THE PRESCRIBER E-LETTER

The Prescriber E-Letter is a quarterly update designed to enhance the transparency and efficiency of the MassHealth drug prior authorization (PA) process and the MassHealth Drug List. Each issue will **highlight** key clinical **information and updates** to the **MassHealth Drug List**. The Prescriber E-Letter was prepared by the MassHealth Drug Utilization Review Program and the MassHealth Pharmacy Program.

Pediatric Behavioral Health Medication Initiative

The MassHealth Pediatric Behavioral Health Medication Initiative was created after consultation with the Department of Children and Families (DCF) and the Department of Mental Health (DMH) to assist in ensuring appropriate use of behavioral health medications among pediatric MassHealth members. An expert workgroup convened by the DMH served as an advisory board to create the approval criteria that will be used to evaluate prior authorization (PA) requests submitted to the Drug Utilization Review Program. This initiative will proactively require PA for potentially dangerous combinations of behavioral health medications prescribed to members 18 years of age and younger, as well as for medication classes that have limited evidence of safety and efficacy in the pediatric population.

To ensure continuous quality assurance, improvement, and transparency, a multidisciplinary Therapeutic Class Management workgroup will retrospectively review PAs that do not meet the required criteria and provide an increased level of clinical expertise to evaluate outlier cases. The workgroup may also conduct outreach to individual prescribers to discuss clinically appropriate treatment options and ensure safe, effective care of MassHealth pediatric members.

The Pediatric Behavioral Health Medication Initiative was implemented on November 24, 2014. Further information on the Pediatric Behavioral Health Medication Initiative and the MassHealth Drug List can be found at www.mass.gov/masshealth/pharmacy.

PA is required for polypharmacy for the following behavioral health medications and/or classes in members 18 years of age and younger.*

- Alpha$_2$ Agonists
- Antidepressants
- Antipsychotics
- Atomoxetine
- Benzodiazepines
- Buspirone
- Cerebral Stimulants
- Hypnotics
- Mood Stabilizers

*Additional age restrictions may apply.

Buprenorphine Use During Pregnancy

Subutex® (buprenorphine) sublingual tablets were FDA approved to treat opioid dependence in October 2002. Subutex ® (buprenorphine) is not FDA-approved for the treatment of opioid dependency during pregnancy, but mounting evidence of its effectiveness in gravid women has led to the widespread use of buprenorphine clinically in this patient population.

In 2012, the American College of Obstetricians and Gynecologists conceded that buprenorphine could be used as a first-line medication for the treatment of opioid-dependent pregnant women. Clinicians are urged to discuss Neonatal Abstinence Syndrome (NAS) as a possible sequela of buprenorphine use during pregnancy.

There is no consensus on the initiation dose of buprenorphine during pregnancy as this can vary, but the maintenance dose after initial stabilization may need to increase throughout pregnancy. Buprenorphine/naloxone (Suboxone®) is not recommended during pregnancy because the safety profile of naloxone used alone or in combination with drugs during pregnancy has not been well studied.

Due to the potential for serious drug-drug interactions, buprenorphine must be used cautiously with certain other types of medications, including benzodiazepines, medications with sedative properties, medications metabolized by the cytochrome P450 3A4 system, and opioid agonists. Additionally, the use of buprenorphine with other central nervous system depressants may increase the risk of medication adverse effects including hypotension, respiratory depression, profound sedation, and coma.

The prior authorization process for buprenorphine was implemented in May 2007. Currently buprenorphine tablets are listed on the MassHealth Drug List with a prior authorization (PA) restriction for all doses. The PA criteria restrict against concurrent long-acting or >7 days of short-acting opioid therapy due to the lack of clinical evidence and the potential risks associated with concomitant use.

