STATE OF KANSAS

Proposed

Kansas Department of Health and Environment
Division of Health Care Finance

Notice of Hearing on Proposed Administrative Regulations

A public hearing will be conducted at 3:00 p.m. on Monday, June 23, 2014 in the Landon State Office Building, Room 900-N, 900 S.W. Jackson Street, Topeka, Kansas 66612-1220, to consider the adoption of amended changes to existing rules and regulations on a permanent basis effective 15 days after publication in the Kansas Register. Chapter 187, 2005 Session Laws of Kansas transferred specific powers, duties, and regulatory authority from the Department of Social and Rehabilitation Services to the Division of Health Policy and Finance (DHPF) within the Department of Administration, and then transferred those powers, duties and regulatory authority to the Kansas Health Policy Authority (KHPA), effective July 1, 2006. Executive Reorganization Order (ERO) #38 has transferred these powers, duties, and regulatory authority to the Kansas Department of Health and Environment, Division of Health Care Finance. The ERO provides that KDHE will be the single state agency for Kansas Medicaid effective July 1, 2011. Telephone conference is not available.

This 30-day notice of the public hearing shall constitute a public comment period for the proposed regulation as stated in K.S.A. 2007 Supp. 77-421(a)(3). All interested parties may submit written comments before the hearing to Bobbie Graff-Hendrixson, KDHE, Division of Health Care Finance, Landon State Office Building, 900 S.W. Jackson, Room 900-N, Topeka, Kansas 66612-1220, or by e-mail at Bgraff-hendrixson@kdheks.gov. At the hearing, the Division of Health Care Finance will give all interested parties a reasonable opportunity to present their views, but it may be necessary to request each participant to limit any oral presentation to five minutes. You may obtain a copy of the regulation and the economic impact statement by

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contacting Bobbie Graff-Hendrixson at (785) 296-4109 or the DHCF Website at www.kdheks.gov.

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Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed regulation and economic impact statement in an accessible format. Please make any request for accommodation to participate in the hearing at least five working days before the hearing by contacting Bobbie Graff-Hendrixson at (785) 296-4109 or by calling the Kansas Relay Center at 1-800-766-3777.

A summary of the regulation and the economic impact follows:

Article 5.–PROVIDER PARTICIPATION, SCOPE OF SERVICES, AND REIMBURSEMENT FOR THE MEDICAID (MEDICAL ASSISTANCE) PROGRAM

129-5-1. Prior Authorization. The following changes will be made to regulation 129-5-1 regarding prior authorization of pharmaceutical products:

These therapeutic classes of drugs have been evaluated by the Preferred Drug List Advisory Committee and found to be clinically equivalent to agents within their respective drug classes. To ensure the most clinically appropriate utilization of these drugs in the most cost-effective manner, the following drugs will require prior authorization:

- Adjunct antiepileptic drugs: eslicarbazepine, perampanel, ezogabine, oxcarbazepine
- Triptans: rizatriptan, sumatriptan pens, vials, cartridges, and nasal sprays
- Inhaled long-acting beta2-agonsists & corticosteroids: budesonide & formoterol, fluticasone & vilanterol
- Miscellaneous anti-lipemic agents: lomitapide, mipomersen
- Dipeptidyl peptidase IV inhibitors: alogliptin, linagliptin
- Antimuscarinics & Antispasmodics: aclidinium bromide

The following drugs 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:

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- Antibiotics: rifaximin
- Antiemetics: doxylamine succinate & pyridoxine hydrochloride
- Antirheumatics: tofacitinib
- Cervical Dystonia agents: incobotulinum toxin A
- Drugs for the treatment of obesity: lorcaserin, phentermine & topiramate ER
- Complement inhibitors: eculizumab
- Anti-hepatitis C virus agents: simprevir, sofosbuvir
- Topical acne agents: adapalene, adapalene & benzyl peroxide, azelaic acid, dapsone, tazarotene, tretinoin & clindamycin
- Interferons: interferon alfacon-1, interferon alfa-2b, interferon beta-1a, interferon beta-1b, peginterferon alfa-2a, peginterferon alfa-2b
- Pulmonary arterial hypertension agents: ambrisentan, bosentan, epoprostenol, ilprost, macitentan, riociguat, sildenafil, tadalafil, treprostinil
- Testosterone agents: Androderm Transdermal®, AndroGel®, Axiron Topical Solution®, Delatestryl®, Fortesta Gel®, Striant Buccal®, Testim Gel®, Testopel Pellets®
- Antineoplastic agents: afatinib, dabrafenib, everolimus, methotrexate, sipuleucel-T, trametinib, trastuzumab
- Multiple Sclerosis agents: dalfampridine, dimethyl fumarate, fingolimod, glatiramer, teriflunomide
- Immunosuppressive agents: belimumab
- Ammonia detoxicants: glycerol phenylbutyrate, sodium phenylbutyrate
- Heavy metal antagonists: deferasirox, deferiprone, trientine
- Pituitary corticotropin: H.P. Acthar Gel®
- Ocular agents: ocriplasmin, ranibizumab
- Miscellaneous analgesics: ziconotide intrathecal infusion
- Miscellaneous central nervous system agents: riluzole

- Calcimimetics: cinacalcet
- Radioactive agents: radium Ra 223 dichloride

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Federal Mandate: This regulation change is not federally mandated.

