Arkansas Medicaid DUR Board Meeting Minutes July 17, 2019

DUR Board Meeting

July 17, 2019

Voting Board Members Present	Medicaid Pharmacy Representatives Present
Paula Podrazik, M.D.	Cinnamon Pearson, Pharm. D., Chair
Jill Johnson, Pharm. D.	Cynthia Neuhofel, Pharm. D.
Laurence Miller, M.D.	Tara Groff, Pharm. D.
Brian King, Pharm. D.	Michael Munnerlyn, MBA
James Magee, M.D.	Jordan Brazeal, Pharm. D. (RDUR—HID)
Clint Boone, Pharm. D.	Karen Evans, P.D. (ProDUR—Magellan)
Michael Mancino, M.D.	Annette Jones, B.S.

Non-Voting Board Members Present	Board Members and Others Absent
Kristin Pohl, Pharm. D. (ATC)	Lana Gettman, Pharm. D
Christopher Page, Pharm. D. (Empower)	
Jonathan Jones, Pharm. D. (Summit)	

A quorum was present, and the chair called the meeting to order at 9:03am.

I. SPEAKERS

The Chair stated there are 4 speakers present to give public comment today:

NUZYRA® (Steve Saint Onge, Pharm. D. from Paratek); Alpha-1 Proteinase Inhibitor class (Kathryn Perrotta, Pharm. D. from Grifols); VYNDAQEL® (Alice Kelly Morgan, Pharm. D. and Ellen McMahon, PhD from Pfizer); EMFLAZA® (Brian Pfister, PhD from PTC Therapeutics). Public comments in the form of letters and PowerPoint presentations were provided to the Board members prior to the meeting. Board members did not ask questions after any speaker comment.

II. UNFINISHED/OLD BUSINESS AND GENERAL ORDERS

a. ANNOUNCEMENTS BY THE CHAIR

i. Chair read the disclosure of conflict of interest statement. Chair has no conflicts, and none noted by Board members.

ii. Resignations

1. Ashley McPhee, Pharm. D.
2. Richard Ward, Pharm. D.

iii. Introduction of new board members

1. Clint Boone, Pharm. D.
2. Paula Podrazik, M.D.

iv. Introduction of Arkansas Medicaid Magellan Clinical Pharmacist—Tara Groff, Pharm. D. AND Division of Medical Services Deputy Director—Catherine Silva; All Board members introduced themselves for the new members present

v. Update on meeting location

1. October 2019 meeting will be held again in the Magellan Health Boardroom at #1 Allied Drive Suite 1120 in Little Rock

2. All 2020 meetings will be held in conference room A/B in the DHS Donaghey South Building at 700 Main Street in Little Rock

b. REVIEW MINUTES FROM THE APRIL 2019 QUARTERLY MEETING

Motion by Dr. Magee to approve the minutes as written; Dr. King seconded the motion. All members present voted to accept the minutes as written. Motion passed.

c. UPDATE ON SYSTEM EDITS, IMPLEMENTATIONS FROM THE PREVIOUS DUR BOARD MEETINGS AND OTHER UNFINISHED BUSINESS OR FOLLOW-UP ITEMS:

i. No further correspondence needed for April 2019 Board meeting

ii. DRUG UTILIZATION REVIEW BOARD AND DRUG REVIEW COMMITTEE IMPLEMENTATION DATES

PDL changes for proton pump inhibitors from the May 2019 DRC meeting were implemented July 1, 2019 and implementation of PDL changes for oral antipsychotics for adults was postponed until October 1, 2019; April 2019 DUR PA manual review drugs were effective immediately; The oral antipsychotics edits were postponed to October 1, 2019;

iii. REVIEW PROPOSED CHANGES TO THE DUR BOARD BYLAWS

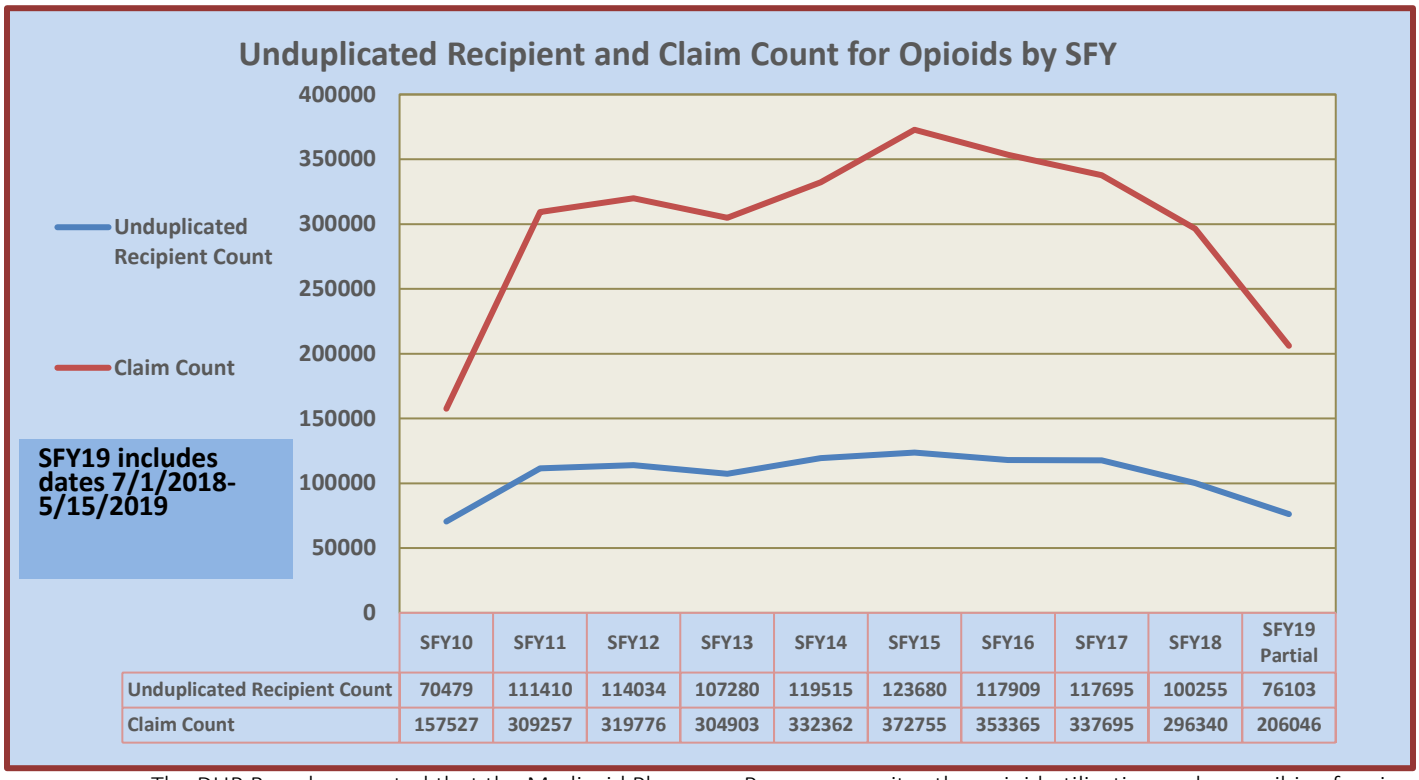

DUR Bylaws 041719 DRAFT w Proposed I

DUR Bylaws FINAL - 071719.pdf

DMS Deputy Director Catherine Silva discussed the proposed changes with the Board. See the attachment for the marked-up version with proposed changes. Motion by Dr. Mancino to approve as proposed; Dr. Johnson seconded the motion. All members present voted to accept the bylaws changes as presented. Motion passed.