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Drug/Drug Class	Addition/Deletion/Change	Rationale
Androgens	Addition; **requires PA** Testosterone 1% gel tube, packet, pump (Vogelxo®) Testosterone undecanoate (Aveed®)^ ^This drug is available through the health care professional who administers the drug. MassHealth does not pay for this drug to be dispensed through a retail pharmacy.	Testosterone is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism or hypogonadotropic hypogonadism. Given that all testosterone products require PA to ensure appropriate use, these agents require PA.
Antiretroviral Agents	Addition; **requires PA** Raltegravir powder for suspension (Isentress®) Change in PA status; **requires PA** Raltegravir 25 mg and 100 mg chewable tablets (Isentress®)	Raltegravir powder for suspension and chewable tablets are indicated for the treatment of human immunodeficiency virus (HIV)-1 infection in patients four weeks of age and older in combination with other antiretroviral agents. Due to more cost-effective alternatives available for the management of the same clinical condition, including raltegravir 400 mg film-coated tablets, this agent requires PA.
Butalbital Containing Agents	Deletion; no longer on MassHealth Drug List Butalbital/aspirin/caffeine tablet Butalbital 50 mg/acetaminophen 500 mg/caffeine 40 mg	Butalbital/aspirin/caffeine tablets and butalbital 50 mg/ acetaminophen 500 mg /caffeine 40 mg have been removed from the MassHealth Drug List because they have been discontinued by the manufacturer.
Opioids and Analgesics	Change in PA status; **requires PA < 10 years** Acetaminophen/codeine (Tylenol® with codeine) - **PA > 4 grams of acetaminophen/day and > 360 mg of codeine/day** Butalbital 50 mg/ acetaminophen 325 mg / caffeine 40 mg / codeine 30 mg (Fioricet® with codeine) - **PA > 60 units/month** Butalbital/aspirin/caffeine/codeine (Fiorinal® with codeine) **PA > 60 units/month** Codeine - **PA > 360 mg/day**	In August 2012, the FDA issued a safety announcement warning prescribers of the risks of pediatric codeine use, especially for those who have undergone tonsillectomy and/or adenoidectomy for OSA. This announcement resulted in the requirement of the following black-box warning for all codeine-containing products: Respiratory depression and death have occurred in children who received codeine following tonsillectomy and/or adenoidectomy and had evidence of being ultra-rapid metabolizers of codeine due to a CYP2D6 polymorphism. Given the risk of respiratory depression associated with pediatric codeine use, agents containing codeine require PA in patients10 years of age and younger and for requests over quantity limits.
Oral Immunotherapy Agents	Addition; **requires PA** Ragweed pollen allergen extract (RAGWITEK®) Timothy grass pollen allergen	Ragweed and timothy grass pollen allergen extract are FDA-approved for the treatment of short ragweed pollen-induced and grass-pollen induced allergic rhinitis, respectively, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific immunoglobulin E antibodies.

