September 15th 2017 Drug Utilization Review Committee

Members Present	**Non-Members Present**
Dr. Bob Carlson, MD	John McCall, RPh (Magellan)
Dr. Jenna Hiestand, MD	
Erin Narus, Pharm D (DHSS)	
Dr. Barb Piromalli, DO	
Ryan Ruggles, Pharm D	
Chuck Semling, Pharm D	

Introduction

Erin Narus introduced new members to the Committee, Dr. Barb Piromalli, DO, Dr. Jenna Hiestand, MD. Erin Narus gave a brief overview of the Drug Utilization Review Committee. The committee uses aggregate data. The committee uses Robert's Rules of order. The meeting is more conversational and less formal than the P&T meeting. Meeting agendas are posted 30 days in advance. Once discussion is concluded on a topic a motion is expected followed by a second, then a call to question and vote, yay, nay, or abstain. Any topic that comes up and a member has a financial interests in that topic the member should exclude himself or herself from discussion or voting. Erin Narus introduced John McCall a non-voting member in the DUR committee. His presence is for clinical support. Minutes from the last DUR meeting will be emailed to members.

New Criteria for Hepatitis C was proposed

John McCall gave a brief review of Hepatitis C and of Direct Acting Antivirals.

Erin Narus commented that discussion of Hepatitis C has been a focus of the DUR committee for a long time. In April the committee discussed a patient readiness model versus a urine screen and review. Erin introduced the two pangenotypic medications for initial treatment of Hepatitis C, Epclusa and Mavyret. Erin asserted that cost-effectiveness is an important factor in choosing Hepatitis C criteria. Evidence based literature is used to guide decisions for prioritizing patients most at risk for developing near term complications while providing as much access as possible. The American Association for the study of Liver Disease, ASLD, the European Association for the Study of Liver Disease (EASL) were evidence based guidelines that gave a framework for prioritizing treatment to those patients who need it the most. The Medicaid program is responsible for assuring the breadth of services to all Medicaid patients. In creating criteria the program has relied on the use of clinical literature, as well as colleagues that are liver specialist to identify those patients most at risk for progression to liver disease.

Today, there is a significant change in the cost of medications. The proposed criteria for DUR review was posted early for public review and public comment. This provided feedback that we will review today.

Erin Narus displayed a graph. Right now there are two pangenotypic products that are FDA approved for initial treatment, Epclusa and Mavyret. Epclusa costs $75,000 per treatment for a 12 week course of therapy.

Mavyret has different lengths of treatments. For Genotypes 1-6, those patients naïve to treatment an 8 week course can be the initial treatment. In general if Mavyret was the drug used in a population of Hepatitis C patients, based on recollection from information presented in the P&T meeting 80% of those patients would receive an 8 week treatment, 15% would receive a 12 week treatment, and 5% would receive a 16 week treatment.

The Medicaid budget is fixed and has to stay within what is appropriated. Medicaid pays an ingredient cost and professional dispensing fee. The two together makeup the pharmacy reimbursement. A medication that cost $75,000 for a 3 consecutive month treatment is $25,000 per month. Erin graphed out a comparison of 10 patients per day receiving treatment for hepatitis C, over 180 days to produce a graphic representation of the difference between Mavyret and Epclusa. The graph does not take into account cost after rebates. However rebates are paid after pharmacies are reimbursed.

Approximately 7500-10,000 people in Alaska may be infected with hepatitis C and if we assume 50% of those patients are covered by Medicaid which equals 3700 people treated in a year 12 weeks of Epclusa would cost an initial payout of $107 million to pharmacies. Mavyret payout would cost $55 million if all patients received a 12 week course. If all patients receive an 8 week course of Mavyret the payout cost would be $39 million.

Medicaid would like to propose Mavyret as the preferred product to allow individuals without manifestations of disease to receive the treatment. This year Alaska Medicaid treated approximately 200 patients. With the new criteria the state could treat closer to 800-900 patients. Treating more patients with the less costly regimen could overall be more costly, but there is public benefit.

Ryan Ruggles asked about the effect of rebates on cost and if that was considered. Erin Narus commented that there is a 6 month payment delay between Medicaid reimbursement to the pharmacy and receiving the rebate. On a budget, this makes the initial cost to reimburse pharmacies crucial. Erin also reminded the committee that rebates are protected information, but the state office did consider the effect of rebates before presenting the proposal.

Ryan Ruggles asked why broaden availability now beyond F2-F4 versus in the future? Erin said that the question is valid.

Erin then presented the proposed Criteria for Direct Acting Antivirals for Hepatitis C.

Erin stated that viral resistance is a reality that has developed with the DAAs. She pointed out that we are just 4 years into treatment with DAAs and already we need a salvage therapy. We have windows of opportunity to treat more patients, by treating more patients early we can bend the curve and decrease the overall population burden.

As the document was reviewed she pointed out the continued need to document genotype and hepatic status as well as the viral load. Mavyret is only indicated for 18 years old and over. For 12 to 18 years old Medicaid will authorize the FDA approved product.

The criteria is moving towards readiness assessment versus a urine screen. The committee is open to allow prescribers to use individual tools they have developed. A prescriber has to be able to demonstrate patient readiness and the patient must agree to complete the regimen. HCV RNA levels will be obtained 12 weeks after treatment. The HCV/HIV co-infected phrase needs to be included, as regimen changes for HIV could impact treatment. There is a general broad statement about testing for polymorphisms.
The renewal requirement in the document for treatments with a duration longer than 16 weeks will be rarely used due to shorter treatment regimens currently available.