Final copy of the Arkansas Medicaid DUR Board bylaws is above.

iv. UPDATE ON OPIOID USAGE



	SFY10	SFY11	SFY12	SFY13	SFY14	SFY15	SFY16	SFY17	SFY18	SFY19 Partial
Unduplicated Recipient Count	70479	111410	114034	107280	119515	123680	117909	117695	100255	76103
Claim Count	157527	309257	319776	304903	332362	372755	353365	337695	296340	206046

The DUR Board requested that the Medicaid Pharmacy Program monitor the opioid utilization and prescribing for six months after the November 14, 2018 dose reduction implementation and present the findings to the DUR Board to determine if further reductions are necessary. The Chair shared the above graph with the Board.

Dr. Mancino asked for additional data that would make an adjustment for the number of beneficiaries since the graph above did not account for beneficiaries that moved to the PASSEs (i.e. usage per 10,000 patients). This information will be shared at the October 2019 DUR Board meeting. Dr. Johnson also wanted the same information for PASSE patients which will be available during the January 2020 meeting.

v. MEDICATION-ASSISTED TREATMENT FORMS

The chair provided an overview of the new Medication-Assisted Treatment (MAT) forms that were effective 7/1/19. Vivitrol® can now be billed as a pharmacy claim or a medical claim effective 7/1/19 and would be manually reviewed on a case-by-case basis with previously approved criteria. Also the Chair discussed the new legislation that removes PA criteria from preferred Buprenorphine products as of January 1, 2020. Dr. Mancino asked about reimbursement for Sublocade and Vivitrol and asked if Sublocade would be covered under the pharmacy program in the future. Chair stated that is being considered. Dr. Boone noted that community pharmacies can obtain these products so would not require a specialty pharmacy only.

MAT PA Form Vivitrol 062719 - FIN

MAT PA Form Bup Products 062719 - FI

d. PROPOSED CHANGES TO EXISTING CRITERIA, INCLUDING POINT OF SALE (POS) CRITERIA, MANUAL REVIEW PA CRITIERIA OR CLAIM EDITS:

1) EMFLAZA® (deflazacort) 6mg, 18mg, 30mg,& 36mg; 22.75mg/ml oral suspension

This medication was previously reviewed by the Arkansas Medicaid DUR Board in April 2017 and July 2018.

Chair gave an example of doses needed for both deflazacort and prednisone based on daily doses for Duchenne muscular dystrophy.

SUGGESTED UPDATED CRITERIA

APPROVAL CRITERIA and information needed:

- Beneficiary has a confirmed genetic diagnosis of Duchenne muscular dystrophy (DMD);
- Age ≥ 5 years old
- Provide documentation of the mutation in the dystrophin gene;
- Prescribed by a provider who specializes in the treatment of DMD and/or neuromuscular disorders;
- Provide a letter of medical necessity with a significant reason specific to the beneficiary that EMFLAZA® is needed over other glucocorticosteroids, such as prednisone or prednisolone;
- Prescriber must submit documentation to substantiate the medical necessity request of EMFLAZA® over other glucocorticoid agents, including submitting chart notes, data on all previous glucocorticosteroid(s) tried, and include explanation of failure or explanation of an adverse effect caused by prednisone or prednisolone that is not also caused by EMFLAZA®;
- Provide documentation of current weight and dosage requested;
- Provide documentation that beneficiary has received a baseline eye examination;
- Provide documentation that the beneficiary is currently receiving, or planning to receive, physical therapy and provide physical therapy notes;
- Provide documentation of Child-Pugh Score (no clinical experience in patients with severe hepatic impairment);

DENIAL CRITERIA:

- Beneficiary is < 5 years of age;
- Beneficiary does not meet above approval criteria;
- Beneficiary has not received prednisone or prednisolone;
- Beneficiary did not receive the weight-based dose on a daily schedule of prednisone or prednisolone (0.75 mg/kg/day);
- Beneficiary is classified as Child Pugh C;

CONTINUATION CRITERIA:

- Beneficiary continues to receive physical therapy;
- Provide current chart notes and physical therapy notes;
- Provide current weight and dosage requested;
- Provide documentation of yearly eye examinations;
- Beneficiary is adherent to the prescribed dose of EMFLAZA®

DISCUSSION:

Dr. Boone mentioned that the new indicated age has been updated to ≥ 2 years of age. Dr. Mancino asked about patients issued a wheelchair. Chair confirmed that with new criteria that removes mobility requirement, an issued wheelchair will not cause a PA denial. Dr. Johnson asked that at the point a patient loses ambulation, is it standard practice to continue steroids? Chair commented on pattern of other Medicaid states and other factors are involved included upper body movement and lung function. Emflaza rep gave additional information. Dr. Podrazik asked the rep for what other things would be monitored. Dr. Podrazik asked if continuation would be considered futile if no effect. Chair stated that upon renewal request, the clinical pharmacists would review and question the need to continue if the patient had no

improvement. Dr. Johnson asked what the benefit of deflazacort over other corticosteroids is and at what point do we acknowledge there is no benefit of deflazacort. Dr. Johnson indicates that data is very inconsistent with efficacy of the agents, but there is a huge difference in cost. Chair concurred that literature is not consistent, and over treatment history there is no significant difference in mobility or side effects between deflazacort and prednisone/prednisolone. Dr. Neuhofel stated we review on case-by-case basis. The medical director can be consulted as well. Dr. Johnson stated she was for keeping the ambulation requirement. Chair stated that we have to be cautious of perceived discrimination but agreed with the concern made by Dr. Johnson. Dr. Boone asked when additional information would be available, and the rep responded data would be available later this year. Dr. Golden stated we are consistently reviewing new literature and take those into consideration when reviewing requests. Dr. Mancino stated we need to give them the benefit of the doubt even if lost ambulation and trust PA reviewers to determine medical necessity.

