Arkansas Medicaid DUR Board Meeting Minutes

Date / Time:	January 18, 2023 8:30 AM– 12:30 PM Central		**Location:**	ZOOM webinar	
Chair:	Cindi Pearson, Pharm.D.		**Reports:**	Lesley Irons, Pharm.D. Magellan Karen Evans, P.D. Magellan	
		Panelist (voting members)		**Panelist (non-voting members)**	**Organization**
	x	Geri Bemberg, Pharm.D.	X	Barry Fielder, Pharm.D.	ATC
	X	Clint Boone, Pharm.D.	X	Shannon Burke, Pharm.D.	Empower
	X	Lana Gettman, Pharm.D.	X	Phuong Luu, Pharm.D.	Empower
		Florin Grigorian, M.D.	X	Lauren Jimerson, Pharm.D.	Summit
	X	Jill Johnson, Pharm.D.		Turkesia Robertson-Jones, Pharm.D.	CareSource
	X	Brian King, Pharm.D.		Jennifer Chapin, Pharm.D.	CareSource
	X	James Magee, M.D.	X	Ifeyinwa Onowu, Pharm.D.	CareSource
	X	Michael Mancino, M.D.		Elizabeth Pitman	DHS Director
	X	Melissa Max, Pharm.D.	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
	X	Laurence Miller, M.D.	X	Cynthia Neuhofel, Pharm.D.	DHS pharmacy
		Daniel Pace, M.D.	X	William Golden, M.D.	DHS advisor
	X	Paula Podrazik, M.D.	X	Shane David, Pharm.D.	ADH advisor
	X	Tonya Robertson, Pharm.D.	X	Karen Evans, P.D.	Magellan
		Chad Rodgers, M.D.	X	Lynn Boudreaux, Pharm.D.	Magellan
		Vacant Pharm.D. position	X	Lesley Irons, Pharm.D.	Magellan
Call to order		Meeting held virtually by ZOOM webinar. A quorum was present, and the chair called the meeting to order at 8:37am.			
Public comments		1) Nav Ramcharran, Pharm.D.—Taiho Oncology Lytgobi® 2) Michael Pham, M.D.—Nobelpharma America Hyftor™ 3) Keanna Dandridge, MSN, RN, CNL—Novartis Kesimpta®			
Announcements		1. There were no conflicts of interest by any voting Board member, Dr. Pearson, or Dr. Irons. 2. Reimbursement rates are based on WAC, FUL or NADAC.  Arkansas Medicaid Quarterly Newsletter 3. Quarterly provider newsletter-- 4. Welcomed new members for the combined DUR/DRC Board—Daniel Pace, M.D., Melissa Max, Pharm.D., Chad Rodgers, M.D.			
Minutes		Motion to approve October 2022 DUR meeting minutes was made by Dr. Mancino, seconded by Dr. Podrazik. All voting members present voted to approve the minutes as written. Motion passed. Motion to approve November 2022 DRC meeting minutes was made by Dr. Max, seconded by Dr. Miler. No other previous DRC members were present. Motion passed.			
Board Updates		• Discussed PA summary with breakdown of total PA requests and top 20 drugs reviewed with PA			
PDL Class Review		• **Cephalosporins** This review is a new drug class. Chair provided a list of current products that require a prior authorization. Dr. Irons presented a PowerPoint with the following information.			

		a) FDA approved indications b) Product availability c) Pharmacology for beta-lactams d) Classification of bacteria e) Spectrum of activity f) Overview of treatment considerations g) Claims summary from 1/1/2022-12/31/2022 **DISCUSSION:** Dr. Golden noted that DHS has an antibiotic utilization project on the medical home side, and they are looking at third generation cephalosporin misuse. The chair recommended 2 preferred agents from each generation. Dr. Max noted a recent supply issue with cefdinir and would support 2 preferred agents from each generation. The chair proposed the motion to consider the overall best net cost for the State while making 2 medications preferred from each generation. Anything non-preferred would require a PA. **ACTION:** Motion was made by Dr. Max; seconded by Podrazik. All members in attendance voted for the motion. Motion passed.

