MaineCare Services
An Office of the Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner

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TO: Maine Drug Utilization Review Board
DATE: November 18th, 2014
RE: Maine DUR Board **Meeting** minutes from November 18th, 2014

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Robert Weiss, M.D., Cardiologist, Chair			X
Amy Enos, Pharm. D. Waltz LTC Pharmacy	X		
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Lindsey Tweed, M.D., Psychiatrist	X		
Mark Braun, M.D., FACP, Internist/Geriatrician			X
Mike Ouellette, R.Ph., GHS	X		
Linda Glass, M.D.			X
Non –Voting			
Jan Yorks-Wright, Pharmacy Supervisor, OMS	X		
Kevin Flanigan, M.D., Internist, Medical Director, OMS			X
Roger Bondeson, Director of Operations, OMS	X		

Guests of the Board: Jeffrey S. Barkin MD, DFAPA, Ed Bosshart, PharmD, Renee Hall

CALL TO ORDER: 6PM

PUBLIC COMMENTS

Paul with VIIV Healthcare here to present Triumeq. Triumeq is the newest single tablet regimen that contains abacavir, dolutegravir and lamivudine. It is indicated for once a day for treatment naïve as well as for patient's treatment experienced as a single regiment or add on regiment. It is on the recommended DHHS guidelines for treatment of the HIV patients. It has no restrictions on viral load, CDC cell count, it can be taken with or without food and can be taken at any time during the day. There have been 4 head to head clinical trials using Triumeq verses other DHHS recommended guideline regimens. 3 out of the 4 head to head trials showed the Triumeq arm statistically superior to the comparator arm. In the 3 treatment naïve trials there were no treatment emergent mutations to any of the component of Triumeq. It is well tolerated, the dropout rates in the trial due to adverse events were somewhere between 2%- 4%. There is a Box warning for Patients who carry the HLA-B*5701 allele is at high risk for experiencing a hypersensitivity reaction to abacavir. Abacavir is a drug that has been

around for a long time and most providers are already aware of this warning. Today single tablet regimen is the standard of care for treatment naïve patients unless there is a compelling reason not to because adherence is a **must** there are significant dire consequences to partial adherence. Paul provided to the board three clinical articles that support single tablet regimen as the standard of care. With that please consider allowing Triumeq a preferred status on the PDL.

Mr. Ouellette asked if any of these studies sponsored by the manufacturer.

Paul answered not by VIIV one of the studies provider is completing independent the other two were supported by Gilead.

Dr. Barkin stated that what the board has to contend with is the cost difference between the once a day or twice daily. In the head to head trials how were the drop outs handled.

Paul answered that when we look at HIV trials we look at a snapshot analysis. If you change regimens for whatever reason those are counted as a failure.

Dr. Barkin stated that design tells us that it was only counted if they finished the trial since dropouts were counted as failures.

OLD BUSINESS

DUR MINUTES

The October 14th, 2014 minutes were approved.

NEW BUSINESS

HARVONI

Dr. Barkin stated that Harvoni**:** For the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults. This is a pregnancy category B medication. The safety and efficacy of use in children have not been established. Take one tablet QD with or without food. The duration of treatment: Use of Harvoni® for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pre-treatment Hepatitis C virus (HCV) RNA <6million IU/ml. To assess the safety and efficacy of Harvoni®, there were three Phase 3 trials performed, with sustained virologic response (SVR) as the primary endpoint. The most frequently reported adverse events included fatigue (13%), headache, <1% permanently discontinued treatment due to an adverse event. It is recommended that this be placed on the non preferred side of the PDL. Also included in the packets was a draft Sovaldi/Harvoni PA form. The grid on the first page allows the prescriber to easily check off what Genotype the patient is. The most interesting part of the form for discussion is the section on abstinence for alcohol and abuse of drugs for 6 months.

Mr. Ouellette stated that looking at what some of the other states are doing with this drug we are seeing a wide range. Some states are requiring no abstinence, some 3 months, and some 6 months with the

consensus leaning more towards 6 months. The draft PA form that we have provided stated 6 months and we would require some sort of drug screen along with the PA to show that they are no longer using the patient's drug of choice. It will be interesting to see what the guidelines end up saying.

Dr. Tweed asked if abuse of drugs would include marijuana.