Action:
Dr. Mancino made a motion to approve all proposed criteria changes including removing ambulation requirement; Dr. King seconded the motion. Dr. Johnson voted against the motion and all other members voted for the motion. Motion passed.

2) PROTON PUMP INHIBITORS REVIEW

The proton pump inhibitor (PPI) criteria was last reviewed in April 2014. Most recently, the proton pump inhibitors' class was reviewed by the Drug Review Committee (DRC) for placement on the preferred drug list (PDL) in May 2019.
The DRC re-approved the placement of PPIs on the PDL with the request to bring the class back to the DUR Board for re-review. DRC members were concerned about long-term use of PPIs without some accountability with lifestyle changes.

UTILIZATION: *Relatively no change from same time period in the previous year.
July 2018-March 2019
Total claims= 43,835 (avg. 4,871 per month)
Total Recipients= 18,693

Magellan Help Desk receives approximately 1000 PA requests per quarter for PPIs. Requests are for non-preferred, excessive doses or exceeding total day supply limit.

CURRENT APPROVAL CRITERIA FOR PREFERRED AGENTS WITH CRITERIA:

- Approve up to 93 days of proton pump inhibitor therapy per year for all recipients age 15 months and older;
- Approve treatment beyond 93 days for recipients 15 months or older who have a diagnosis in history for Zollinger-Ellison Syndrome, Barrett's esophagus, esophageal varices, or an endoscopy in the past 24 months
- Approve treatment beyond 93 days for recipients 15 months or older who have a diagnosis in history for Cystic Fibrosis, pancreatic insufficiency, or pancreatic disease in the past 24 months

DISCUSSION:
Dr. Hailey stated that PDL wants to make criteria stricter. Dr. Mancino stated that lifestyle changes would be difficult to measure. The DUR Board decided there should be no changes to the current approval criteria. The Board did want to bring more attention to the overuse of PPIs and potential long-term effects. Also they ask providers to consider H2-receptor antagonists and lifestyle changes when possible. In addition to the current criteria, Retrospective Drug Utilization Review will be added in an attempt to help monitor PPI usage.

ACTION:
Dr. Mancino made the motion to keep current criteria and add the PPI class for Retrospective review; Motion was seconded by Dr. Podrazik. All board members present voted for the motion. Motion passed.

3) OSTEOPOROSIS DRUG CLASS REVIEW

Endocrine Society 2019 guidelines

Pharmacologic agent(s)	Recommendation(s)
Bisphosphonates	• Bisphosphonates are recommended as the initial therapy in postmenopausal women at high risk for fractures. • Ibandronate is not recommended to reduce risk for nonvertebral or hip fractures. • After 3 to 5 years of use, fracture risk should be reassessed. Women with a low-to-moderate risk for fracture should be considered for a bisphosphonate drug holiday.
Denosumab (Prolia®)	• Denosumab is recommended as an alternative initial treatment in postmenopausal women with osteoporosis and high fracture risk. Recommended dosage is 60 mg every 6 months. • Fracture risk should be reassessed after 5 to 10 years and therapy should be continued in women who remain at high risk.
Teriparatide (Forteo®) and abaloparatide (Tymlos®)	• Teriparatide or abaloparatide treatment is recommended for ≤2 years in postmenopausal women with osteoporosis at very high risk for fractures. • To maintain improvements in bone mineral density (BMD), antiresorptive therapy should be prescribed after completing a course of teriparatide or abaloparatide.
Selective estrogen receptor modulators (Evista® & Duavee®)	• Raloxifene or bazedoxifene are recommended to reduce the risk for vertebral fractures in postmenopausal women with osteoporosis and high fracture risk. Treatment should be initiated in women with a low risk for deep vein thrombosis for whom bisphosphonates or denosumab are not appropriate. • Treatment with raloxifene has an added benefit of reducing incidence of breast cancer and may be particularly suitable for women at high risk for invasive estrogen receptor-positive breast cancer.
Menopausal hormone therapy	• To prevent fractures, menopausal hormone therapy is suggested for patients age <60 years or <10 years past menopause with bothersome vasomotor symptoms who have a low risk for deep vein thrombosis. • Estrogen-only hormone therapy should be used in women with hysterectomy. • Patients prescribed menopausal hormone therapy should not have breast cancer or a history or myocardial infarction or stroke.

Calcitonin (Fortical®)	• Nasal spray calcitonin can be prescribed to women who cannot tolerate raloxifene, bisphosphonates, estrogen, denosumab, tibolone, abaloparatide, or teriparatide.
Calcium and vitamin D	• Calcium and vitamin D should be used as adjunct therapies to osteoporosis treatment in postmenopausal women with low BMD and high fracture risk. • In women unable to tolerate other osteoporosis treatment, daily calcium and vitamin D supplementation is recommended to prevent hip fractures.

SUGGESTED APPROVAL CRITERIA:

EVENITY™ (romosozumab-aqqg) injection

EVENITY is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

The anabolic effect of EVENITY™ wanes after 12 monthly doses of therapy. Therefore, the duration of EVENITY™ use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

EVENITY™ inhibits the action of sclerostin, a regulatory factor in bone metabolism. EVENITY™ increases bone formation and, to a lesser extent, decreases bone resorption.

RECOMMENDED DOSAGE

- The recommended dose of EVENITY™ is 210 mg administered subcutaneously in the abdomen, thigh or upper arm. Administer EVENITY™ once every month.
- The treatment duration for EVENITY™ is 12 monthly doses.
- Patients should be adequately supplemented with calcium and vitamin D during treatment with EVENITY™.
- If the EVENITY™ dose is missed, administer as soon as it can be rescheduled. Thereafter, EVENITY™ can be scheduled every month from the date of the last dose.

▲*DENOTES PULLED FROM CLINICAL TRIAL NCT01575834*

APPROVAL CRITERIA and information needed:

- Manual review on a case-by-case basis;
- Age ≥ 55 years old▲*;*
- Provide baseline calcium and vitamin D levels;
- Must be postmenopausal;
- Bone marrow density score at the hip or femoral neck of ≤ -2.50▲;
- Documentation that patient is at high risk for fracture (osteoporotic fracture or multiple risk factors) or has failed or intolerant to therapy available without a PA;
- Chart notes and documentation of previously tried medications

DENIAL CRITERIA:

- Myocardial infarction or stoke within the preceding year;

- Uncontrolled hypocalcemia;
- No documentation of current calcium and vitamin D usage;
- No medical necessity was established over the medications available without a PA

CONTINUATION CRITERIA:

- Maximum treatment duration is 12 months

QUANTITY EDITS:

2 syringes = 1 dose; 2 syringes per 30 days; maximum of 1 year

DISCUSSION:

Dr. Boone asked if medication is a one time 12-month treatment or if can be repeated in the future. Chair responded that indication is for 12 months only. Dr. Mancino asked about missed doses and if there is evidence to support continuing the medication if noncompliant. Dr. Pohl consulted the package insert which states duration of use should be limited to 12 monthly doses which is interpreted as 12 total doses. Dr. Hailey states it would seem to matter about missed doses especially if not taking a bone anti-resorptive agent. Dr. Neuhofel stated medical necessity would be questioned on renewal if noncompliant. Chair states approval would be 3-6 months at a time and if only received for 2-3 months in 6 months, medical necessity would be in question.