PDL Class Review with Criteria		• **Leukotriene Receptor Antagonists**
		This review is a renewal for the LRA class. Chair provided current PDL, current POS criteria, Xolair criteria for CIU, and proposed approval POS criteria.
		POS EDITS:
		• TD edit for other LTRA if >25% of the days' supply of the claim in history remains
		• Age edits
		  • Montelukast 10 mg tablet— ≥ 15 years
		  • Montelukast 4 & 5 mg chew tablets— 24 months to 16 years
		  • Montelukast 4 mg granule— ≥ 6 months to < 24 months
		Criterion 1:
		• Diagnosis of asthma in the previous 2 years
		OR
		• AR Medicaid pharmacy claim for any of the following in the previous 180 days:
		  • Inhaled corticosteroid (ICS)
		  • Inhaled long-acting beta2 agonist (LABA)
		  • Inhaled short-acting beta2 agonist (SABA)
		  • Inhaled ICS/LABA
		Criterion 2:
		• Diagnosis of allergic rhinitis in the previous 2 years
		OR
		• AR Medicaid pharmacy claim for any of the following within the previous 60 days:
		  • ≥ 1 claim for an inhaled nasal steroid
		  • ≥ 1 claim for a first or second-generation antihistamine
		  • ≥ 1 claim for azelastine nasal spray or ipratropium nasal spray
		Criterion 3:
		• Diagnosis of Chronic Idiopathic Urticaria in the previous 2 years
		
		Dr. Irons presented a PowerPoint with the following information.
		a) FDA approved indications
		b) Overview of asthma
		c) Overview of allergic rhinitis
		d) Pharmacology for LRA
		e) Asthma guidelines for 12+ years
		f) Asthma guidelines for 6-11 years
		g) Allergic rhinitis guidelines
		h) Additional drug information
		i) Overview of treatment considerations
		j) Claims summary from 1/1/2022-12/31/2022

		DISCUSSION: The chair recommended to keep the current PDL status. Dr. Johnson asked if montelukast was cheap enough to allow just POS edits and no PA. The chair stated that it is fairly cheap, but our concerns are for misuse and potential side effects. Dr. Johnson stated that in her mind, she can justify doing without the PA criteria, but leave POS edits. It's not super effective so people will abandon the medication if it doesn't work. Since it requires a prescription, the provider would still have control. The chair clarified that the criteria provided were POS criteria, and if a patient met the criteria, then no PA would be needed. Dr. Magee stated that he feels we should not remove all criteria. The chair stated that we could keep the criteria as presented but look back at utilization in 6 months. If we are approving many who did not process at POS, then maybe we can consider removing POS criteria. Dr. Johnson agreed with Dr. Magee once the POS issue was clarified including the CIU diagnosis since it shows support on the Compendia. Dr. Golden did comment that utilization may need to be monitored if use is focused on a subset of clinicians. The chair stated that we can monitor through RDUR. **ACTION:** Motion was made by Dr. Magee to accept the criteria as presented; seconded by Dr. Johnson. All members in attendance voted for the motion. Motion passed.
Criteria Update		• **Non-Triptan Antimigraine Agents** **PROPOSED APPROVAL CRITERIA:** **<u>ACUTE MIGRAINE TREATMENT</u> (MIGRANAL/TRUDHESA, ELYXYB, NURTEC ODT, REYVOW, UBRELVY)** Any new medications for acute migraine treatment released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply. • Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; AND • Recipient must have a diagnosis of acute migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3) OR a diagnosis consistent with FDA indication; AND • Recipient must have a failure of at least TWO (2) preferred 5HT1B/1D receptor agonists (triptans) using two (2) different chemical agents not just different dosage forms at maximally tolerated doses ~~<u>AND</u> one of those trials should include a non-steroidal anti-inflammatory steroid (NSAID)~~ unless recipient has one of the following contraindications: ~~o For triptans~~ ▪ Ischemic coronary artery disease; OR ▪ Arrhythmias; OR ▪ History of stroke or transient ischemic attack (TIA); OR ▪ Peripheral vascular disease; OR ▪ Ischemic bowel disease; OR ▪ Uncontrolled hypertension ~~o NSAID allergy~~ • A request for a nonpreferred agent requires documentation of the medical necessity over preferred options; AND • Prescriber must submit **ALL** of the following: o Current chart notes; AND o Documentation of migraine frequency and severity/duration; AND o List of all therapies trialed with timeframes; AND o Attestation that medication overuse headaches have been ruled out. **<u>MIGRAINE PROPHYLAXIS</u> (NURTEC ODT, QULIPTA, AIMOVIG, EMGALITY, AJOVY)** Any new medications for migraine prevention released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply. • Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; AND • Recipient must have a diagnosis of either:

