April 2014, Volume 6, Issue 2

THE PRESCRIBER e-LETTER

Iodine Intake is Important for Both Pregnant and Nursing Women

Iodine has a crucial role in maintaining proper thyroid function, and this is particularly so in pregnant and breastfeeding women. Women who are pregnant need increased iodine intake due to physiologic changes that produce an increased demand for thyroid hormone. Women who are breastfeeding need increased iodine intake because iodine is secreted into breast milk. The need to maintain adequate levels of iodine is supported by numerous health care organizations, including the Institute of Medicine, the World Health Organization, the American Thyroid Association, the Endocrine Society, the American Association of Clinical Endocrinologists, and the Teratology Society.

Nonpregnant adults need to ingest 150 µg iodine daily. Requirements increase to 220 µg daily in pregnancy and 290 µg daily for women who are breastfeeding. In order to ensure adequate iodine intake, it is recommended that U.S. women who are pregnant or breastfeeding should take a supplement containing 150 µg iodine daily in the form of potassium iodide. A recent survey of all U.S. prescription and nonprescription prenatal vitamins noted that only 50% contained any form of iodine. Therefore, providers caring for pregnant and nursing females should discuss appropriate intake and supplementation with their patients.

Please see the following websites for a patient-oriented fact sheet from the American Thyroid Association and a provider-oriented fact sheet from the National Institutes of Health.

ods.od.nih.gov/factsheets/Iodine-HealthProfessional/

www.thyroid.org/iodine-deficiency/

Updated Opioid High-Dose Limits

As part of the continuous monitoring of drug utilization within the MassHealth population, and in light of opioid misuse concerns, the MassHealth Pharmacy Program has conducted an analysis of updated opioid utilization, as well as recent published medical literature. Although there is no one single definition of “high-dose” opioid therapy, a review of clinical studies and guidelines indicates that the highest daily dose of morphine allowed in randomized opioid trials was 240 mg/day, and the highest average dose was 120 mg/day. Given this information, MassHealth implemented lower dose limits for opioids on April 28, 2014. A link to the most current pain initiative document can be found below.

masshealthdruglist.ehs.state.ma.us/MHDL/

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The *Prescriber e-Letter* is an 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.

Hepatitis C Treatment Agents

In late 2013, two new hepatitis C virus (HCV) treatment agents received Food and Drug Administration (FDA)-approval. Olysio (simeprevir) is an oral HCV protease inhibitor, FDA-approved for the treatment of HCV infection genotype 1 as a component of a combination therapy with peginterferon alfa and ribavirin for duration of 12 weeks. Sovaldi (sofosbuvir) is an oral HCV nucleotide analog NS5B polymerase inhibitor, FDA-approved as a component of combination therapy for HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma (HCC) and human immunodeficiency virus (HIV) co-infection. The American Association for the Study of Liver Diseases treatment recommendations for HCV were updated in January 2014 to include Olysio (simeprevir) and Sovaldi (sofosbuvir). Guidelines recommend Sovaldi (sofosbuvir) combination therapy as the first-line treatment regimen for HCV genotype 1 to 6 in both treatment-naive and treatment-experienced patients.

The table to the right lists the FDA-approved indications for Sovaldi (sofosbuvir)-based HCV treatment regimens. Based on a patient's HCV genotype or co-morbid conditions, the components of therapy and the duration of therapy may vary.

	Sovaldi in combination with:	**Duration of therapy**
Genotype 1	Peginterferon alfa and Ribavirin	12 weeks
	Ribavirin	24 weeks
Genotype 2	Ribavirin	12 weeks
Genotype 3	Ribavirin	24 weeks
Genotype 4	Peginterferon alfa and Ribavirin	12 weeks
HIV	Dosing regimen based on HCV genotype	
HCC	Ribavirin	Up to 48 weeks or until liver transplant