Mr. Ouellette answered that he believed that they are concerned that we would have IV drug use.

Dr. Barkin add that one of his main concerns is with re-infection. So anything that you can do to educate prevention of transmission to eliminate other risk factors drugs and alcohol.

Dr. Tweed suggested clarifying to say abuse of IV drugs that way to be clear that our main concern isn't with for example marijuana.

Dr. Barkin stated that it is better to include all abuse of drugs and in all of the other PA form this is what we put rather than being so specific.

Dr. Tweed asked if we know how many prescribers there are.

Dr. Barkin answered it is mostly the virologist but this drug will be prescribed by primary care providers as well as gastroenterologists.

Dr. Tweed stated that then the prescribers are expanding.

Mr. Ouellette asked the Drug Rep/Pharmacist in the audience what he has been seeing.

Drug Rep/Pharmacist stated that the majority of states are limiting it to being prescribed by a specialist either hepatologists, gastroenterologist or an infectious disease.

Dr. Barkin added that the PCP may take over after the initial consultation of the specialist.

Drug Rep/Pharmacist responded that given the short amount of time of these new regimens there is no reason that the specialist shouldn't be managing the patients during that time.

Mr. Ouellette asked what is being seen in other states are far as abstinence.

Apothecary by Design stated that they have seen many of the chart notes and see that the patient may have a glass of wine once every 6 months and the providers are aware of this but if you are looking for total abstinence they aren't seeing that.

Dr. Tweed stated that he now agrees with stating abstinence from abuse of drugs but maybe we need to reword the section on alcohol

Dr. Barkin, Mr. Ouellette and Dr. Tweed clarified it to say instead of abstinence it could say "abuse from alcohol and abuse of drugs for 6 months"

SYNAGIS (RSV- PREVENTION)

Mr. Ouellette stated that provided within the board's packet a copy of the final Synagis PA form. Dr. Biczak and Dr. Glass worked together to add the second bullet "Infants who are 12 months of age or

younger, born prior to 35 weeks, 0 days AND who required intensive pulmonary services during the neonatal period AND continue to require chronic medication therapy for their neonatal based pulmonary issues". This was added to be able to capture children that don't fit the above bullet but was not to capture children that only have asthma. The other changes to the form are the dates of accepting PA and the RSV season which we are constantly monitoring.

PRO- DUR DATA REVIEW

Mr. Ouellette stated that this is mostly just an informational update for the board. Every year GHS and the state work on a CMS report of the DUR actives. Included in the packets is a sample of one of the reports that we compile. As you look through it you will see some of the alerts that we send back to the pharmacies whether is drug to drug, high dose, duplicate therapy or another intervention that we have put into place. We are reviewing this report and looking into some of these alerts that are coming back.

PCM PROGRAM

Mr. Ouellette stated that this topic wasn't on the agenda but we were asked by the state to give an update at today's meeting. For those of you not aware, we have a pharmacist that monitors patient's fills, pharmacy billing and adherence. Currently we have reached out to 650 patient as well as the pharmacy and provider. Last quarter we avoided an unnecessary spend of over 400,000. Most of that came from guiding providers to more cost effective treatments in MS and Hep C categories. Also, PCM is working with the pharmacies to return unused medications.

Dr. Tweed asked how much does it cost to run the program.

Mr. Ouellette answered that currently we have one pharmacist that primarily runs PCM.

Dr. Barkin stated that not only do we look at cost abatement but we look at compliance as well as looking at what this is doing with other medical spending. As you will see on page 4 of the report, there is an aggregate medical spend update looking at total spend for all medical services, total hospital admissions, total spend for hospital admissions(in-patient) and total ER visit 3 months pre and post enrollment to PCM. We have seen a decrease in all these and although we can't say for sure that this program caused this we can say that there is a high likelihood that the program is associated with this drop. More to follow because this is based off of real time data.

Mr. Bondeson added that based off of last year's contract value the state got back 3 times the value just in the cost abatement, not even taking looking at the medical spend. From the state's perspective the program is working very well.

Ms. Wendler asked what the criteria is for the enrollment.

Mr. Ouellette answered that it varies, one way is that we get a weekly report of new starts on high cost drugs and we do an initial review of the patients profile and to see if the patient should be enrolled. We also look at different classes of medication, most recently Hep C new high cost drugs. But not only do we look at high cost, but also medications that we see errors in prescribing, either doses that aren't supported or frequency of dosing.