		○ Chronic migraines with or without auras as defined by the International Classification ○ of Headache Disorders 3rd edition (ICHD-3) with ≥ 15 headache days per month with ≥ 8 migraine days per month (EMGALITY, AJOVY, or AIMOVIG); OR ○ Episodic migraine or episodic cluster headache (EMGALITY, AJOVY, NURTEC ODT, or QULIPTA); OR ○ Diagnosis consistent with FDA indication; AND • Recipient has documented failure of a 3-month trial of at least ONE agent from TWO of the following preventative classes: ○ Anticonvulsants (e.g., valproate, topiramate) ○ Antidepressants (e.g., amitriptyline, venlafaxine) ○ Beta blockers (e.g., propranolol, metoprolol, atenolol) • Recipient requesting an oral CGRP agent (including preferred medications) must have a documented failure of a 6-month trial with at least ONE injectable CGRP agent or a contraindication to the use; AND • A request for a nonpreferred agent requires documentation of the medical necessity over preferred options; AND • Prescriber must submit **ALL** of the following: ○ Current chart notes; AND ○ Documentation of migraine frequency and severity/duration; AND ○ List of all therapies trialed with timeframes; AND ○ Attestation that medication overuse headaches have been ruled out. **DISCUSSION:** No comments **ACTION:** Motion was made by Dr. Johnson to accept the criteria as presented; seconded by Dr. Robertson. All members in attendance voted for the motion. Motion passed.
New Business		**1) Vivjoa™** **PROPOSED APPROVAL CRITERIA:** • Recipient is an adult, female with a history of recurrent vulvovaginal candidiasis (RVVC) defined as ≥4 episodes of vulvovaginal candidiasis in a 12-month period OR a diagnosis consistent with any updated FDA approved indications or support on the official Compendia • Recipient must have permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy, or post-menopausal) • Recipient should not be approved with any of the following: • Severe renal impairment or ESRD • Moderate to severe hepatic impairment • For diabetic recipients with HbA1c >9%, prescriber must provide efforts taken to achieve better glycemic control • Prescriber must submit ALL of the following: • Current chart notes • History of symptomatic vulvovaginal candidiasis with previous treatment • Vaginal discharge culture or microscopy report • Current HbA1c • Documentation verifying that the current infection is recurrent and not a non-clearance of a previous infection • Note which therapy will be initiated • VIVJOA-only; OR • Fluconazole/VIVJOA • PA will be approved for a maximum of 12/14 weeks (maximum quantity of #18 capsules) • Renewal request • Reviewed on a case-by-case basis • Prescriber should submit the following: • Current chart notes with confirmation of RVVC despite previous treatment • Diabetic recipients must maintain glycemic control with HbA1c < 9%

- Rationale for a subsequent treatment when the package insert does not support beyond one 12/14-week course

DISCUSSION:
Dr. Johnson noted that the Vivjoa trial did show lower unresolved episodes versus fluconazole, but the fluconazole arm was discontinued and Vivjoa was continued for 11 weeks. So there is not enough evidence to justify this more expensive therapy over maintaining with another antifungal. Dr. Johnson wants to include the rationale for not allowing continued fluconazole. She agrees with the A1c requirement. Dr. Golden commented that he expects requests would come from clinicians stating their patient has recurrent infections and with that FDA indication, it can get tricky. If we do a manual review to ensure they are truly recurrent and not a first time use, the approval rate would be modest. The chair stated that she would add expected fluconazole use to the criteria to make it a little more clear. Dr. Johnson noted a PubMed that article recommended fluconazole 150mg once weekly for 6 months which is effective against recurrent VVC. Dr. Johnson asked that this requirement be added to the criteria.

ACTION:
Motion was made by Dr. Johnson to accept the criteria as amended; seconded by Dr. Gettman. All members in attendance voted for the motion. Motion passed.

