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 12, 2015
RE: Maine DUR Board **Meeting** minutes from November 10, 2015

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Linda Glass, MD			X
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Mark Braun, M.D., FACP, Internist/Geriatrician	X		
Mike Antoniello, MD	X		
Mike Ouellette, R.Ph., GHS	X		
Jeffrey S. Barkin MD, DFAPA	X		
Non –Voting			
Jan Yorks-Wright, Pharmacy Supervisor, OMS	X		
Roger Bondeson, Director of Operations, OMS			X

Guests of the Board: Elizabeth Clark, Sanjay Gupta, MD., Jacquelyn Hedlund, MD., Lacey Solloway

CALL TO ORDER: 6:10PM

PUBLIC COMMENTS

Tim Burner from Alkermes presented Aristata® Inj. Aristata® is an extended release injectable of atypical antipsychotic indicated for the treatment of schizophrenia. Efficacy of Aristata® is based on data from a 12 week randomized, double blinded, placebo controlled trial which resulted in the improvement of symptoms which were statistically significant and clinically meaningful as measured by PANSS score and CGI scores. Aristata® offers patients with a prefilled syringe that does not required refrigeration. Benefits of Aristata®, a prodrug of aripiprazole, include a long dosing interval and multiple dosing options. Depending on individual patient's needs, treatment with ARISTADA can be initiated at a dose of 441 mg, 662 mg or 882 mg administered monthly, which corresponds to 300 mg, 450 mg and 600 mg of aripiprazole, respectively. Treatment may also be initiated with the 882 mg dose every 6 weeks.
Dr. Barkin asked how Abilify Maintena® inj differs from Aristata® inj.

Mr. Burner, R.Ph, responded that Aristata® is a prodrug of apiprazole and the pharmacokinetic profile allows there to be a longer dosing window with a more flexible dosing schedule. Aristata® is available as three prefilled syringe strengths as compared to Abilify Maintena® inj.

Jim McKay from Sandoz presented Zarxio®. Zarxio® is a recombinant colony stimulating factor and the first FDA approved biosimilar product. Zarxio® is biosimilar to Neupogen®(filgrastim) and is approved for the same 5 indications of Neupogen®; Zarxio® has identical dosing schedule and route of administration as Neupogen®. A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products. Zarxio® structure and functional pharmacokinetic and pharmacodynamic profile as well as clinical safety and efficacy were studied in patients with breast cancer. Immunogenicity was also compared to Neupogen® and showed they had similar dose dependent pharmacokinetic and pharmacodynamic profile.

DUR MINUTES

The October 2015 minutes were approved.

PSYCH WORK GROUP UPDATE

Dr. Barkin stated that the psych work group met last week. Maine Care initiatives that had been made over the last 7 years have increased monitoring for metabolic status of atypical antipsychotics; the monitoring rate for metabolic status is now 45% compared to 5% before initiatives were in place. They will re meet in February. No other update at this time.

OLD BUSINESS

ADDITIONAL VOTING FOR JANUARY 2015 PDL

ANTIVIRALS, HEPATITIS AGENTS	**DAKLINZA TAB**	**NP**		**All in favor**	
	HARVONI TAB	**P**	***Clinical PA***		
	RIBAPAK	**NP**			
	RIBASPHERE TAB	**P**			
	SOVALDI TAB	**P**	***Clinical PA***		
	TECHNIVIE TAB	**P**	***Clinical PA***		
	VIEKIRA PAK	**P**	***Clinical PA***		
BIOLOGIC IMMUNOMODULATORS	COSENTYX	P		All in favor	Cosentyx- Preferred position with Step Edit allowing trial and failure of one preferred agent
	ENBREL INJ	P			
	HUMIRA CROHN	P			
	STARTER PK	P			
	HUMIRA KIT	P			
	HUMIRA PEN	P			
	SIMPONI INJ	NP			

	STELARA INJ XELJANZ TAB	NP

Board Decision: The Board unanimously approved all the above recommendation.

MAINECARE UPDATE

No updates at this time.

NEW BUSINESS

HEPATITIS C PA FORM

Mr. Ouellette presented the updated Hep C PA from. Dr. Biczak and GHS have diligently worked on this PA form. There are no changes in documentation; however, there have been regimens that have been updated or added to the PA form.

Dr. Wendler states that the PA form makes patients with Genotype 3 often refuse to attempt treatment because they must fail interferon in order to qualify for another treatment regimen. Patients and prescribers are fearful of interferon use in patients suffering from PTSD.

Dr. Barkin stated that IFN ineligible patients are those with severe depression.

Mr. Ouellette stated that the PCM pharmacist is in touch with both Maine Med and pharmacies and hasn't seen patients being denied regimens.

Board Decision: No action required

PSCK 9 INIHIBITORS CRITERIA AND PA FORM

Dr. Barkin presented the PA form and criteria form for PSCK 9 inhibitor. Dr. Biczak and GHS have diligently worked on this PA form. The updated PA form shows a clear separation of the indications for use. The new form breaks it down by indication and the form makes it very clear on what the PA requirements are.

