DUR Board Meeting
October 21, 2020
Department of Human Services
Zoom Webinar

Voting Board Members Present
Lana Gettman, Pharm.D.
Jill Johnson, Pharm.D.
Laurence Miller, M.D.
Geri Bemberg, Pharm.D.
Brian King, Pharm.D.
James Magee, M.D.
Clint Boone, Pharm. D.
Michael Mancino, M.D.
Paula Podrazik, M.D.

Medicaid Pharmacy Representatives Present
Cinnamon Pearson, Pharm.D., Chair
Cynthia Neuhofel, Pharm.D. (DHS)
Elizabeth Pitman, J.D. (DHS)
Karen Evans, P.D. (Magellan)
Scott Donald, Pharm.D. (RDUR—HID)
Lynn Boudreaux, Pharm.D. (Magellan)

Non-Voting Board Members Present
William Golden, M.D. (advisor)
Kristen Pohl, Pharm.D. (ATC)
Shannon Burke, Pharm.D. (Empower)
Lauren Jimerson, Pharm.D. (Summit)
Shane David, Pharm.D. (in place of Dr. Romero (advisor))

Board Members and Others Absent
1 physician vacancy
1 pharmacist vacancy

Meeting held in a ZOOM webinar due to COVID-19. A quorum was present, and the chair called the meeting to order at 8:34 a.m.

I. SPEAKERS

The Chair stated there were 7 speakers present to give public comment today:

a. Fintepla® (Ron Kaufman, Sr. MSL with Zogenix)
b. Qinlock™ (Julie Baker, Pharm D, MBA with Deciphera Pharmaceuticals)
c. Nurtec™ ODT (Chelsea Leroue, PhD with Biohaven Pharmaceuticals)
d. Dojolvi™ (Tom Arnhart, Pharm D with Ultragenyx Pharmaceutical)
e. Ubrelvy™ (Patricia Jacob, Pharm D, M.S. with Allergan)
f. Evrysdi™ (Eardie Curry, PhD with Genentech)
g. Enspryng™ (Eardie Curry, PhD with Genentech)

Public comments in the form of letters were provided to the board members prior to the meeting.

- Dr. Johnson asked Ultragenyx Pharmaceutical a question about Dojolvi.
- Dr. Golden asked Genentech a question about Evrysdi.

II. UNFINISHED/OLD BUSINESS AND GENERAL ORDERS

A. ANNOUNCEMENTS BY THE CHAIR

1. Chair read the disclosure of conflict of interest statement. Chair has no conflicts, and none noted by board members.
2. Chair announced Chris Page has left Empower and Shannon Burke, Pharm D will be taking his place as a non-voting member.

3. Dr. Nate Smith no longer works for the Arkansas Department of Health. Dr. Jose Romero is the current Secretary of Health. Per the bylaws, Dr. Romero would be the ex-officio advisor to the Board. Due to scheduling issues with COVID-19, Dr. Shane David attended in his place.

B. **REVIEW MINUTES FROM THE JANUARY 2020 QUARTERLY MEETING**

Motion by Dr. Mancino to approve the minutes as written; Dr. Gettman seconded the motion. All members present voted by roll call 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:**

1. **IMPLEMENTATION INFORMATION FROM JULY 15, 2020 DUR BOARD MEETING AND AUGUST 12, 2020 DRC MEETING**

Preferred Drug List changes were effective October 1, 2020; DUR PA manual review drugs' criteria was effective immediately; Lysteda® POS edit (from April 2020 meeting) was effective August 18, 2020; new Acthar® form was posted on the Magellan website on August 26, 2020.

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

1. **ADULT CII STIMULANT UPDATE**

Chair discussed current criteria for CII stimulants and provided CDC maps with prevalence of ADHD and treatment of ADHD in patients 2-17 years of age.

SUGGESTED CRITERIA:

For children--increase minimum age and expand maximum age

- Recommendation is to change minimum age for all CII stimulants from ≥ 5 years to ≥ 6 years of age to better correlate with the manufacturers' package inserts.
- Recipients ≤ 5 years of age will require a PA.
- Recommendation is to change the maximum age to be considered a "child" when prescribed a CII stimulant. Currently, recipients ≥ 18 years of age require a PA for every request. The change will allow recipients 6-18 years of age to receive a preferred medication without a PA if they meet current therapeutic duplication, quantity requirements, and swallow criteria.
- These changes would apply to preferred and nonpreferred medications.