2) Enspryng®

PROPOSED APPROVAL CRITERIA:

- Prescribed by a specialist experienced with NMOSD
- Recipient is diagnosed with neuromyelitis optica spectrum disorder (NMOSD) and is anti-aquaporin-4 (AQP4) antibody positive **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia **AND** confirmed with the following:
  - Test indicating recipient is seropositive for AQP4-IgG antibodies
  - Recipient has at least one core clinical characteristic (i.e., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions)
  - Exclusion of alternative diagnoses (i.e., Lupus, multiple sclerosis, sarcoidosis, cancer, chronic infection like HIV)
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Recipient must have history of at least one documented relapse (including first attack) in the last 12 months
- Recipient must have an Expanded Disability Status Scale (EDSS) score ≤ 6.5
- Recipient is not prescribed medication for the treatment of multiple sclerosis (i.e., interferon, dimethyl fumarate, fingolimod, glatiramer, etc.)
- Recipient is not prescribed other treatment options for NMOSD concomitantly (i.e., eculizumab or inebilizumab)
- Prescribed to prevent future attacks (not meant to treat an acute attack)
- Trial and failure of immunosuppressants (e.g., azathioprine, mycophenolate, methotrexate) unless there is a contraindication to their use
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Confirmation of NMOSD diagnosis
  - Baseline Expanded Disability Status Scale score
  - Medical necessity over the use of immunosuppressants
  - Results for Hepatitis B virus and tuberculosis screens (should be negative for approval)
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy which is defined by any of the following:
  - Decrease in acute relapses

- Improvement in EDSS
- Reduced hospitalizations
- Reduction/discontinuation in plasma exchange treatments or corticosteroids

QUATITY EDITS:
#1/28 days

DISCUSSION:
Dr. Johnson concluded from the meta-analysis for ADP4 antibody positive supports the use of rituximab over Enspryng and with similar effects to Soliris. Dr. Johnson noted that she wouldn't want to force an inferior medication (oral immunosuppressants) if the patients has severe symptoms like bilateral vision loss. There is data to support the use of rituximab despite its off-label non-FDA approval use. Dr. Robertson asked why the immunosuppressant bullet was included. The chair sited recommendations in UpToDate. Dr. Mancino questioned why we are requiring an off-label treatment. He would not recommend that in his practice. He is not going to use an off-label medication when there is an FDA approved medication. Dr. Robertson stated that studies are not always done to get FDA approval even though literature supports the use. Dr. Podrazik quoted UpToDate with the authors suggested treatment with these more expensive immunotherapies including rituximab over the other immunosuppressive agents. Due to the expense of these newer agents, many clinicians use rituximab. Dr. Podrazik stated that we go by best evidence (there doesn't appear to be a set protocol) and its helpful when this is also FDA approved. Dr. Johnson recommended to remove the third bullet on the 2nd criteria slide. Dr. Podrazik and Dr. Johnson wanted to include rituximab in the bullet where the medical necessity should be given for other products. Dr. Boudreaux noted that the MicroMedex does list mycophenolate as showing support for NMOSD. Dr. Johnson found a meta-analysis showing that mycophenolate reduced the annual relapse rate. The chair stated the change would be to include rituximab in 5th bullet under what should be submitted by prescriber and remove the 10th big bullet about trial and failure. Dr. King stated he could support that.

ACTION:
Motion was made by Dr. Johnson to accept the criteria as amended; seconded by Dr. King. All members in attendance voted for the motion. Motion passed.

3) Multiple Sclerosis Drugs

PROPOSED APPROVAL CRITERIA:
All non-preferred medications:

- Confirmed diagnosis of a relapsing form of MS including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Initial request must be submitted by or in consultation with a neurologist or other appropriate specialist
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Recipient with moderately active disease must have tried at least 2 preferred agents for a minimum of 6 months each and treatment must be considered a failure as defined by any of the following:
  - At least one relapse during therapy with preferred medications
  - MRI indicates additional lesions compared to baseline
  - Recipient demonstrates an increased disability as measured by the Expanded Disability Status Scale compared to baseline
  - Documented adverse effects to the preferred agents
- Recipient with highly active or rapidly evolving aggressive disease will be reviewed on a case-by-case basis
- Recipient is not prescribed other DMTs for the treatment of MS to be used concomitantly
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies with response