ACTION:

Dr. Mancino made a motion to accept the proposal as amended; motion was seconded by Dr. King. All members present voted for the motion. Motion passed.

RECOMMENDATIONS FOR THE WHOLE CLASS:

- Add quantity edits based on normal dosing schedule for each medication
- Follow the Endocrine Society 2019 Guidelines
  - Bisphosphonates—for postmenopausal women at high risk for fractures with fracture risk reassessed after 3-5 years. Suggest no changes.
  - Denosumab—for postmenopausal women with osteoporosis who are at high risk for osteoporotic fractures, consider alternative initial treatment if Bisphosphonates are not an option. Fracture risk should be reassessed after 5-10 years. If Denosumab is stopped, antiresorptive therapy should be started. Suggest no changes.
  - Teriparatide and Abaloparatide—for postmenopausal women with osteoporosis at very high risk of fracture, such as those with severe or multiple vertebral fractures. Indicated for only 2 years of therapy. When stopped, antiresorptive therapy should be started. Suggest keeping manual review and require the medical necessity over Denosumab if Bisphosphonates are not appropriate.
  - Raloxifene—for postmenopausal women with osteoporosis at high risk of fracture with low risk of DVT and bisphosphonates and denosumab are not appropriate or has a high risk of breast cancer. Suggest no changes.
  - Calcitonin—for postmenopausal women at high risk of fracture with osteoporosis who cannot tolerate any of the medications above. Suggest making manual review?? Currently has POS criteria.

- romosozumab-aqqg—Suggest making manual review.

DISCUSSION:
Dr. Page asked if Calcitonin would require documentation of failure of all products. Chair confirmed.
ACTION:
Dr. Mancino made the motion to approve as presented; Motion was seconded by Dr. Podrazik. All members present voted for the motion. Motion passed.

III. NEW BUSINESS

A. PROPOSED NEW CLINICAL P OINT OF SALE CRITERIA WITH OR WITHOUT ADDITIONAL CLAIM EDITS.

NONE

B. MANUAL REVIEW PROPOSED CRITERIA WITH OR WITHOUT ADDITIONAL CLAIM EDITS

1) NUZYRA® (omadacycline) for injection and oral tablets

NUZYRA® is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

- Community-Acquired Bacterial Pneumonia (CABP) caused by one of the following organisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin susceptible isolates), *Haemophilus influenza, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, Chlamydophila pneumoniae; **OR***
- Acute Bacterial Skin and Skin Structure Infections (ABSSSI) caused by one of the following organisms: *Staphylococcus aureus* (methicillin susceptible and resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus group (includes: S. anginosus, S. intermedius, S. constellatus), Enterococcus faecalis, Enterobacter cloacae, Klebsiella pneumoniae;*

To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA® and other antibacterial drugs, NUZYRA® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Table 1: Dosage of NUZYRA in Adult CABP Patients

Loading Doses	Maintenance Dose	Treatment Duration
200 mg by intravenous infusion over 60 minutes on day 1. OR 100 mg by intravenous infusion over 30 minutes, twice on day 1.	100 mg by intravenous infusion over 30 minutes once daily. OR 300 mg orally once daily.	7 to 14 days

Table 2: Dosage of NUZYRA in Adult ABSSSI Patients		
Loading Doses	Maintenance Dose	Treatment Duration
200 mg by intravenous infusion over 60 minutes on day 1. OR 100 mg by intravenous infusion over 30 minutes, twice on day 1.	100 mg by intravenous infusion over 30 minutes once daily. OR 300 mg orally once daily.	7 to 14 Days
450 mg orally once a day on day 1 and day 2.	300 mg orally once daily	

SUGGESTED APPROVAL CRITERIA:

▲*DENOTES PULLED FROM CLINICAL TRIAL NCT02531438, NCT02378480 OR NCT02877927.*

NUZYRA® tablet and vials for injection will require manual review PA on a case-by-case basis using all of the following:

APPROVAL CRITERIA:

- Beneficiary is ≥ 18 years old;
- Beneficiary has a diagnosis of:
  - Community-Acquired Bacterial Pneumonia (CABP)
  - Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
- Prescriber should provide culture and susceptibility report;
- Prescriber must provide explanation of medical necessity for use of this antibiotic over a different agent that does not require prior authorization;
- Prescriber must submit documentation of loading dose of IV infusion or loading dose of oral tablets beneficiary received for the diagnosis and submit planned length of therapy;
- Negative pregnancy test

DENIAL CRITERIA:

- No diagnosis of CABP or ABSSSI with an organism listed in the approval criteria;
- Age ≤ 18 years old;
- Tetracycline allergy;
- Susceptibility report shows organism is resistant ;
- Female beneficiary is in 2nd or 3rd trimester of pregnancy or breastfeeding;
- Known or suspected healthcare associated infection;
- Request is for greater than 14 days of therapy

CONTINUATION CRITERIA:

- PA approval will not be extended beyond 14-day course of treatment

QUANTITY LIMIT:

- Quantity limit for either tablets or vials for length of therapy (7 to 14 days) will be entered at the time of the PA approval;
- Length of therapy will not exceed 14 days

DISCUSSION:
Dr. Magee states that he rarely identifies bacteria in his population even community-acquired pneumonia and would not require proof of bacteria involved for approval. Dr. Mancino suggested not requiring proof of specific bacteria for approval, but if cultures are available, then a typical causative bacteria for the indications would be expected. Dr. Podrazik states with certain infections we typically know the bacteria involved and resistance and would treat empirically. Chair asked if we simply should ask for the medical necessity over other antibiotics. Dr. Pohl stated she does see some C&S reports with her clinical reviews. Dr. Mancino asked if this would be considered with documentation of failure with other medications. Dr. Johnson quoted data with comparison of efficacy between Nuzyra® and multiple other antibiotics, and the results were not impressive. Chair suggested that the requirement of a C&S and documentation of the indicated organisms listed above be removed and continue to require the medical necessity over preferred antibiotics.

ACTION:
Dr. Magee made a motion to approve as amended; motion seconded by Dr. Mancino. All members present voted for the motion. Motion passed.