Economic Impact: It is expected that these changes will reduce Medicaid expenditures by $1,160,948.58 SGF and $1,533,292.74 FFP annually.

Bearer of Cost: The cost of reviewing Prior Authorization will be borne by DHCF. 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.

Kari Bruffett, Director
KDHE; Division of Health Care Finance

Proposed

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; ~~and~~

(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) etonercept;

(F) abatacept;

(G) rituximab;

(H) golimumab;

(I) certolizumab; ~~and~~

(J) tocilizumab; and

(K) tofacitinib;

(11) cervical dystonias:

(A) Onabotulinum toxin A;

(B) abobotulinum toxin A; ~~and~~

(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) l-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®;

(ii) Cardizem CD®;

(iii) Cartia XT®;

(iv) Dilacor XR®;

(v) Taztia XT®; and

(vi) Cardizem LA®;

(B) verapamil sustained release, with the following brand names:

(i) Covera HS®; and

(ii) Verelan PM®;

(C) nifedipine sustained release, with the following brand names:

(i) Nifedical XL®; and

(ii) Procardia XL® 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® and all generic equivalents; and

(ii) Procardia® and all generic equivalents;

(19) fibric acid derivatives:

(A) Antara®; and

(B) Lofibra®;

(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 $NaHCO_3$; and

(H) dexlansoprazole;

(24) monoclonal antibody for respiratory syncitial 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; ~~and~~

(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_2 antagonists: nizatidine;

(33) triptans:

(A) Zolmitriptan;

(B) frovatriptan;

(C) almotriptan;

(D) ~~Alsuma™~~ Alsuma®; ~~and~~

(E) Sumavel®;

(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®;

(F) Fortamet®;

(G) Glumetza®;

(H) exenatide;

(I) pramlintide acetate; and

(J) liraglutide;

(35) the following types of syringes, penfills, and cartridges of insulin:

(A) Humalog®;

(B) Humalog Mix®;

(C) Humulin R®;

(D) Humulin N®;

(E) Humulin 70/30®;

(F) Novolog®;

(G) Novolog Mix®;

(H) Novolin R®;

(I) Novolin N®;

(J) Novolin 70/30®;

(K) Velosulin BR®; and

(L) insulin determir;

(36) hypnotics:

(A) Zaleplon;

(B) zolpidem;

(C) zolpidem CR; and

(D) eszopiclone;

(37) serotonin 5-HT_3 receptor antagonist antiemetics:

(A) Granisetron;

(B) dolasetron; and

(C) ondansetron film;

(38) influenza vaccines: Flumist®;

(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® (topical formulation); and

(B) Elidel®;

(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®;

(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) rilonacept;

(50) stem cell mobilizers: plerixafor;

(51) antidotes: methylnaltrexone;

(52) ~~hereditary angioedema agents~~ complement inhibitors:

(A) C1 esterase inhibitor;

(B) ecallantide; ~~and~~

(C) icatibant; and

(D) eculizumab;

(53) anti-hepatitis C virus agents:

(A) Boceprevir; ~~and~~

(B) telaprevir;

(C) simeprevir; and

(D) 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: collegenase clostridium histolyticum; ~~and~~

(63) agents for cataplexy: sodium oxybate;

(64) topical acne agents:

(A) Adapalene;

(B) adapalene-benzyl peroxide;

(C) azelaic acid;

(D) dapsone;

(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®;

(B) AndroGel®;

(C) Axiron Topical Solution®;

(D) Delatestryl®;

(E) Fortesta Gel®;

(F) Striant Buccal®;

(G) Testim Gel®; and

(H) Testopel Pellets®;

(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 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® Gel;

(75) ocular agents:

(A) Ocriplasmin; and

(B) ranibizumab;

(76) miscellaneous antilipemic 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: aclidinium 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. ~~2011~~ 2013 Supp. 39-7,120, ~~as amended by L. 2012, ch. 102, sec. 9,~~ K.S.A. ~~2011 Supp. 65-1,254, K.S.A. 2011 Supp. 75-7412, as amended by L. 2012, ch. 102, sec. 43~~ 75-5625; implementing K.S.A. ~~2011~~ 2013 Supp. 39-7,120~~, as amended by L. 2012, ch. 102, sec. 9,~~ and K.S.A. ~~2011~~ 2013 Supp. 39-7,121a~~, as amended by L. 2012, ch. 102, sec. 11~~; 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 P-_____.)

Proposed

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:

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- Calcimimetics: cinacalcet
- Radioactive agents: radium Ra 223 dichloride

Federal Mandate: This regulation change is not federally mandated.

Economic Impact: It is expected that these changes will reduce Medicaid expenditures by $1,160,948.58 SGF and $1,533,292.74 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.