- Letter of medical necessity over the preferred medications
- Baseline MRI with documentation of lesions
- Baseline Expanded Disability Status Scale (EDSS)

- See additional criteria noted below for specific medications
- Renewal requirements
  - Prescriber must submit current chart notes with documentation of response to therapy
  - Recipient must have a positive response to therapy which may include any of the following:
    - Decrease in the number of relapses
    - Improvement or no decline in Expanded Disability Status Scale (EDSS)
    - Improvement in MRI findings since initiating therapy

FUMARATES (Bafiertam®, Brand Tecfidera®, Vumerity®)

- Recipient does not have any of the following:
  - Moderate to severe renal impairment
  - Moderate to severe hepatic impairment
  - Previous failure with any fumarate product
  - Prescribed concomitant fumarate therapies
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including a CBC including lymphocyte count and LFTs
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reprodu

INTERFERONS (Betaseron®, Extavia®, Plegridy®, Rebif®/Rebif Rebidose®)

- Recipient must submit **ALL** of the following (in addition to info requested above):
  - Current labs including CBC with differential and LFTs
  - Attestation that patient has been counseled about depression
  - Medical necessity over Avonex®

GLATIRAMER (Copaxone® 40 mg, Glatopa® 20 mg or 40 mg)

- Prescriber must submit the necessity over Copaxone® 20mg daily (convenience would not be considered medically necessary)

SPHINGOSINE 1-PHOSPHATE RECEPTOR MODULATOR (Gilenya®, Mayzent®, Ponvory®, Tas Zeposia®)

- Recipient does not have any of the following:
  - Current systemic or clinically significant infection
  - Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat oth
  - Baseline heart rate ≤ 55 bpm
  - Moderate to severe hepatic impairment (Child-Pugh class B or C)
  - MI, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Cl heart failure in the last 6 months
  - Presence of Mobitz type II second-degree, third-degree AV block, sick sinus syndrome, or s unless have a pacemaker
  - Previous treatment with alemtuzumab
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including a CBC including lymphocyte count and LFTs
  - Documentation of CYP2C9 genotype to determine dose for Mayzent®
  - Documentation of cardiac evaluation with ECG if recipient has preexisting conditions (Contra recent MI, angina, stroke, TIA, severe HF, baseline QTc interval ≥500 msec, or cardiac arrh requiring therapy).
  - Baseline eye exam report
  - Vaccinate for varicella zoster virus before initiation if VZV antibody negative

- Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive pot
- Gilenya® recipient must be ≥ 10 years of age
- Mayzent® recipient must NOT have a CYP2C9 *3/*3 genotype (homozygous)

MONOCLONAL ANTIBODIES (Kesimpta®)
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Medical necessity over the use of Ocrevus® (convenience would not be considered medically neces
  - Confirmed negative for Hepatitis B
  - Baseline serum immunoglobulin levels (monitor periodically for any decrease)
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive pot

PYRIMIDINE SYNTHESIS INHIBITOR (Aubagio®)
- Recipient does not have any of the following:
  - Severe hepatic impairment
  - Concomitant leflunomide or antineoplastic, immunosuppressive or immunomodulator drugs to treat conditions
  - Severe immunodeficiency, bone marrow disease, or severe, uncontrolled infection
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including LFTs and CBC
  - Documentation of negative tuberculosis test
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive pot

PURINE ANTIMETABOLITE (Mavenclad®)
- Recipient should NOT have a diagnosis of clinically isolated syndrome
- Recipient does not have any of the following:
  - Human immunodeficiency virus (HIV), hep B or C, TB or other current systemic or clinically significa infection
  - Current malignancy
  - Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat other condi
  - Moderate to severe renal impairment (CrCl < 60 mL/minute)
  - Moderate to severe hepatic impairment (Child-Pugh score > 6)
- Prescriber must submit **ALL** of the following (in addition to info request above):
  - Medical necessity over all other DMTs
  - Treatment plan after two years of therapy
  - Current labs including a CBC with differential including lymphocyte count and LFTs
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive po
  - Reports for screening Hepatitis B and C, HIV, and tuberculosis
  - Vaccinate for varicella zoster virus before initiation if VZV antibody negative

DISCUSSION:
No comments on general criteria. The chair noted a typo under the interferons (change recipient to prescriber). No other comments.