2) ABILIFY MYCITE® 2mg, 5mg, 10mg, 15mg, 20mg, and 30mg tablet

ABILIFY MYCITE®, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion, is indicated for the:

- Treatment of adults with schizophrenia
- Treatment of bipolar I disorder
  - Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate
- Adjunctive treatment of adults with major depressive disorder (MDD)

Limitations of Use:

- The ability of ABILIFY MYCITE to improve patient compliance or modify aripiprazole dosage has not been established.
- The use of ABILIFY MYCITE to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur.

SUGGESTED APPROVAL CRITERIA

ABILIFY MYCITE® will require manual review PA on a case-by-case basis using all of the following:

APPROVAL CRITERIA:

- Prescriber must explain and submit documentation to substantiate the medical necessity of beneficiary receiving the drug-device combination over receiving aripiprazole tablet, another preferred oral antipsychotic agent, or a long-acting injectable antipsychotic;
- Prescriber must submit documentation detailing how the beneficiary will be monitored including:
  - Who will be monitoring compliance?
  - Whose smartphone will receive the data especially if the beneficiary does not have one
  - How will beneficiary receive additional MYCITE patches if needs more than 7 per month
  - Provide treatment plan and corrective action plan if noncompliant;
- Approval for a maximum of 3 months at a time

DENIAL CRITERIA:

- Beneficiary does not meet approval criteria;
- Beneficiary does not remain compliant on therapy

CONTINUATION CRITERIA:

- Beneficiary must be compliant on medication

QUANTITY LIMIT:

- Quantity limit of 1 tablet daily; #30 for 30 days

DISCUSSION:
Dr. King asked if someone else could apply your patch and take the medication therefore the incorrect patient would be monitored. Drug rep states patient would use own smartphone, and physician should choose patients with whom they feel would not abuse the system.

ACTION:
Dr. Mancino made a motion to approve as written; Dr. Johnson seconded the motion. All members present voted for the motion. Motion passed.

3) FIRDAPSE® / RUZURGI (amifampridine) 10mg tablets

FIRDAPSE® is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. Ruzurgi will be available later this year for patients 6-17 years old.

Lambert-Eaton myasthenic syndrome (LEMS) is a rare presynaptic disorder of neuromuscular transmission in which quantal release of acetylcholine (ACh) is impaired, causing a unique set of clinical characteristics, which include proximal muscle weakness, depressed tendon reflexes, posttetanic potentiation, and autonomic changes. The initial presentation can be similar to that of myasthenia gravis. LEMS disrupts the normally reliable neurotransmission at the neuromuscular junction (NMJ). This disruption is thought to result from an autoantibody-mediated removal of a subset of the P/Q-type Ca^{2+} channels involved with neurotransmitter release.

DOSING:

- The recommended starting dosage is 15 mg to 30 mg daily taken orally in divided doses (3 to 4 times daily).
  - Starting dosage is 15 mg daily for patients with renal impairment, hepatic impairment, and in known N-acetyltransferase 2 (NAT2) poor metabolizers
- Dosage can be increased by 5 mg daily every 3 to 4 days.
- Dosage is not to exceed a maximum of 80 mg daily.
- The maximum single dose is 20 mg.

SUGGESTED APPROVAL CRITERIA

APPROVAL CRITERIA and needed information:

- Manual review on a case-by-case basis;
- ≥18 years of age;
- Confirmed diagnosis of LEMS based on either neurophysiology studies or a positive anti-P/Q type voltage-gated calcium channel antibody test;
- Current chart notes;
- If receiving peripherally acting cholinesterase inhibitors, a stable dose is required for at least 7 days▲;
- If receiving oral immunosuppressants, a stable dose is required for the last 30 days▲;
- Negative pregnancy test;
- Provide labs including renal and liver function
  - Creatinine clearance from 15-90ml/min must start on lower dose of 15mg per day; no dosage recommendations for ESRD
  - Any decrease in liver function requires a lower starting dose of 15mg per day;

- Provide either the Quantitative Myasthenia Gravis (QMG) score or the Subject Global Impression (SGI) score for baseline;
- Medical necessity over guanidine hydrochloride ???

DENIAL CRITERIA:

- < 18 years old;
- No confirmation of the LEMS diagnosis;
- History of seizures or taking other medications that can lower the seizure threshold ▲;
- Pregnant;
- End stage renal disease;
- Caution with lactation;
- Use of guanidine hydrochloride in the last 7 days;
- Currently uncontrolled asthma due to increased respiratory infections with this medication ▲

CONTINUATION CRITERIA:

- Current QMG or SGI scores showing improvement;
- Not pregnant;
- Current labs to monitor kidney and liver function;
- Current chart notes

QUANTITY EDITS:

- #240 / 30 days

DISCUSSION:
Dr. Mancino expressed that if there is a chance of cancer it should not be ignored. Dr. Golden stated LEMS would be so rare. Chair stated that hopefully after the provider has gone through the trouble to diagnose with LEMS, cancer would be ruled in or out. Chair suggested that provider send a cancer treatment plan for the cancer patients. Dr. Mancino asked if data shows this medication does not improve symptoms, what are we targeting? Chair confirmed there is an improvement in symptoms, but not a cure if the patient continues to have cancer which is also true for guanidine. Dr. Johnson would also open it up to require IVIG and possibly an immunosuppressant such as azathioprine in addition to the guanidine (UpToDate has treatment algorithm). Dr. Johnson supported requiring a cancer treatment plan. Dr. Johnson did mention the side effects associated with guanidine. Dr. Johnson suggested to remove the requirement for the Subject Global Impression score as there is no known clinically important difference at this time. QMG does not show improvement but a measure of symptoms.

ACTION:

Dr. Johnson made a motion to approved as amended; Dr. Mancino seconded the motion. All members present voted for the motion. Motion passed.

4) BALVERSA® (erdafitinib) 3mg, 4mg, and 5mg tablets

BALVERSA™ is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC), that has

- susceptible FGFR3 or FGFR2 (fibroblast growth factor receptor) genetic alterations AND
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

The recommended starting dose of BALVERSA™ is 8 mg (two 4 mg tablets) orally once daily, with a dose increase to 9 mg (three 3 mg tablets) once daily based on serum phosphate (PO4) levels and tolerability at 14 to 21 days. Assess serum phosphate levels 14 to 21 days after initiating treatment. Increase the dose of BALVERSA™ to 9 mg once daily if serum phosphate level is < 5.5 mg/dL, and there are no ocular disorders or Grade 2 or greater adverse reactions. Monitor phosphate levels monthly for hyperphosphatemia. Dose may be reduced up to four times with lowest dose of 4mg per day.