Dr. Tweed asked how the cost avoidance measured.

Dr. Barkin answered that one way is a time waiting technique. For example if a treatment should last 6 months either by FDA or by average utilization and let's say the patient only takes one month of the medication because of a PCM intervention we then claim the 5 months that they did not take the medication as cost avoidance.

NEW DRUG CRITERIA

Aptiom used for adjunctive treatment of partial-onset seizures

- PDL category Anticonvulsants
- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications
- Not being used as monotherapy
- DDIs

Cerdelga use for Long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

- PDL category Gaucher Disease
- The indicated diagnosis supported by documentation from the patient's medical records
- Results from CYP2D6 genotype testing
- Dosing limits
- DDIs

Entyvio use for *Treatment of adult ulcerative colitis (UC)* for inducing and maintaining clinical response, inducing and maintaining clinical remission, improving the endoscopic appearance of the mucosa, and achieving corticosteroid-free remission: In adults with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids. *Treatment of adult Crohn's disease* for achieving clinical response, achieving clinical remission, and achieving corticosteroid-free remission: In adults with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids

- PDL category Rheumatoid Arthritis

  The board questioned if this should be listed in this category Mr. Ouellette stated that he will review the category and see if it can be broken up the issue is so many of these medications have multiple indications.
- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications, including TNF blockers and immunomodulators or corticosteroids (Update PA form)
- DDIs

Grastek use for Immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens and is not indicated for immediate relief of allergic symptoms.

- The indicated diagnosis supported by documentation from the patient's medical records, along with allergy testing results
- Prior trials/failures of preferred medications for allergic rhinitis and clinical justification for using/not using subcutaneous immunotherapy (SCIT)
- First dose given in healthcare setting
- Received auto-injectable epinephrine
- Age limitations
- Therapy must start 12 weeks prior to the start of grass pollen season

Hetlioz used for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)

- FDA approved use for appropriate diagnosis as evidence by a sleep study
- Sleep medicine consultation and a MLST
- Trial of Melatonin

Invokamet FDA uses adjunct to diet and exercise to improve glycemic control in adults with type 2 DM who are not adequately controlled on a regimen containing metformin or canagliflozin, or in patients who are already treated with both metformin and canagliflozin. Not recommended in those with type 1 DM or for the treatment of diabetic ketoacidosis

- The indicated diagnosis supported by documentation from the patient's medical records
- Prior trials of preferred medications from other diabetic classes
- Monitor for DDIs and need for increased dose
- Age limits

Jardiance FDA uses adjunct to diet and exercise to improve glycemic control in adults with type 2 DM and not recommended for those with type 1 DM or for treatment of diabetic ketoacidosis.

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications from other diabetic classes
- Age limits

Jublia FDA approved uses are for topical treatment of noychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes.*

- The indicated diagnosis supported by documentation from the patient's medical records
- Documentation of positive KOH results
- Previous trials/failure of multiple preferred medications (including oral dosage forms)

Luzu is used for the Topical treatment of inter-digital tinea pedis, tinea cruris, and tinea corporis caused by organisms *Trichophyton rubrum* and *Epidermophyton floccosum.*

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications

Northera is used for the Treatment of orthostatic dizziness, lightheadedness, or the 'feeling that you are about to black out' in adults with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Efficacy beyond 2 weeks of treatment not established.

- The indicated diagnosis supported by documentation from the patient's medical records
- Prior trials of preferred medications
- Approvals based on two weeks of treatment

Orenitram is used for the treatment of pulmonary arterial hypertension (PAH, WHO Group 1) to improve exercise capacity; established effectiveness included mostly patients with WHO functional class II-III symptoms.

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications
- DDIs

Otezla is used for the Treatment of adults with active psoriatic arthritis and the new indication of moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications (Update Psoriasis-Biologicals PA form)
- DDIs

Ragwitek used for Immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen. Not indicated for immediate relief of allergic symptoms.