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	extract (GRASTEK®)	Due to more cost-effective alternatives available for the management of the same clinical condition, including inhaled triamcinolone, generic inhaled fluticasone propionate and flunisolide, as well as generic loratadine and cetirizine, these agents require PA.
Pediatric Behavioral Health Medications	Change in PA status; **requires PA for polypharmacy and <18 years*** $Alpha_2$ Agonists Antidepressants Antipsychotics Atomoxetine Benzodiazepines Buspirone Cerebral Stimulants Hypnotic Agents Mood Stabilizers *Additional age restrictions may apply.	The MassHealth Pediatric Behavioral Health Medication Initiative was created to assist in ensuring appropriate use of behavioral health medications in pediatric MassHealth members. This initiative will proactively require PA for potentially dangerous combinations of behavioral health medications prescribed to members 18 years of age and younger. In addition, PA is required for medication classes that have limited evidence of safety and efficacy in the pediatric population, such as antipsychotics, antidepressants, atomoxetine, benzodiazepines, buspirone, mood stabilizers or hypnotic agents for use in pediatric members less than six years of age, as well as $alpha_2$ agonists and cerebral stimulants for use in pediatric members younger than three years of age. Further information on the Pediatric Behavioral Health Medication Initiative and the MassHealth Drug List can be found at www.mass.gov/masshealth/pharmacy.
Phosphate Binders	Addition; **requires PA** Sucroferric oxyhydroxide (Velphoro®) Change in PA status; **requires PA** Lanthanum (Fosrenol®)	Lanthanum and sucroferric oxyhydroxide are phosphate binders indicated for use in patients with kidney disease. Given the pending availability of generic sevelamer hydrochloride and availability of more cost-effective alternatives for the management of the same clinical condition, including generic calcium carbonate/acetate and sevelamer carbonate, these agents require PA.
Acyclovir buccal tablet (Sitavig®)	Addition; **requires PA**	Acyclovir buccal tablets are indicated for the treatment of recurrent herpes labialis in immunocompetent adults. Due to more cost-effective alternatives available for the management of the same clinical condition, including generic oral famciclovir, valacyclovir, and acyclovir, this agent requires PA.
Albiglutide (Tanzeum®)	Addition; **requires PA**	Albiglutide is a glucagon-like peptide FDA-approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Due to more cost-effective alternatives available for the management of the same clinical condition, including generic metformin, glimepiride, glipizide, and micronized glyburide, this agent requires PA.
Apremilast (Otezla®)	Addition; **requires PA**	Apremilast is indicated for the treatment of adult patients with active psoriatic arthritis. Due to more cost-effective alternatives available for the management of the same clinical condition, including generic methotrexate, sulfasalazine, and hydroxychloroquine, this agent requires PA.
Carbidopa	Addition; does not require PA	Carbidopa is the new "A"-rated generic to Lodosyn. This agent does not require PA.

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Carbinoxamine extended-release (Karbinal® ER)	Addition; **requires PA**	Carbinoxamine is an H_1 receptor antagonist indicated for the treatment of certain allergic conditions. Due to more cost-effective alternatives available for the management of the same clinical conditions, including inhaled triamcinolone, generic inhaled fluticasone propionate and flunisolide, as well as generic diphenhydramine, chlorpheniramine, promethazine, and hydroxyzine, this agent requires PA.
Ceritinib (ZYKADIA®)	Addition; **requires PA**	Ceritinib is indicated for the treatment of anaplastic lymphoma kinase-positive non-small cell lung cancer in patients who have progressed on or are intolerant to crizotinib. Given the high cost and specific indication, this agent requires PA.
Eslicarbazepine (Aptiom®)	Addition; **requires PA**	Eslicarbazepine is FDA-approved for the adjunctive treatment of partial-onset seizures in patients 18 years of age and older. Due to more cost-effective alternatives available for the management of the same clinical condition, including generic carbamazepine, oxcarbazepine, levetiracetam, and lamotrigine, this agent requires PA.
Estrogens, conjugated/bazedoxifene (Duavee®)	Addition; does not require PA	Estrogens, conjugated/bazedoxifene is indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause and for the prevention of postmenopausal osteoporosis. This agent does not require PA.
Fentanyl nasal spray (Lazanda®)	Addition; **requires PA**	Fentanyl nasal spray is indicated for the treatment of breakthrough cancer pain in opioid tolerant patients 18 years of age and older, who are already receiving opioid therapy for persistent and underlying cancer pain. Given the potential for off-label use and more cost-effective alternatives available for the management of the same clinical condition, including generic immediate-release hydromorphone, morphine, oxycodone, and fentanyl lozenges, this agent requires PA.
Hyaluronate (Monovisc®)	Addition; **requires PA**	Hyaluronate is FDA-approved for the treatment of pain in osteoarthritis of the knee refractory to non-pharmacologic therapy or simple analgesics. Due to more cost-effective alternatives available for the management of the same clinical condition, including generic non-steroidal anti-inflammatory drugs such as ibuprofen and naproxen, this agent requires PA.
Leuprolide/norethindrone (Lupaneta® Pack)	Addition; **requires PA**	Leuprolide/norethindrone is FDA-approved for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Given the high cost of therapy, this agent requires PA.
Methoxsalen capsules	Addition; does not require PA	Methoxsalen capsules is the new "A"-rated generic to Oxsoralen-Ultra. This agent does not require PA.
Metreleptin (Myalept®)	Addition; **requires PA**	Metreleptin is a leptin analog approved by the FDA to treat complications of leptin deficiency, in addition to diet, in patients with congenital or acquired generalized lipodystrophy. Given its place in therapy and high cost, this agent requires PA.
Ondansetron film (Zuplenz®)	Addition; **requires PA**	Ondansetron film is indicated for the prevention of nausea and