Require a billed diagnosis of ADHD

- Recommendation is to require a billed diagnosis of ADHD in the last 2 years to allow POS claims for children 6-18 years of age.
- If the ADHD diagnosis is not billed, a PA will be required.
  - Prescriber would need to submit documentation of an ADHD diagnosis with current chart notes.
  - If recipient does not have ADHD, a letter of medical necessity would need to be provided.
- The goal is to prevent off-label use of CII stimulants in children.

Updated CII stimulant form

ARRx_SMN_Adult_C-II_Stimulant.pdf

DISCUSSION:
Dr. Miller made the comment that we try to review the symptoms ADHD as many have diagnosis that may mimic ADHD, such as trauma related disorders. Dr. Podrazik asked who can order the CII stimulants for children and has concern over proper diagnosis. Chair stated that we receive requests from pediatricians, family medication, and psychiatrists. Dr. Magee stated that nurse practitioners cannot initiate a CII stimulant. Dr. Miller stated they can continue a CII stimulant at same dose previously ordered by a physician.

ACTION:
Motion was made to accept criteria as presented by Dr. Johnson; seconded by Dr. Bemberg. All members present voted by roll call to accept as amended. Motion passed.

2. CONTROLLED DRUG EARLY REFILL THRESHOLD UPDATE

Chair discussed current early refill threshold procedures and shared a CMS survey report from FFY2018 comparing the refill threshold between the states.

SUGGESTED CRITERIA:

- Change early refill edit threshold to 90% for scheduled III-V medications. This would allow a refill 2-3 days early.
- Change early refill edit threshold to 90% for scheduled II medications. This would allow a refill 2-3 days early.
- Change sedative hypnotics from 100% to 90% early refill edit threshold for consistency. This would allow a refill 2-3 days early.
- All other quantity and therapeutic duplication edits would remain the same.

DISCUSSION:
No discussion.

ACTION:
Motion was made to accept criteria as presented by Dr. Bemberg; seconded by Dr. Johnson. All members present voted by roll call to accept as amended. Motion passed.

III. NEW BUSINESS

1. PALFORZIA™ (peanut allergy)

Chair discussed that Palforzia was on the July 2020 agenda but was tabled due to unanswered questions that prevented a consensus on a vote. Aimmune Therapeutics answered our previous questions, and that data was forwarded to the Board members prior to the meeting. Chair gave the responses from Aimmune Therapeutics during the meeting. Chair shared the dosage packaging for Palforzia along with all information provided during the last DUR meeting. Highlighted sections were discussed in detail.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 4 years of age and ≤ 17 years of age to initiate treatment; **AND**
- Recipient must have a confirmed diagnosis of a peanut allergy; **AND**
- Prescriber must be an Allergy and Immunology specialist; **AND**
- Prescriber, clinic, pharmacy and recipient must be enrolled in the Risk Evaluation and Mitigation Strategy (REMS) program and remain compliant with program requirements; **AND**

- Prescriber must attest that the recipient has been counseled to continue a peanut-avoiding diet as this medication is for accidental exposure to peanuts; **AND**
- Recipient must continue to have injectable epinephrine on hand with a pharmacy claim within the last year; **AND**
- Prescriber must require Initial Dose Escalation and first dose of each up-dosing stage to occur in the office to monitor for anaphylaxis for at least 60 minutes and provide a plan on how to manage potential anaphylaxis reactions while in the office; **AND**
- Prescriber should provide the following:
    - Current chart notes; **AND**
    - Documentation of a systemic reaction to peanuts **AND** at least one of the following:
        - Serum immunoglobulin E (IgE) to peanuts ≥ 14 kUA/L (kilos of allergen-specific units per liter) within the past 12 months; **OR**
        - Skin prick test (SPT) to peanut with a mean wheal diameter of ≥ 8 mm compared to control; **OR**
        - Documented reaction to peanut upon supervised oral food challenge at a dose of ≤ 100 mg peanut protein (≤ 200 mg peanut flour).
- PA options
    - PAs will be approved for each up-dosing pack individually based on progression of dose. Until recipient has titrated to 300 mg maintenance daily dose, PAs should be for one (1) 15-day supply only. Prescribers **OR** pharmacies can call with dose needed for taper escalation; **OR**
    - PAs will be approved for 2 months at a time with correct dosages per the taper. Compliance, response to therapy and tolerance will be reviewed on renewal request; **OR**
    - PAs for all NDCs will be approved at one time since the pharmacy can only send one dose at a time.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has uncontrolled asthma, markedly compromised lung function, severe mast cell disorder or cardiovascular disease (decreased ability to survive anaphylaxis); **OR**
    - Uncontrolled asthma is defined per the 2007 NHLBI, and involves: asthma symptoms throughout the day, nighttime awakenings often (7x/week), poor lung function (FEV1 < 60% predicted; FEV1/FVC reduced > 5%), extreme limitation on normal activity, and the need to use a short-acting beta agonist (rescue inhaler) several times a day.
- Recipient has suspected eosinophilic esophagitis and/or other eosinophilic gastrointestinal disease; **OR**
- Recipient cannot tolerate doses up to and including the 3 mg dose during Initial Dose Escalation; **OR**
- Recipient had a severe or life-threatening anaphylaxis within the previous 60 days.