To ensure appropriate utilization of Olysio (simeprevir) and Sovaldi (sofosbuvir), both agents have been added to MassHealth's drug list requiring prior authorization (PA). Due to the number of important updates to the treatment of HCV, a clinical information document was developed and posted on the MassHealth Drug List website to serve as a resource. This document highlights recommendations from current consensus guidelines, reviews information on direct-acting antivirals and summarizes treatment regimens for the different HCV genotypes. A link to the HCV clinical information document can be found below.

masshealthdruglist.ehs.state.ma.us/MHDL/

Recent MassHealth Drug List Updates		
Drug/Drug Class	**Addition/Deletion/Change**	**Rationale**
abacavir/lamivudine/ zidovudine	Addition; **does not require PA**	Abacavir/lamivudine/zidovudine is the new "A" rated generic to Trizivir. This agent does not require PA.
alemtuzumab (Campath)	Deletion; **removed from *MassHealth Drug List***	This product is no longer available except through the manufacturer and has been removed from the *MassHealth Drug List*.
brimonidine 0.33% topical gel	Addition; **requires PA**	Brimonidine 0.33% topical gel is indicated for the treatment of persistent facial redness of rosacea. Given that all anti-acne and rosacea products require PA for members 22 years or older, this agent requires PA.
buprenorphine (Subutex)	Deletion; **removed from *MassHealth Drug List***	The production of this product has been discontinued by the manufacturer and has been removed from the *MassHealth Drug List*.
buprenorphine/naloxone tablet (Suboxone)	Deletion; **removed from *MassHealth Drug List***	The production of this product has been discontinued by the manufacturer and has been removed from the *MassHealth Drug List*.
clonazepam orally disintegrating 0.125 mg and 0.25 mg tablets	Change in PA status; **requires PA >90 units/month**	To ensure appropriate use and dose consolidation of clonazepam 0.125 mg and 0.25 mg orally disintegrating tablets, these agents require PA if quantities > 90 units/month.
dexmethylphenidate extended-release	Addition; **requires PA if quantity > 60 units/month**	Dexmethylphenidate extended-release is the new "A" rated generic to Focalin XR. To ensure appropriate dose consolidation, when applicable, this agent requires a PA if quantities > 60 units/month.
diclofenac 18 mg, 35 mg capsule (ZORVOLEX)	Addition; **requires PA**	Diclofenac is indicated for the treatment of mild to moderate acute pain in adults. Given the availability of generic diclofenac sodium as a less-costly alternative, this agent requires PA.
diclofenac eye drops (Voltaren)	Deletion; **removed from *MassHealth Drug List***	The production of this product has been discontinued by the manufacturer and has been removed from the

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		MassHealth Drug List.
Antibiotics – Oral	Change in PA status; **does not require PA** Doxycycline monohydrate	Given the issues in availability of various strengths and formulations of doxycycline products, doxycycline monohydrate 50 mg and 100mg capsules and doxycycline monohydrate 50 mg, 75 mg, and 100 mg tablets do not require PA.
filgrastim (NEUPOGEN)	Change in PA status; **requires PA**	Given the higher cost compared to the available less-costly alternative, this agent requires PA.
fluorouracil 0.5% cream (Carac)	Change in PA status; **requires PA**	Given the higher cost versus fluorouracil solution, this agent requires PA.
gabapentin powder	Deletion; **removed from *MassHealth Drug List***	The production of this product has been discontinued by the manufacturer and has been removed from the MassHealth Drug List.
glycopyrrolate 1.5 mg tablet (Glycate)	Addition; **requires PA**	Glycopyrrolate is indicated for the adjunctive treatment of peptic ulcer disease. Given the availability of generic glycopyrrolate tablets, this agent requires PA.
isotretinoin (ABSORICA)	Addition; **requires PA**	Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older. Given that all anti-acne and rosacea products require PA for members 22 years or older, this agent requires PA.
levomilnacipran (Fetzima)	Addition; **requires PA**	Levomilnacipran is an antidepressant agent indicated for the treatment of major depressive disorder (MDD). Given the availability of less-costly alternatives, this agent requires PA.
lipase/protease/amylase 5,000 unit capsule (Zenpep delayed-release)	Addition; **does not require PA**	Lipase/protease/amylase is the new generic equivalent to Zenpep delayed-release 5,000 unit capsules. This agent does not require PA.
macitentan (Opsumit)	Addition; **requires PA**	Macitentan is an oral endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH) to delay disease progression. Given the cost of therapy, the lack of head-to-head trials demonstrating superior efficacy