ACTION:
Motion was made by Dr. Johnson to accept the general criteria as presented; seconded by Dr. Mancino. All members in attendance voted for the motion. Motion passed.
Motion was made by Dr. Mancino to accept the MOA specific criteria as presented; seconded by Dr. Podrazik. All members in attendance voted for the motion. Motion passed.

4) Qutenza®

PROPOSED APPROVAL CRITERIA:

- Prescriber must be a specialist in treating neuropathic pain
- Recipient must be diagnosed with neuropathic pain associated with postherpetic neuralgia (PHN) or neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- QUTENZA may be purchased through buy and bill from specialty distributor or by prescription from specialty pharmacy. QUTENZA must be delivered to prescriber directly.
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Application time must be consistent with the actual diagnosis (60 minutes for postherpetic neuralgia and 30 minutes for diabetic peripheral neuropathy)
- Recipients being treated for PHN pain must have continued pain at least 6 months after healing of herpes zoster rash
- Prescriber must submit **ALL** of the following:
    - Current chart notes with documentation if treating PHN or DPN
    - Previous therapies tried
    - Medical necessity over other treatment options
    - Size of area to be treated. PA will be entered for a specific package size pertaining to the amount needed based on treatment area size.
    - If received from the specialty pharmacy as an outpatient prescription, prescriber must attest that the patient will not have access to this medication. The prescription must be delivered directly to the prescriber's office.
- Recipient must have tried and failed at least 3 of the following prior to consideration for this medication:
    - Postherpetic Neuralgia (PHN)
        - Topical capsaicin or lidocaine
        - Gabapentin and/or pregabalin
        - Tricyclic antidepressants (e.g., amitriptyline, nortriptyline)
        - Antiepileptic agents (e.g., valproic acid, carbamazepine, lamotrigine)
        - Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine)
    - Diabetic Peripheral Neuropathy (DPN)
        - Topical capsaicin or lidocaine
        - Gabapentin and/or pregabalin
        - Tricyclic antidepressants (e.g., amitriptyline, nortriptyline)
        - Antiepileptic agents (e.g., valproic acid, carbamazepine, lamotrigine)
        - Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine)
        - Electrical nerve stimulation
        - Spinal cord stimulation
        - Alpha-lipoic acid
- If approved, PA will be entered for one (1) treatment at a time. Subsequent treatments will require additional PA review.
- Renewal requirements
    - Prescriber must submit the following:
        - Current chart notes
        - Documented improvement in neuropathic pain
    - PAs will be entered for one (1) treatment at a time and only one (1) treatment is allowed every 3 months

QUANTITY EDITS:
1 single use topical system per 90 days (carton can include 1, 2, or 4 systems)

DISCUSSION:
No comments

ACTION:

Motion was made by Dr. King to accept the criteria as presented; seconded by Dr. Podrazik. All members in attendance voted for the motion. Motion passed.

5) Lytgobi®

PROPOSED APPROVAL CRITERIA:

- Recipient is diagnosed with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Recipient must have failed prior platinum-based therapy (e.g., gemcitabine/cisplatin, FOLFOX, FOLFIRI)
- Recipient should not be approved or continue on this therapy with any of the following:
    - Pregnancy
    - Diagnosed with retinal pigment epithelial detachment (RPED)
    - Uncontrolled hyperphosphatemia with continued phosphate >7 mg/dL on lowest dose
    - Does not tolerate the minimum dose of 12 mg daily
    - Require concomitant dual P-gp and strong CYP3A inhibitors or inducers (e.g., itraconazole and rifampin)
- Prescriber must submit **ALL** of the following:
    - Current chart notes
    - Test results confirming the presence of FGFR2 gene fusion or other rearrangements
    - Documentation of the previous therapies
    - Current labs including CBC and serum phosphate
    - Baseline comprehensive ophthalmological exam (repeat every 2 months for first 6 months then every 3 months)
    - Attestation that patients of reproductive potential are using contraception
- Initial approval for 1 month, PA renewals may be 3 months if patient tolerates potential toxicities
- Renewal request requires the following:
    - Prescriber must submit current chart notes and labs
    - Prescriber must submit response to therapy (approval requires the lack of disease progression and lack of unacceptable toxicity)
    - Recipient continues to meet approval criteria

QUANTITY EDITS:
#155/31 days

DISCUSSION:
No comments

ACTION:
Motion was made by Dr. Johnson to accept the criteria as presented; seconded by Dr. Gettman. All members in attendance voted for the motion. Motion passed.