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		vomiting associated with certain types of cancer chemotherapy and radiotherapy, as well as for postoperative nausea and/or vomiting. Due to more cost-effective alternatives available for the management of the same clinical conditions including generic ondansetron, this agent requires PA.
Oxycodone/acetaminophen extended-release (XARTEMIS® XR)	Addition; **requires PA**	Oxycodone/acetaminophen extended-release is indicated for the management of acute pain severe enough to require opioid treatment for which alternative treatment options are inadequate. Due to more cost-effective alternatives available for the management of the same clinical condition, including generic oxycodone/acetaminophen, codeine/acetaminophen, and hydrocodone/ibuprofen, this agent requires PA.
Propranolol solution (Hemangeol®)	Addition; **requires PA**	Propranolol solution is indicated for the treatment of proliferating infantile hemangioma requiring systemic therapy. Given the specific indication, this agent requires PA.
quinacrine	Deletion; no longer on MassHealth Drug List	This product has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
Ramucirumab (Cyramza®)	Addition; **requires PA**	Ramucirumab is FDA-approved for the treatment of patients with advanced or metastatic, gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy. Given the potential for off-label use, this agent requires PA.
Siltuximab (Sylvant®)	Addition; **requires PA**	Siltuximab is an interleukin-6 antagonist indicated for the treatment of patients with multicentric Castleman's disease who are human herpesvirus-8 and HIV negative. Given the cost of therapy and required monitoring parameters, this agent requires PA.
Tasimelteon (Hetlioz®)	Addition; **requires PA**	Tasimelteon is indicated for the treatment of non-24 hour sleep-wake disorder. Given the potential for off-label use, this agent requires PA.
Tinzaparin (Innohep®)	Deletion; no longer on MassHealth Drug List	This product has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
Topiramate extended-release capsule (Qudexy® XR)	Addition; **requires PA**	Topiramate extended-release capsules are FDA-approved for initial monotherapy in patients ≥ 10 years of age and as adjunctive therapy in patients ≥ 2 years of age with partial onset or primary generalized tonic-clonic seizures. It is also indicated for use as an adjunctive therapy in patients ≥ 2 years of age with seizures associated with Lennox-Gastaut syndrome. Due to more cost-effective alternatives available for the management of the same clinical conditions including generic topiramate, this agent requires PA.
Treprostinil tablet (Orenitram®)	Addition; **requires PA**	Treprostinil is indicated for the treatment of pulmonary arterial hypertension to improve exercise capacity. Due to more cost-effective alternatives available for the management of the same clinical condition including epoprostenol, this agent requires PA.

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Umeclidinium/vilanterol (ANORO ELLIPTA®)	Addition; **requires PA**	Umeclidinium/vilanterol is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease. Given the potential for off-label use, this agent requires PA.
Vedolizumab (Entyvio®)	Addition; **requires PA**	Vedolizumab is FDA-approved for the treatment of adult patients with moderately to severely active ulcerative colitis or Crohn's disease who have an inadequate response with, lost response to, or were intolerant to a tumor-necrosis factor blocker or immunomodulator, or who had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids. Due to more cost-effective alternatives available for the management of the same clinical conditions, including sulfasalazine, mesalamine, azathioprine, and 6-mercaptopurine, this agent requires PA.
Vorapaxar (ZONTIVITY®)	Addition; **requires PA**	Vorapaxar is indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease. Due to its place in therapy and availability of more cost-effective alternatives for the management of the same clinical conditions, including generic aspirin and clopidogrel, this agent requires PA.