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		compared to other PAH agents, and the lack of consensus guidelines addressing the potential place in therapy, this agent requires PA.
mechlorethamine (Valchor)	Addition; **does not require PA**	Mechlorethamine is a topical agent indicated for treatment of Stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) in patients who have received prior skin-directed therapy.
obinutuzumab (GAZYVA)	Addition; **requires PA**	Obinutuzumab is an intravenously infused monoclonal antibody indicated for the treatment of chronic lymphocytic leukemia (CLL) in combination with chlorambucil in patients that have not undergone previous treatments for CLL. Due to the high cost of therapy and potential for off-label use, this agent requires PA.
rabeprazole delayed-release capsule (Aciphex Sprinkle)	Addition; **requires PA**	Rabeprazole is a proton pump inhibitor FDA-approved for the treatment of heartburn, stomach ulcers, gastroesophageal reflux disease, esophagus damage, and a variety of other hypersecretory conditions. Given the availability of generic rabeprazole, this agent requires PA.
riociguat (Adempas)	Addition; **requires PA**	Riociguat is an oral soluble guanylate cyclase inhibitor indicated for the treatment of persistent/recurrent chronic thromboembolic hypertension and PAH. Due to the high cost of therapy, the lack of head-to-head studies indicating that Adempas has greater clinical efficacy compared to other PAH agents and lack of guideline recommendations outlining the place in therapy, this agent requires PA.
simeprevir (Olysio)	Addition; **requires PA**	Simeprevir is an oral HCV protease inhibitor indicated for the treatment of chronic HCV genotype 1 infection. To ensure appropriate utilization and optimal duration of therapy, this agent requires PA.
sofosbuvir (Sovaldi)	Addition; **requires PA**	Sofosbuvir is an oral HCV nucleotide analog NS5B polymerase inhibitor indicated for the treatment of HCV genotype 1, 2, 3, or 4 infections, including those with HCC awaiting a liver transplant, and those with HCV/HIV co-infection. To ensure appropriate

		utilization and optimal duration of therapy, this agent requires PA.
sulindac (Clinoril)	Deletion; **removed from MassHealth Drug List**	The production of this product has been discontinued by the manufacturer and has been removed from the MassHealth Drug List.
TBO-filgrastim (GRANIX)	Addition; **does not require PA**	Granix is a leukocyte growth factor indicated for reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. This agent does not require PA.
tobramycin inhalation solution	Addition; **requires PA**	Tobramycin inhalation solution is the new "A" rated generic to TOBI. This agent does not require PA.
tobramycin inhalation solution (BETHKIS)	Addition; **requires PA**	BETHKIS is an inhaled aminoglycoside antibacterial agent indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. Given the availability of a generic tobramycin inhalation solution formulation, this agent will require PA.
tobramycin inhalation powder (TOBI Podhaler)	Change in PA status; **requires PA**	TOBI Podhaler is an inhaled aminoglycoside antibacterial agent indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. Given the availability of a generic tobramycin inhalation solution formulation, this agent will require PA.
vincristine liposome (Marqibo)	Addition; **requires PA**	Vincristine liposome is indicated for the treatment of Philadelphia chromosome-negative acute lymphoblastic leukemia in patients with two or more prior relapses or whose disease has progressed following two or more anti-leukemia therapies. Given the high cost of this agent and the availability of less-costly alternatives, this agent requires PA.
vortioxetine (Brintellix)	Addition; **requires PA**	Vortioxetine is indicated for the treatment of MDD. Given the availability of less-costly alternatives, this agent requires PA.

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