- The indicated diagnosis supported by documentation from the patient's medical records, along with allergy testing results
- Prior trials/failures of preferred medications for allergic rhinitis and clinical justification for using/not using subcutaneous immunotherapy (SCIT)
- First dose given in healthcare setting
- Received auto-injectable epinephrine
- Age limitations
- Therapy must start 12 weeks prior to ragweed pollen season

Sitavig is used for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications

Sivextro is used for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), and *Enterococcus faecalis.* To reduce development of drug-resistant bacteria and maintain the effectiveness of Sivextro® and other antibacterial agents, Sivextro® should only be used to treat ABSSSI that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

- The indicated diagnosis supported by documentation from the patient's medical records

- Previous trials/failure of preferred medications (Update PA form)

Striverdi Respimat is used for long-term, maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Not indicated to treat acute deteriorations of COPD. Not indicated to treatment asthma.

- The indicated diagnosis supported by documentation from the patient's medical records
- Prior trials/failures of preferred medications, including preferred agents from other PDL categories (e.g. Spiriva®)

Tanzeum is used in adjunct to diet and exercise to improve glycemic control in adults with type 2 DM. Not recommended as first-line therapy for those inadequately controlled on diet and exercise. Not indicated for treatment of type 1 DM or for treatment of patients with diabetic ketoacidosis; it is not a substitute for insulin in these patients. Not studied in the following and as such other anti-diabetic therapy should be considered: patients with a history of pancreatitis or patients with pre-existing severe GI disease including severe gastroparesis. Has not been studied in combination with prandial insulin.

- The indicated diagnosis supported by documentation from the patient's medical records, including lab HbA1c results

    The Board asked why A1c lab results are not required in the other diabetic mediations being discussed.

    Mr. Ouellette answered that it can be added to those drugs as well

- Previous trials/failure of multiple preferred medications (Update PA form)
- Dosing limitations

Triumeq is used for the Treatment of HIV-1 infection. Use alone is not recommended in patients with current or past history of resistance to any components of Triumeq®. Use alone is not recommended in patients with resistance-associated integrase substitutions or clinically suspected integrase strand transfer inhibitor resistance because the dose of dolutegravir in Triumeq® is insufficient in these sub-populations.

- The indicated diagnosis supported by documentation from the patient's medical records, including testing of HLA-B*5701 allele testing
- Prior trials of multiple preferred medications
- DDI monitoring (including dofetilide) and use of additional dolutegravir tablet when needed

Vogelxo is used for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone including primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). *Primary hypogonadism*: testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals; these men usually have low serum testosterone levels and gonadotropins above the normal range. *Hypogonadotropic hypogonadism*: idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation; these men have low testosterone levels but have gonadotropins in the normal or low range.

- The indicated diagnosis supported by documentation from the patient's medical records

- Previous trials/failure of multiple preferred medications, including preferred topical testosterone gels

Xartemis ER is used for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate. Due to the risks of addiction, abuse, misuse, overdose, and death with opioids, even at recommended doses, Xartemis® XR should be reserved for use in patients for whom alternative treatment options (e.g. non-opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications

Zonitivity is used for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). Has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization.

- The indicated diagnosis supported by documentation from the patient's medical records
- Verify not being used as monotherapy
- Previous trials/failure of multiple preferred medications
- Monitor for DDIs

Zydelig is used for the Treatment of patients with: 1.) Relapsed chronic lymphocytic leukemia (CLL) in combination with rituximab for whom rituximab alone would be considered appropriate therapy due to other co-morbidities; 2.) Relapsed follicular B-cell non-Hodgkin lymphoma (FL) who received at least 2 prior systemic therapies; 3.) Relapsed small lymphocytic lymphoma (SLL) who have received at least 2 prior systemic therapies. Accelerated approval was granted for FL and SLL based on overall response rate (ORR); however, an improvement in patient survival or disease related symptoms have not been established. Continued approval for these 2 indications may be contingent upon verification of clinical benefit in confirmatory trials.

- The indicated diagnosis supported by documentation from the patient's medical records
- Prior trials/failures of at least 2 systemic therapies
- DDIs

Zykadia is used for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed or are intolerant to crizotinib. Indication approved under accelerated FDA approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

- The indicated diagnosis supported by documentation from the patient's medical records
- Verify for prior crizotinib therapy
- Monitor for DDIs

ADJOURNMENT: 6PM

The next meeting will be held on **February 10, 2015** 6:00p.m. – 8:00p.m at the Augusta Armory.