peginterferon alfa-2a; and

- (F) peginterferon alfa-2b;
- (66) pulmonary arterial hypertension agents:
  - (A) Ambrisentan;
  - (B) bosentan;
  - (C) epoprostenol;
  - (D) iloprost;
  - (E) macitentan;
  - (F) riociguat;
  - (G) sildenafil;
  - (H) tadalafil; and
  - (I) treprostinil;
- (67) testosterone agents:
  - (A) Androderm Transdermal<sup>®</sup>;
  - (B) AndroGel<sup>®</sup>;
  - (C) Axiron Topical Solution<sup>®</sup>;
  - (D) Delatestryl<sup>®</sup>;
  - (E) Fortesta Gel<sup>®</sup>;
  - (F) Striant Buccal<sup>®</sup>;
  - (G) Testim Gel<sup>®</sup>; and
  - (H) Testopel Pellets<sup>®</sup>;
- (68) antineoplastic agents:
  - (A) Afatinib;
  - (B) dabrafenib;

- (C) everolimus;
- (D) methotrexate;
- (E) sipuleucel-T;
- (F) trametinib; and
- (G) trastuzumab;
- (69) multiple sclerosis agents:
  - (A) Dalfampridine;
  - (B) dimethyl fumarate;
  - (C) fingolimod;
  - (D) glatiramer; and
  - (E) teriflunomide;
- (70) immunosuppressive agents: belimumab;
- (71) inhaled long-acting ~~beta2-agonists~~ beta 2 agonists and corticosteroid products:
  - (A) Budesonide-formoterol; and
  - (B) fluticasone-vilanterol;
- (72) ammonia detoxicants:
  - (A) Glycerol phenylbutyrate; and
  - (B) sodium phenylbutyrate;
- (73) heavy metal antagonists:
  - (A) Deferasirox;
  - (B) deferiprone; and
  - (C) trientine;

- (74) pituitary corticotropin: H.P. Acthar<sup>®</sup> Gel;
- (75) ocular agents:
  - (A) Ocriplasmin; and
  - (B) ranibizumab;
- (76) miscellaneous anti-lipemic agents:
  - (A) Lomitapide; and
  - (B) mipomersen;
- (77) miscellaneous analgesics: ziconotide intrathecal infusion;
- (78) miscellaneous central nervous system agents: riluzole;
- (79) calcimimetics: cinacalcet;
- (80) radioactive agents: radium Ra 223 dichloride;
- (81) dipeptidyl peptidase IV inhibitors:
  - (A) Alogliptin; and
  - (B) linagliptin; and
- (82) antimuscarinics-antispasmodics: acridinium bromide.
- (c) Failure to obtain prior authorization, if required, shall negate

reimbursement for the service and any other service resulting from the unauthorized or noncertified treatment. The prior authorization shall affect reimbursement to all providers associated with the service.

- (d) The only exceptions to prior authorization shall be the following:
  - (1) Emergencies. If certain surgeries and procedures that require prior authorization are performed in an emergency situation, the request for authorization shall be made within two working days after the service is provided.

(2) Situations in which services requiring prior authorization are provided and retroactive eligibility is later established. When an emergency occurs or when retroactive eligibility is established, prior authorization for that service shall be waived, and if medical necessity is documented, payment shall be made.

(e) Services requiring prior authorization shall be considered covered services within the scope of the program, unless the request for prior authorization is denied.

(Authorized by K.S.A. ~~2013~~ 2014 Supp. 39-7,120, K.S.A. 75-5625; implementing K.S.A. ~~2013~~ 2014 Supp. 39-7,120 and K.S.A. ~~2013~~ 2014 Supp. 39-7,121a; effective Oct. 28, 2005; amended June 2, 2006; amended Aug. 11, 2006; amended Nov. 17, 2006; amended March 16, 2007; amended Oct. 19, 2007; amended May 23, 2008; amended Feb. 17, 2012; amended Oct. 19, 2012; amended Aug. 1, 2014; amended, T-\_\_\_\_\_, \_\_\_\_\_.)

## ECONOMIC IMPACT STATEMENT

Regulation Number: 129-5-1

Regulation Name: Prior Authorization

Summary of Proposed Changes: The following changes will be made to regulation 129-5-1 regarding prior authorization of pharmaceutical products:

The following drug will require prior authorization to ensure appropriate utilization because of safety issues, potential for off-label use, abuse potential, cost effectiveness, and/or clinical appropriateness:

- Anti-hepatitis C virus agents: ledipasvir-sofosbuvir

Federal Mandate: This regulation change is not federally mandated.

Economic Impact: It is expected that these changes will reduce Medicaid expenditures by \$1,194,794.93 SGF and \$1,560,093.07 FFP annually.

Bearer of Cost: The cost of reviewing Prior Authorization will be borne by DHCF and the contracted KanCare Managed Care Organizations. If a Medicaid consumer wishes to have a drug despite a PA denial the cost will be borne by the consumer.

Affected Parties: Medicaid consumers, pharmacists, prescribers, and the Medicaid agency.

Other Methods: There were no other appropriate methods for the desired outcome.