SUGGESTED APPROVAL CRITERIA:

▲*DENOTES PULLED FROM CLINICAL TRIAL NCT02365597*

APPROVAL CRITERIA and information needed:

- Manual review on a case-by-case basis;
- ≥18 years old;
- Metastatic or surgically unresectable urothelial cancer with presence of FGFR alteration documented by FDA-approved companion diagnostic with disease progression on prior chemotherapy;
- Chart notes;
- Provide the following:
    - Current labs including CBC
    - Serum phosphate level
    - Pregnancy tests results if applicable
    - Baseline ophthalmological examination;
- ECOG ≤2
- Currently erdafitinib is considered category 2A in the treatment of urothelial cancer per the NCCN guidelines--Provide the medical necessity of erdafitinib over other agents indicated as category 1 in the NCCN guidelines

DENIAL CRITERIA:

- Doesn't meet the above approval diagnosis;
- Pregnancy;
- Hold if received chemotherapy or definitive radiotherapy within the last 2 weeks▲;
- Must withhold BALVERSA™ if serum phosphate is ≥7 mg/dL until returns to < 5.5mg/dL or baseline. Has persistent phosphate level greater than upper limit of normal (ULN) during screening (within 14 days of treatment and prior to Cycle 1 Day 1) and despite medical management▲;
- Grade 4 Central Serous Retinopathy/Retinal Pigment Epithelial Detachment (CSR/RPED) and withhold ;
- Caution use with CYP2C9 or CYP3A4 inhibitors or inducers

CONTINUATION CRITERIA:

- Monthly ophthalmological examination during the first 4 months of treatment and every 3 months afterward;
- Provide current chart notes
- Provide current labs including serum phosphate;
- Discontinue if experiences disease progression or unacceptable toxicity

DOSING ADJUSTMENT / MODIFICATION:

- Withhold BALVERSA™ if serum phosphate level ≥7 mg/dL (consider adding phosphate binder until serum phosphate <5.5mg/dL)—PI has detailed modification schedule;
- Withhold BALVERSA™ if ≥ Grade 1 CSR/RPED—PI has detailed modification schedule based on severity

QUANTITY EDITS:

- 3mg tablet; #84 per 28 days
- 4mg tablet; #56 per 28 days
- 5mg tablet; #28 per 28 days

DISCUSSION:

Dr. Johnson suggested the provider document the medical necessity over pembrolizumab which is NCCN Category 1 while erdafitinib is currently Category 2A.

ACTION:

Dr. Johnson made a motion to approve as amended; Dr. Mancino seconded the motion. All members present voted for the motion. Motion passed.

5) ALPHA-1 PROTEINASE INHIBITORS

Alpha-1 Proteinase Inhibitors are indicated for chronic augmentation and maintenance therapy in adults with Alpha-1 Antitrypsin Deficiency (AATD) and clinical evidence of emphysema with the goal to slow down the progression of emphysema.

The GOLD 2019 guidelines state that clinical trials to assess efficacy with spirometric outcome for AAT augmentation therapy for AATD patients has never been done, but observational studies of treated vs non-treated patients shows an effective improvement in patients with predicted FEV1 of 35-49 percent. This limitation is also listed on each of the drugs' package inserts. Also, non-smokers or ex-smokers with an FEV1 of 35-60% are the most suitable for AATD augmentation therapy.

Current available products with dosing:

- 60 mg/kg body weight IV once weekly with varying administration rates
    - Prolastin-C®: 0.08 mL/kg/min by patient response and comfort
    - Aralast NP: 0.02 mL/kg/min by patient response and comfort
    - Glassia: 0.02 mL/kg/min by patient response and comfort
    - Zemaira®: 0.08 mL/kg/min by patient response and comfort

SUGGESTED APPROVAL CRITERIA:

APPROVAL CRITERIA with needed information:

- Age ≥18 years old;
- Manual review on a case-by-case basis;
- Request from pulmonologist;
- Required diagnoses consistent with indication
    - Diagnosis of emphysema in the previous 2 years; AND
    - Diagnosis of alpha-1 antitrypsin deficiency in the previous 2 years
- Documentation of smoking status—must be a current non-smoker and need confirmation with carbon monoxide test;
- Documentation of low serum concentration of AAT ≤ 11µM/L or ≤ 80mg/dL OR documentation of high-risk homozygous protein phenotypes (i.e. PiZZ, PiSZ, or Pi (null, null));
- Baseline PFTs with FEV1 30-65%;
- Current chart notes with weight for calculating dosage;
- Continued optimal conventional treatment for emphysema (e.g. bronchodilators, supplemental oxygen if needed, etc.)

DENIAL CRITERIA:

- Does not meet above approval criteria;
- Pregnant;
- Request for diagnoses considered investigational (i.e. Cystic Fibrosis, no AATD)
- Billed diagnosis of Immunoglobulin A (IgA) deficiency (IgA < 15mg/dL)
    - D80.2 Selective deficiency of immunoglobulin A (IgA)

CONTINUATION CRITERIA:

- Current chart notes;
- Documentation of elevation of AAT levels above baseline;
- Continued use of conventional treatment for emphysema;
- Current PFTs

QUANTITY EDITS:

- Dose is weight-based; appropriateness of requested dose will be evaluated.

DISCUSSION:

Dr. Pohl mentioned an additional phenotype of PiSZ. Dr. Magee asked if we are requiring an IgA level or just billed diagnosis. Chair stated the intention was a billed diagnosis of IgA deficiency. Dr. Neuhofel indicated this would be on a case-by-case basis and if the documentation was not available concerning IgA levels, then that would be requested. Dr. Mancino asked about removing PFTs on continuation since these patients typically do not improve. Dr. Podrazik stated that treatment below FEV1 30% would be futile. Decision was made to keep continuation PFTs to establish that the patient remains in the 30-65% range but not for improvement.

ACTION:
Dr. Mancino made a motion to approve as amended; Dr. Magee seconded the motion. All members present voted for the motion. Motion passed.

6) HEPATITIS C VIRUS (HCV) TEATMENT IN PEDIATRICS

Until recently, treatment with Direct-Acting Antivirals (DAA) for pediatric patients was not indicated. Now three DAAs along with Ribavirin are available for our pediatric population with chronic HCV.

Chair gave an overview of treating HCV in pediatrics including Arkansas prevalence, general information in children, and summary of HCV treatment options with indicated ages.