6) Hyftor™

PROPOSED APPROVAL CRITERIA:

- Recipient is diagnosed with tuberous sclerosis with facial angiofibromas **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®

- Recipient must have at least 3 angiofibromas measuring ≥2 mm in diameter
- Recipient should not be approved or continued on this therapy with any of the following:
  - Pregnancy
  - Requires live vaccine (should be completed prior to therapy initiation)
  - No improvement after 12 weeks of treatment
  - Does not have at least 3 angiofibromas measuring ≥2 mm in diameter
- Prescriber must submit **ALL** of the following:
  - Current chart notes documenting a diagnosis of tuberous sclerosis
  - Baseline description of facial angiofibromas
- If approved, PA duration will be 3 months
- Renewal requests require the following:
  - Prescriber must submit current chart notes with documented change from baseline
  - Recipient must have a least a 50% reduction in angiofibroma size and redness by 3 months of use.

QUANTITY EDITS:
2 tubes/ 31 days

DISCUSSION:
The chair noted our office discussed whether angiofibromas would be cosmetic in patients with TSC. Since there is a gene mutation, we felt it was not just cosmetic. Dr. Johnson noted that regardless of cause, it is definitely cosmetic. The lesions do not go on to cause cancer, but they can be disfiguring. Dr. Johnson stated that this medication does not treat the epilepsy and is not terribly effective, but it may help some people with facial disfigurement. No comments on criteria.

ACTION:
Motion was made by Dr. Johnson to accept the criteria as presented; seconded by Dr. Miller. All members in attendance voted for the motion. Motion passed.

7) Rezlidhia™

PROPOSED APPROVAL CRITERIA:
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Recipient is diagnosed with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient should not be approved or continued on this therapy with any of the following:
  - Continued signs of differentiation syndrome despite dosage modification
  - Require concomitant moderate or strong CYP3A inducers
  - Severe renal or hepatic impairment
  - No previous induction therapy
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Previous therapies tried
  - Current labs including CBC with differential and LFTs
  - Report confirming the presence of an IDH1 mutation
  - Treatment plan for hematopoietic cell transplant
- Initial PA for 1-month, future PAs can be longer if recipient tolerates medication
- Renewal requests require the following:
  - Current chart notes with response to therapy
  - Current labs including CBC and LFTs (labs drawn at least once weekly for first 2 months, once every other week for third month, once in fourth month, and once every other month thereafter)
  - Lack of disease progression (trial at least 6 months to assess clinical response) or unacceptable toxicities

QUANTITY EDITS:

		#62/31 days **DISCUSSION:** Dr. Johnson suggested to change PA length to 6 months since it may take that long for a response. And if they cannot tolerate the medication, the prescriber will discontinue. Dr. Johnson wanted to know if this product had a REMS. The chair didn't remember seeing a REMS requirement. **ACTION:** Motion was made by Dr. Johnson to accept the criteria as amended; seconded by Dr. Podrazik. All members in attendance voted for the motion. Motion passed.

Reports		• Dr. Pearson gave the ProDUR report for the PASSEs
		• Dr. Evans from Magellan gave the fee-for-service ProDUR report
		• Dr. Irons from Magellan gave the fee-for-service RDUR report
		  ○ February 2023—criteria 6459 Tizanidine-use with caution for patients on HTN meds
		  ○ March 2023—High dose benzo and/or quetiapine
		  ○ April 2023—criteria 7244 FDA Alert-possible association between use of montelukast and behavioral/mood changes, suicidality and suicide
		ACTION: Motion was made by Dr. Mancino for the above criteria; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed.

Adjourn		Meeting adjourned at 11:56 am.