CONTINUATION CRITERIA:

- Recipient's Medicaid profile will be reviewed for compliance for PA renewal; **AND**
- Prescriber should submit current chart notes with response/tolerance to medication; **AND**
- PA renewals for maintenance dosing may be approved for 3-6 months depending on length of proven tolerance.

QUANTITY EDITS:

Initial Dose Escalation blister pack— 1 pack per 365 days
Each up-dosing pack— #1 pack/15 days
Maintenance pack of 300 mg daily— #1 pack (30 powder packs)/ 30 days

DISCUSSION:

Dr. Magee questioned if all labs use kUA/L. Chair will contact Arkansas Children's Hospital to verify what is used to measure IgE in their facility. Dr. Bemberg discussed the 3 PA options and would consider the 2nd and 3rd options. The Chair stated that the 2nd option would be the best at this time. So that was added as an amendment. Dr. Podrazik states she has continued concern with no new updates from clinical trials. Dr. Johnson agreed with Dr. Podrazik. With increase need for Epi-pens in trials, Dr. Johnson states that the medical necessity for this drug has not been established. Information on the trials needs to be peer-reviewed and published and so far, Palforzia has not. Dr. Johnson states that the correct endpoint has not been established and patients aren't appreciating a difference yet. The Chair stated she wasn't sure how any stricter the criteria could be, but our whole team including the Medical Director would be reviewing requests. Dr. Boudreaux stated that we have to cover when rebateable, but we can put the criteria to force the documentation of medical necessity. Dr. Johnson stated that she would have to abstain from voting on this drug. Dr. Bemberg asked if the Board could have an update in utilization at a year. Chair agreed.

ACTION:

Motion was made to accept criteria as amended by Dr. Mancino; seconded by Dr. King. Dr. Johnson abstained from voting. All other members present voted by roll call to accept as amended. Motion passed.

2. FASENRA® (benralizumab) injection

Chair gave dosing information and mechanism of action for Fasenra along with ICER report findings for the 5 available products.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 12 years of age (If the indicated ages change, the criteria will reflect the change); **AND**
- Recipient must have a diagnosis of severe asthma, eosinophilic phenotype with a history of 2 or more exacerbations in the previous year **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must be compliant on at least two (2) asthma maintenance medications for at least one (1) year (one must be an inhaled corticosteroid); **AND**
- Recipient has a morning lung function pre-bronchodilator FEV1 < 90% in adolescents and < 80% in adults despite treatment with medium or high dose ICS plus LABA; **AND**
- Recipient must have a baseline blood eosinophil count ≥ 300 cells/µL; **AND**
- Recipient must be ordered FASENRA PEN as prefilled syringes are excluded from the pharmacy program; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current pulmonary function tests (PFTs); **AND**
    - Current labs including baseline blood eosinophil count; **AND**
    - Baseline Asthma Control Questionnaire-6 (ACQ-6) for all patients **OR** Standardized Asthma Quality of Life Questionnaire (AQLQ(S)+12) for adults only; **AND**
    - Documentation of all previous therapies tried with response; **AND**
    - Letter of medical necessity for the use over other therapies outlined in treatment guidelines.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**

- Recipient has helminth infections. Pre-existing helminth infections should be treated prior to beginning FASENRA; **OR**
- Recipient has approval for other interleukins (daclizumab, mepolizumab, or others new to the market) or omalizumab; **OR**
- Recipient is not compliant on asthma controller medication for at least 1 year including inhaled corticosteroid; **OR**
- Recipient is a current smoker; **OR**
- Recipient must remain compliant on asthma controller medications (inhaled corticosteroids) if medication is approved.