SUGGESTED APPROVAL CRITERIA:

APPROVAL CRITERIA with information needed:

- Manual review on a case-by-case basis;
- Ribavirin will be considered for patients ≥ 3 years old;
- Sovaldi, Harvoni and Mavyret
    - Sovaldi --must be ≥12 years old or ≥35kg
    - Harvoni --must be ≥12 years old or ≥35kg
    - Mavyret --must be ≥12 years old or ≥45kg
- Until age indications change for the remaining Direct-Acting Antivirals (DAAs), these medications will be considered for patients ≥ 18 years old;
- Preferred Drug List (PDL) will remain the same with Zepatier, Epclusa and Mavyret remaining preferred at this time;
- Provide a completed Hepatitis C Virus (HCV) request form and provide all documentation requested on the form;
- Provide current chart notes;
- Provide current labs including CBCs, LFTs, urine drug screens when applicable, documentation of genotype, HIV test results, and documentation of Child-Pugh score;
- Documentation of Metavir score—liver biopsy sampling in children may be problematic. Liver elastography (i.e. FibroSCAN®) and patented serum panels (i.e. FibroStat®) are less invasive and probably more appropriate in children;
- Clinical review will require the documentation of medical necessity for HCV pediatric patients

DENIAL CRITERIA:

- Medical necessity is not established

DISCUSSION:
No discussion
ACTION:
Dr. Mancino made a motion to approve as written; Dr. Magee seconded the motion. All members present voted for the motion. Motion passed.

7) TIBSOVO® (ivosidenib) 250mg tablets

TIBSOVO® is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for the treatment of acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test in:

- Adult patients with newly-diagnosed AML who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.
- Adult patients with relapsed or refractory AML.

The recommended dose of TIBSOVO® is 500 mg taken orally once daily until disease progression or unacceptable toxicity. For patients without disease progression or unacceptable toxicity, treat for a minimum of 6 months to allow time for clinical response.

SUGGESTED APPROVAL CRITERIA:

▲*DENOTES PULLED FROM CLINICAL TRIAL NCT02074839*

APPROVAL CRITERIA with information needed:

- Manual review on a case-by-case basis;
- ≥18 years old for relapsed or refractory AML and ≥75 years old for newly-diagnosed AML with comorbidities that preclude intensive induction chemotherapy;
- Provide documentation of the presence IDH1 mutations of the R132 gene▲;
- ECOG ≤ 2;
- Provide current chart notes with documentation of previous therapy;
- Provide the following labs▲
    - CBC with platelets ≥ 20,000/µL (check weekly for first month, every other week for 2nd month then monthly for treatment duration)
    - Liver function panel (safety in Child-Pugh C is unknown)
    - SCr/BUN (safety in severe renal impairment eGFR<30 mL/min/1.73m^2 is unknown)
    - Creatine phosphokinase (weekly for first month of therapy);
- Documentation of pregnancy status if applicable;
- Baseline electrocardiogram (ECG) (repeat weekly for first 3 weeks of therapy then at least monthly for treatment duration)

DENIAL CRITERIA:

- Disease progression or unacceptable toxicity;
- QTc interval prolongation with signs/symptoms of life-threatening arrhythmia;
- Guillain-Barre' syndrome diagnosis;
- Hematopoietic stem cell transplant within 60 days of beginning medication, on immunosuppressive therapy post HSCT at the time of treatment initiation, or clinically significant graft-versus-host disease (GVHD) ▲;
- Multiple cardiac issues were excluded from the clinical trial▲
    - NYHA class III or IV CHF or LVEF<40% by ECHO or MUGA scan
    - Myocardial infarction in the last 6 months
    - Uncontrolled angina or uncontrolled ventricular arrhythmias
    - Heart-rate corrected QT (QTc) interval ≥450ms with other factors that can prolong QT interval such as medications;
- Systemic anticancer therapy or radiation <14 days prior to initiation▲;
- Concomitant use with drugs that prolong QTc (e.g. anti-arrhythmic meds, fluoroquinolones, triazole anti-fungals or 5-HT$_3$ receptor antagonists) and CYP3A4 inhibitors

DOSE MODIFICATION:

- Differentiation syndrome—interrupt if severe symptoms, resume if Grade ≤ 2;
- Noninfectious leukocytosis—interrupt if leukocytosis not improved with hydroxyurea;
- QTc 480-500 msec—Interrupt; restart when QTc ≤ 480 msec;
- QTc ≥ 500 msec—Interrupt; resume at reduced dose when QTc ≤ 480 msec;
- Grade 3 or higher toxicity—Interrupt until resolve to Grade 2 or lower; resume with lower dose;
- Use with strong CYP3A4 inhibitor—reduce dose to 250mg daily

CONTINUATION CRITERIA:

- No disease progression or unacceptable toxicity;
- Treat minimum of 6 months if tolerated to allow time for clinical response;
- Provide updated labs, ECG and chart notes

QUANTITY EDITS:

- #60/ 30 days

DISCUSSION:
Chair asked for guidance on the denial criteria containing stem cell transplant and immunosuppressive therapy. Dr. Johnson suggested to remove that denial criteria.

ACTION:
Dr. Johnson made a motion to approve as amended; Dr. Podrazik seconded the motion. All members present voted for the motion. Motion passed.

8) VYNDAQEL® (tafamidis meglumine) 20mg capsules and VYNDAMAX™ (tafamidis) 61mg capsule

VYNDAQEL® and VYNDAMAX™ are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. The cardiac form of transthyretin amyloidosis affects the heart. People with cardiac amyloidosis may have an abnormal heartbeat (arrhythmia), an enlarged heart (cardiomegaly), or orthostatic hypertension. These abnormalities can lead to progressive heart failure and death.

The recommended dosage is either:

- VYNDAQEL® 80 mg orally once daily OR
- VYNDAMAX™ 61 mg orally once daily
- VYNDAMAX™ and VYNDAQEL® are not substitutable on a per mg basis.

Transthyretin amyloidosis is a slowly progressive condition characterized by the buildup of abnormal deposits of a protein called amyloid (amyloidosis) in the body's organs and tissues.

SUGGESTED APPROVAL CRITERIA:

▲*DENOTES PULLED FROM CLINICAL TRIAL NCT01994889*

APPROVAL CRITERIA with information needed:

- Manual review on a case-by-case basis;
- ≥18 years old;
- Negative pregnancy test if applicable;
- Medical history of Heart Failure (HF) with at least 1 prior hospitalization for HF or clinical evidence of HF (without hospitalization) manifested by signs or symptoms of volume overload or elevated intracardiac pressures▲;
- Baseline NYHA class;
- Documentation of variant TTR genotype and/or TTR precursor protein identification by immunohistochemistry, scintigraphy and mass spectrometry▲;
- Baseline 6-Minute Walk Test▲;
- Baseline KCCQ-OS score▲

DENIAL CRITERIA:

- NYHA class IV▲ (class III doesn't appear to have benefit over placebo in hospitalizations and minimal benefit for all-cause mortality);
- Does not meet the approval criteria;
- Prior liver or heart transplant or has implanted cardiac mechanical assist device▲;
- Pregnant

CONTINUATION CRITERIA:

- Provide current chart notes;
- Recipient's pharmacy profile will be reviewed for medication adherence;

- Provide documentation of any hospitalizations since previous approval;
- Repeat 6-Minute Walk Test every 6 months
- Repeat KCCQ-OS score every 6 months

QUANTITY EDITS:

- VYNDAQEL® 20mg--#120/30 days
- VYNDAMAX™ 61mg (when available)--#30/30 days

DISCUSSION:
Dr. Johnson stated that curves for futility did not separate until month 18 so would not see any benefit at 6 or 12 months, but at 30 months does show improvement of all cause mortality. Dr. Magee asked what we did with scores. Dr. Neuhofel states they are a way of subjectively measuring response. No guidance on NYHA class provided, so will have NYHA class IV as denial criteria and not class III.
ACTION:
Dr. Mancino made a motion to approve as amended; Dr. Johnson seconded the motion. All members present voted for the motion. Motion passed.