In the criteria Mavyret was chosen as preferred because of cost modeling and evidence. In patient populations where Mavyret is not FDA approved prior authorization will be based on FDA approved treatments. If an individual is unable to use Mavyret the second step treatment would be Zepatier for GT1 and GT4, polymorphism testing would be required. If an individual is unable to use Mavyret the second step treatment would be Epclusa for GT2 and GT3.

The criteria for Hepatitis was posted on the website. The criteria was also faxed to prescribers.

Erin Narus pointed to the final portion of the document labeled Regulatory Authority. She reiterated the DUR committee's authority and responsibility in compliance with federal and state regulations to choose clinical criteria in a manner to assure medical necessity and financial solvency of the program.

Dr. Jenna Hiestand, MD asked about the definition of referral for treatment for active substance dependency in the criteria for denial section. What is considered treatment for active substance dependency? Erin Narus responded that it is up to the committee and said that this is a great segue into why now is a good time to treat sooner. Individuals with substance abuse disorder have a higher prevalence of Hepatitis C. Being able to treat people at an earlier stage of hepatitis C provides other opportunities to treat other issues like substance dependence.

One referral option for these patients is the Alaska Medicaid Coordinated Care Initiative (AMCCI). These care managers would help individuals get connected and help them stay in the system. Dr Hiestand pointed out that availability of treatment is limited in certain locations. Ryan Ruggles stated the statement should be vague, so MD can choose the treatment.

Erin Narus stated that historically the state has been fairly open in approving. Retrospective review is next monitoring step. The goal is to guide good care that encourages treatment that is not overly restrictive or punitive. Retrospective drug review can be used to monitor the effect of the program and Hep C approvals and denials would be seen by Erin Narus. Dr Bob Carlson commented that whatever criteria you use, if recidivism is high it should be looked at carefully. How many patients are opiate free? Monitor what you are doing and adjust.

Chuck Semling, asked if treatment should be expanded now versus later. Erin responded preferring Mavyret allows us to treat 3 people for each one. John McCall stated that many other states moved to F0 even before these agents came along. Dr Hiestand stated that from a public health perspective let's begin now.

Ryan Ruggles, Pharm D moved to accept and Dr. Jenna Hiestand, MD seconded.

Erin Narus said we should delay voting until after public comment is reviewed.

Letters Received from the Public

The proposed criteria for Hepatitis C was posted September 1st. If there are no substantive changes to the criteria it could be put into effect October 1st. If the committee decides to change then the criteria would go into effect 30 days from the change.

A letter was reviewed from Lisa Townsend ANHTC. She was glad to see that there were no longer restrictions related to the fibrosis score but still wants to see screening for it. Recommends seeking a consultation with a liver specialist if a patient is positive for Hepatitis B. She asked about contraception changes with Mavyret in patients taking oral contraceptives containing estrogen?

Committee reviewed contraception question. The drug representative for Mavyret pointed out to the committee that it is not that birth control will not work. It may cause ALT elevations. Pointed directly towards information in Package Insert.

Dr McMann from the Hepatitis Advisory Work Group commented in his letter that this is good news, no restriction based on Fibrosis.

Hope McGragy sent a letter and asked when will Mavyret be reviewed? The pricing is encouraging. This is a good option for dialysis patients.

Dr Steven Ingle representing the Internal Medicine Associates expressed concern about removing Harvoni as preferred and switching to what they considered as inferior products compared to Epclusa and Harvoni. They were concerned about impact on quality of care and decreased cure rates in complex patients. According to the letter in their clinic they have seen cure rates nearing 100% using Epclusa and Harvoni.

The committee discussed the public comments and recommendations. The committee reviewed the cure rates from the clinical trials related to Mavyret.

The committee decided to accept with no changes the proposed Hepatitis C criteria. The motion was made by Ryan Ruggles, Pharm D and was seconded by Dr. Jenna Hiestand, MD.

Opioid Initiative

The American Society of State and territorial officials identified strategic initiatives. One was requiring diagnoses on opioid prescriptions. Pharmacy claims have not required ICD codes. Medical claims do. Electronic prescribing often requires diagnoses. Alaska Medicaid has begun a program requiring ICD-10 codes.

John McCall presented slides related to the current progress of ICD 10 diagnosis codes. We have seen a trend upwards since initiating the ICD-10 code requirement. We are now above 40%. Erin has been receiving feedback that this empowers pharmacists.

House bill 159 was passed into law to limit opioid prescriptions to 7 days in opioid naïve patients. Medicaid will be releasing criteria for quantity limits to match the state law.

Erin also stated that Alaska Medicaid is also working on prescriber report cards related to opioids. The committee discussed Medicaid data and how the committee can best review and respond to trends in opioid usage based on data limited to Medicaid claim history.

The DUR committee discussed dental prescriptions. Medicaid would like to encourage pain management strategies that would include alternatives besides opioids. Medicaid would like to develop a patient handout. This could be done in collaboration with professional societies.

Other trends that the state is looking at with the Magellan retrodur program are anxiety disorders treated without benzodiazepines alone, and a sympathomimetic while on beta blockers.

Dr Hiestand was concerned about Viberzi as an opioid agonist and potential risk for substance abuse. Erin Narus stated that we could trend usage.

Dr. Barb Piromalli, DO made a motion to adjourn and Dr. Jenna Hiestand, MD seconded. The motion passed unanimously.