CONTINUATION CRITERIA:

- Recipient is compliant on asthma controller medication (ICS or ICS/LABA) and benralizumab injections; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of response to therapy after 6 months; **AND**
    - Current PFTs with improvement over baseline; **AND**
    - Current labs indicating a decrease in blood eosinophil count; **AND**
- Recipient demonstrates improved control of asthma with fewer exacerbations, improved PFTs and improved asthma questionnaire scores.

QUANTITY EDITS:

#1 FASENRA pen every 8 weeks (will need quantity override for first 3 months)

DISCUSSION:

Dr. Johnson states that the criteria is fine, but the class would be ripe for addition to the PDL. Chair stated that this class is on the agenda for November DRC. No changes were made to the criteria proposed.

ACTION:

Motion was made to accept criteria as proposed by Dr. Johnson; seconded by Dr. Mancino. All members present voted by roll call to accept as written. Motion passed.

3. QINLOCK™ (ripretinib) tablet

Chair provided information on gastrointestinal stromal tumors (GISTs), NCCN recommendations for treating GISTs, mechanism of action of Qinlock, and dosing requirements for Qinlock.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of advanced gastrointestinal stromal tumor (GIST) and previously treated with 3 or more TKIs including imatinib **OR** a diagnosis consistent with FDA indications; AND
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including CBC and LFTs; **AND**
    - Baseline echocardiogram or MUGA scan to monitor ejection fraction; **AND**
    - Current blood pressure; **AND**
    - Documentation of dermatologic evaluations as baseline due to possible cutaneous squamous cell carcinoma; **AND**
    - Pregnancy test for women of childbearing potential.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient requires strong CYP3A inducers; **OR**
- Recipient is unable to tolerate 100 mg once daily dose; **OR**
- Recipient has uncontrolled hypertension or Grade 3 or 4 left ventricular systolic dysfunction LVEF < 50%; **OR**
- Recipient has moderate or severe hepatic impairment; **OR**
- Recipient has documented disease progression or unacceptable toxicity.

CONTINUATION CRITERIA:

- Recipient has no documented disease progression or unacceptable toxicity; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including liver function tests; **AND**
    - Current blood pressure; **AND**
    - Documentation of tumor response assessments every 28 days for the first 4 months then every 56 days thereafter.

QUANTITY EDITS:

#90/ 30 days

DISCUSSION:

No discussion.

ACTION:

Motion was made to accept criteria as presented by Dr. Johnson; seconded by Dr. Mancino. All members present voted by roll call to accept as written. Motion passed.

4. KYNMOBI™ (apomorphine hydrochloride) SL films

Chair discussed the mechanism of action for Kynmobi, comparison of pricing with similar agents, and dosing requirements.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of Parkinson's disease with acute, intermittent "OFF" episodes **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must be compliant on current therapy of levodopa/carbidopa (immediate or CR) at maximally tolerated doses for at least 4 weeks before adding KYNMOBI; **AND**
- At baseline, recipient must experience at least one well defined "OFF" episode per day with a total daily "OFF" time duration of ≥ 2 hours during the waking day, based on patient self-assessment; **AND**
- Recipient is Hoehn and Yahr Stage III or less in the "ON" state; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**

- Current vital signs including blood pressure and heart rate and documentation that recipient has been evaluated for potential hypotension/orthostatic hypotension; **AND**
- Current labs including CBC, BMP and LFTs; **AND**
- Documentation that the recipient has an antiemetic (e.g. trimethobenzamide) beginning 3 days prior to initial dose; **AND**
- Medical necessity of adding this medication over increasing the current levodopa/carbidopa dosage or adding another PD medication that does not require a PA; **AND**
- Baseline Unified Parkinson's Disease Rating Scale (UPDRS) Part III Motor Examination score.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient requires concomitant use of 5HT3 antagonists (i.e., ondansetron, granisetron, dolasetron, palonosetron, alosetron), dopamine antagonists (excluding quetiapine or clozapine) or dopamine depleting agents due to risk for profound hypotension or loss of consciousness; **OR**
- Recipient has a documented history of hypotension; **OR**
- Recipient has drug or alcohol dependency issues noted in the past 12 months; **OR**
- Recipient has major psychiatric disorder including, but not limited to, dementia, bipolar disorder, psychosis OR suicidal ideation/attempt in the last year; **OR**
- Recipient has ≤ 2 hours per day of "OFF" time; OR
- Recipient has Hoehn and Yahr stage > 3 in an "ON" state; **OR**
- Recipient cannot tolerate the 10 mg dose; **OR**
- Recipient reports significant daytime sleepiness or episodes of falling asleep during activities that require active participation.