9) TARCEVA® (erlotinib) 25mg, 100mg and 150mg tablets

Recent generic availability by multiple manufacturers. No criteria was place on this medication in 2004 when it became FDA approved.

TARCEVA® is a kinase inhibitor indicated for:

- The treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.
- First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.

- Safety and efficacy of TARCEVA® have not been established in patients with NSCLC whose tumors have other EGFR mutations.
- TARCEVA® is not recommended for use in combination with platinum-based chemotherapy. (cisplatin or carboplatin with gemcitabine or docetaxel).

The recommended daily dose of TARCEVA® for NSCLC is 150 mg taken on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity occurs.

The recommended daily dose of TARCEVA® for pancreatic cancer is 100 mg taken once daily in combination with gemcitabine. Take TARCEVA® on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity occurs

SUGGESTED APPROVAL CRITERIA:
▲*DENOTES PULLED FROM CLINICAL TRIALS NCT02774278 OR NCT01664533 FOR NSCLC PATIENTS*

▲▲*DENOTES PULLED FROM CLINICAL TRIALS NCT02694536 OR NCT00810719 FOR PANCREATIC PATIENTS*

APPROVAL CRITERIA with information needed:

- Manual review on a case-by-case basis;
- ≥18 years old;
- Must have a diagnosis consistent with the FDA approved indications listed above;
- For NSCLC patient—documentation on the presence of EGFR exon 19 deletions or exon 21 substitution mutations using an FDA-approved test
- Pregnancy test results if applicable;
- ECOG ≤ 2;
- Documentation of smoking status;
- Provide the following labs:
    - CBC
    - Renal function and serum electrolytes
    - Liver function tests
    - INR if taking warfarin
    - Clinical trial required▲▲
        - leukocytes ≥ 3,000/µL
        - absolute neutrophil count ≥ 1,500/ µL
        - platelets ≥ 100,000/ µL
        - total bilirubin ≤ 1.5 X institutional upper limit of normal
        - AST(SGOT)/ALT(SGPT) ≤ 3 X institutional upper limit of normal, unless the liver is involved with tumor, in which case the AST/ALT must be ≤ 5 X institutional upper limit of normal
        - creatinine clearance ≥ 50 mL/min/1.73 m2, as measured by 24hour collection OR
        - creatinine ≤ 1.5 X institutional upper limit of normal;
- For NSCLC patient—documentation of disease progression following course of standard chemotherapy or participants unwilling/unable to undergo chemo▲;
- For pancreatic cancer patient—documentation of combination of gemcitabine with TARCEVA®
- or pancreatic cancer patient--prior adjuvant chemotherapy is allowed provided that patients did not receive gemcitabine and the chemotherapy was completed > six months prior to initiation of therapy. ▲▲

DENIAL CRITERIA:

- NSCLC patient has EGFR mutations different than the approved indication;
- Denied if NSCLC patient continues to take a platinum-based chemotherapy;
- Pregnancy;
- Discontinue or deny if have any of the following:
    - Gastrointestinal perforations
    - Bullous and exfoliative skin disorders
    - Ocular disorders such as corneal perforation, ulceration or severe keratitis
    - Diagnosis of Interstitial Lung Disease (ILD);
- Denied if pancreatic cancer patient is not taking gemcitabine;
- Denied if patient has brain metastases▲ *&* ▲▲;
- Denied if pancreatic cancer patient had prior systemic treatment for metastatic disease▲▲???

DOSE MODIFICATIONS:

- Use of CYP3A4 inhibitors—reduce TARCEVA® by 50mg decrements
- Use of CYP3A4 inducers—increase TARCEVA® by 50mg increments to max of 450mg
- Concurrent smoking—increase TARCEVA® by 50mg increments to max of 300mg
- Use of Proton Pump inhibitors—avoid concomitantly
- Reduce TARCEVA® by 50mg decrements when restarting therapy after toxicity is resolved
    - Withhold for severe renal impairment (risk for Hepatorenal syndrome or renal failure)
    - Withhold for hepatotoxicity (risk for Hepatorenal syndrome or hepatic failure)

- No pre-existing hepatic impairment with bilirubin >3X ULN or transaminases are >5X ULN
- Pre-existing hepatic impairment with doubling of bilirubin or tripling transaminases over baseline
- Discontinue if above not resolved or significantly improved within 3 weeks

CONTINUATION CRITERIA:

- No disease progression or unacceptable toxicity;
- Current labs listed above and chart notes

QUANTITY EDITS:

- 25mg tablets #60/ 30 days
- 100mg tablets #30/ 30 days
- 150mg tablets #30/ 30 days

DISCUSSION:
Chair asked for guidance on the pancreatic cancer patient approval criteria and denial criteria. Dr. Mancino agreed with leaving the approval criteria that allows prior adjuvant chemotherapy in nonmetastatic pancreatic cancer and agreed with leaving the denial criteria for pancreatic cancer patients with prior systemic therapy but has metastatic disease.

ACTION:
Dr. Mancino made a motion to approve as written; Dr. King seconded the motion. All members present voted for the motion. Motion passed.

C. PROPOSED NEW CLAIM EDITS

None

D. ProDUR Report

Dr. Evans explained ProDUR reporting to our new Board members. Dr. Evans did not present a ProDUR report during this meeting as data from the PASSEs skewed the numbers generating incorrect reporting. Reporting strategies will be updated for the next meeting.

E. RDUR Report

Dr. Brazeal gave a presentation on the department's Retrospective Drug Utilization Review Report, provided feedback on the impact of RDUR interventions performed 6 months ago, discussed pharmacy lock-ins, and consulted with the Board on RDUR educational intervention criteria recommendations.

- Criteria recommendations for May 2019—motion by Dr. Mancino; all approved
- Criteria recommendations for June 2019—motion by Dr. Mancino; all approved
- Criteria recommendations for July 2019—motion by Dr. Mancino; all approved
- Criteria revisions 2Q19—motion by Dr. Mancino; all approved
- RetroDUR Quarterly Summary report 1Q19

F. Chair shared a slide with upcoming DUR dates and meeting locations. Meeting adjourned at 12:02pm.