Dr. Mike Antoniello stated that tobacco abstinence should be a required as a requirement for patients with ASCVD. Patients with familial hypercholesterolemia would gain the greatest benefit of PSCK 9 inhibitors because lowering cholesterol would lower their risk for a cardiovascular event significantly. PSCK 9 inhibitors in patients with ASCVD may provide less benefit it multiple other risk factors are not controlled; tobacco abstinence should be required in this subset of patients. The recommendation to add documentation of tobacco abstinence for the previous 90 days for ASCVD patients who previously smoked in the last 5 years was made by a cotinine test or by chart notes provided by the prescribing physician.

Dr. Wendler states concern that overuse potential for patients who are hypersensitive to statin without clear guidelines hypersensitivity in place.

Dr. Barkin states there are other payers that use lab values and duration of muscle ache to determine an absolute contraindication to statins. The recommendation is to include this documentation for statin-ineligible patients.

Dr. Mark Braun states specific lab testing to show intolerance to a statin may be too rigid. The recommendation was made to have a lipidologist who is specialized in familial hypercholesterolemia review the PA form and Criteria sheet.

Board Decision: The Board unanimously approved the recommendation to make tobacco abstinence for 90 days a requirement for patients with ASCVD. One member of the board was not in favor of criteria for labs showing contraindication to statin. GHS will bring back criteria regarding specific lab testing to show an intolerance of statin as well as to bring back feedback from lipidologists to the **February** meeting.

RETRO DUR- **ANALYSIS OF APPROPRIATE TESTOSTERONE USE**

Dr. Barkin presented a Retro DUR initiative on the appropriateness of use of testosterone replacement therapy. Often testosterone is used in healthy middle-aged men for vague complaints such as fatigue when use should be reserved for patients with low testosterone levels. Documentation of low testosterone at baseline as well as a follow up level after 3 – 4 months of treatment is recommended. GHS reviewed Maine paid non-reversed pharmacy claims with dates of service from 7/1/2014 through 6/30/2015 for any of the following medications: Testosterone cypionate and propionate and combinations, fluoxymesterone, methyltestosterone, testosterone and testosterone enanthate, and undecanoate.

Testosterone testing is strongly recommended prior to initiating testosterone therapy and 38% of members who started testosterone therapy lacked a claim for this testing in their profile in the preceding year. Also noteworthy that 1 in 5 members starting and remaining on testosterone therapy for at least 4 months had no testosterone level present in claims data in the year prior to or the four months after therapy was started.

It is important to recognize that claims data has some inherent limitations. Claims data only includes claims that have been paid by Maine Medicaid and that included the information or codes that we have searched for. There are sometimes panels of tests that may include the necessary information but cannot easily be recognized (custom panels by commercial labs).

Recommendations: The recommendation is to perform a chart review of a randomized sample of patient records by first focusing on prescribers who are most often prescribing testosterone replacement therapy. Results will be reported early next year.

NEW DRUG REVIEWS

Aristada® the common name is aripiprazole lauroxil in the PDL category Antipsychotics- Atypical. Aristada® was previously presented by Tim Burner of Alkermes.

Recommendation: The recommendation is for Aristata® to be non-preferred.

Odomzo® the common name is sonidegib in the PDL category cancer. Odomzo® is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy. The effects of Odomzo® on cardiovascular morbidity and mortality have not been determined.

Recommendation: The recommendation is for Odomzo® to be non-preferred.

Synjardy® the common name is empagliflozin/metformin in the PDL category SGLT 2 inhibitor combination. Synjardy® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled.

Recommendation: The recommendation is for Synjardy® to be non-preferred.

Zarxio® the common name is filgrastim-sndz in the PDL category granulocyte CSF. Zarxio® was presented by Jim McKay from Sandoz earlier in the meeting.

Recommendation: The recommendation is for Zarxio® to be non-preferred.

Zecuity Patch® the common name is sumatriptan succinate in the PDL category Migraine-selective serotonin agonists (5HT) transdermal. Zecuity Patch® is indicated for the acute treatment of migraine with or without aura in adults. Zecuity® is an iontophoretic transdermal system that delivers 6.5 mg of sumatriptan over 4 hours.

Recommendation: The recommendation is for Zecuity Patch® to be non-preferred.

Board Decision: The Board unanimously approved all the above recommendation.

FDA SAFETY ALERTS

Invokana and Invokamet (canagliflozin): Drug Safety Communication - New Information on Bone Fracture Risk and Decreased Bone Mineral Density

Safe medicine disposal options

Acetaminophen Tablets by Medline Industries: Recall - Mislabeling with Incorrect Strength

FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie

FDA Drug Safety Communication: FDA requires drug interaction studies with potassium-lowering drug Kayexalate (sodium polystyrene sulfonate)

FDA Drug Safety Communication: FDA review found no increased cardiovascular risks with Parkinson's disease drug entacapone

FDA Drug Safety Communication: FDA cautions about dose confusion and medication error with antibacterial drug Avycaz (ceftazidime and avibactam)

FDA Drug Safety Communication: FDA evaluating the risks of using the pain medicine tramadol in children aged 17 and younger

Auvi-Q (epinephrine injection, USP): Recall - Potential Inaccurate Dosage Delivery

Board Decision: No action required

ADJOURNMENT: 8:20PM

The next meeting will be held on **January 12, 2016** 6:00p.m. – 8:00p.m at the Augusta Armory.