CONTINUATION CRITERIA:

- Recipient has an improvement in the UPDRS Part III motor examination score when measured pre-dose and 30 minutes post dose after 12 weeks of therapy; **AND**
- Recipient is tolerating the medication and compliant on maintenance PD medications; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current UPDRS Part III motor examination score; **AND**
  - Current vital signs.

QUANTITY EDITS:

#1 Titration kit per 365 days
All strengths--#150/ 30 days

DISCUSSION:

Dr. Johnson discussed about the multiple products for "OFF" episodes and would be a new class review for PDL placement**.**

ACTION:

Motion was made to accept criteria as presented by Dr. Johnson; seconded by Dr. Mancino. All members present voted by roll call to accept as written. Motion passed.

5. FINTEPLA® (fenfluramine) oral solution

Chair discussed the black boxed warning for Fintepla, information on Dravet Syndrome, and dosing requirements.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 2 and ≤ 18 years of age; **AND**
- Recipient has a diagnosis of seizures associated with Dravet syndrome **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber, pharmacy and recipient must all be enrolled in the FINTEPLA REMS program; **AND**
- Recipient must have inadequately controlled seizures while on at least one anti-epileptic drug (Trials required a minimum of 6 convulsive seizures in a 6-week baseline period while stable on current AEDs.); **AND**
- Maximum dose for recipients **NOT** taking stiripentol is 0.35 mg/kg twice daily (26 mg per day), and maximum dose for recipients taking stiripentol is 0.2 mg/kg twice daily (17 mg per day); **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of weight and blood pressure; **AND**
    - Current list of medications with doses and all other therapies tried; **AND**
    - Current baseline seizure activity; **AND**
    - Current labs including CBC, BMP and LFTs; **AND**
    - Results from echocardiogram (must evaluate for valvular heart disease and pulmonary arterial hypertension); **AND**
    - Current dose needed based on weight and stiripentol usage.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has moderate or severe renal impairment; **OR**
- Recipient has hepatic impairment; **OR**
- Recipient has valvular heart disease or pulmonary arterial hypertension; **OR**
- Recipient requires concomitant monoamine oxidase inhibitors; **OR**
- Recipient develops acute decrease in visual acuity or ocular pain; **OR**
- Prescriber orders dosing not consistent with FDA approved labeling.

CONTINUATION CRITERIA:

- Recipient demonstrates a reduction in convulsive seizure frequency compared to baseline; **AND**
- Recipient must remain compliant on FINTEPLA; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Update on seizure frequency compared to baseline; **AND**
    - Repeated echocardiogram every 6 months per FINTEPLA REMS.

QUANTITY EDITS:

360mL bottle: 1 bottle/ 30 days—gives maximum dose of 26 mg per day.

DISCUSSION:

Chair asked the Board to discuss age range for approval. Dr. Mancino asked if any of the research studies tested after the age 18. The Chair stated, "not that I found". Dr. Mancino stated without data for over 18 years of age, the proposed should remain. The Chair that our team would monitor the PI and Compendia for any changes and review based on the updates. Dr. Podrazik made a comment on the natural course of the disease. Dr. King asked if there needed to be a request for genetic testing. Chair stated that genetic testing was required for Epidiolex which is also for Dravet Syndrome, and we could add the verbiage to mimic the language in Epidiolex criteria. Dr. King agreed.

ACTION:
Motion was made to accept criteria as amended by Dr. King; seconded by Dr. Podrazik. All members present voted by roll call to accept as written. Motion passed.

6. EVRYSDI™ (risdiplam) powder

Chair discussed spinal muscular atrophy, SMA types, Evrysdi mechanism of action, and dosing requirements.

SUGGESTED CRITERIA:
APPROVAL CRITERIA:

- Recipient must be ≥ 2 months of age; **AND**
- Recipient has a diagnosis of Type 1, Type 2 or Type 3 spinal muscular atrophy (SMA) **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must be a neurologist with expertise in treating SMA; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current weight; **AND**
    - Genetic testing results documenting the SMA diagnosis and SMA type; **AND**
        - Documentation of SMN1 gene deletion or mutation
        - Documentation of at least 2 or more copies of SMN2 gene
    - Current labs including liver function tests; **AND**
    - Female recipients of childbearing potential must have a negative pregnancy test prior to beginning EVRYSDI therapy **OR** has documentation of contraception usage; **AND**
    - Documentation that female members of childbearing potential have been counseled about contraception; **AND**
    - Documentation that male members have been counseled about potential infertility with EVRYSDI therapy; **AND**
    - Documentation of physical therapy; **AND**
    - Documentation of all previous therapies tried; **AND**
    - Baseline results of **one** of the following:
        - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); **OR**
        - Motor Function Measure Score (MFM-32); **OR**
        - Revised Upper Limb Module (RULM); **OR**
        - Hammersmith Infant Neurological Examination Module 2 (HINE-2); **OR**
        - Hammersmith Functional Motor Scale Expanded (HFMSE); **OR**
        - Bayley Scales of Infant and Toddler Development, Third Addition (BSID-III or Bayley-III)
- Recipient with SMA Type 2 or Type 3 must be non-ambulatory. [Only 14% of patients in Part 1 of Study 2 were ambulatory (approximately 7 patients) which was dose-finding and exploratory. Part 2 of Study 2 focused on motor function but had no ambulatory patients.]

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Dosing requested is not consistent with recipient's age and weight; **OR**
- Recipient is pregnant; **OR**
- Recipient has hepatic impairment; **OR**
- Recipient takes a Multidrug and Toxin Extruder (MATE1) substrate such as metformin, cimetidine or acyclovir; **OR**
- Recipient has concomitant or previous administration of a SMN2-targeting antisense oligonucleotide, SMN2 splicing modifier or gene therapy either in a clinical study or as part of medical care;
    - Recipient has been given Zolgensma® (onasemnogene abeparvovec-xioi); **OR**
    - Recipient has history of taking Spinraza® (nusinersen); **OR**
- Recipient has the presence of advanced SMA with permanent ventilation dependence which is defined as requiring a tracheostomy **OR** more than 21 consecutive days of either non-invasive ventilation for ≥ 16 hour per day or intubation; **OR**
- Recipient has been hospitalized in the past 60 days with a pulmonary event; **OR**
- Recipient has had surgery for scoliosis or hip fixation in the last year.

CONTINUATION CRITERIA:

- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current weight; **AND**
    - Current labs including liver function tests; **AND**
    - Female recipients of childbearing potential must have a negative pregnancy test prior to PA renewal **OR** has documentation of contraception usage; **AND**
    - Documentation of continued physical therapy; **AND**
    - Documentation of response to therapy using the same measuring scale as the baseline score; **AND**
- Recipient must demonstrate a clinical response to EVRYSDI by either an improvement in motor function score or no decline in test score compared to baseline; **AND**
- Recipient should not be taking concomitant therapy with Spinraza® or have received Zolgensma®; **AND**
- Recipient does not have hepatic impairment; **AND**
- Recipient does not have a tracheostomy or require a ventilator.

QUANTITY EDITS:

Based on max dose of 5 mg per day, 3 bottles (240mL total) per 31 days

DISCUSSION:

Chair stated that clinical trial data for Type 1 patients was promising but Type 2 and 3 were minimal and has not shown benefit at this time. Dr. Magee stated that he consulted the ACH neurologist. The neurologist had concerns about requiring a patient to lose motor function before we begin treatment. Dr. Magee agreed with the neurologist that it makes no sense to wait until non-ambulatory before approving treatment. Dr. Golden asked if all of these kids have progressive disease. Dr. Johnson discussed Sunfish 1 trial which had no comparator or control arm (historical control), and Sunfish 2 trial was a randomized control trial. Sunfish 1 had a 3.99 point change on MFM32 scale. Sunfish 2 showed a statistically significant change of 1.55 points but that is on a 96 point scale. Therefore, the small increase would not be clinically significant. The minimal important difference (MID) of 3 points was defined during the trials, and Sunfish 2 did not meet that benchmark. Dr. Golden stated that in certain populations it would be considered

investigational when results are pending and unknown. There is potentially a way of covering populations that are investigational. Dr. Mancino stated that the ambulation issue could be tied to another concern of prior treatment. Why would we approve this medication when a patient is progressing and has failed the other available treatments? Stopping the other medications could be due to failure or intolerance. Intolerance would be a different issue. There is nothing in this data that says it will prevent progression. Dr. Mancino stated that we shouldn't support the use of this medication without clear evidence. Dr. Magee agreed that intolerance to the other agents could warrant a switch. Chair asked for clarification—if the patient tried Zolgensma, Evrysdi would be denied, and if they tried and failed Spinraza it would be a denial, but Evrysdi could be approved for an intolerance to Spinraza. Dr. Golden stated that Zolgensma and Spinraza are invasive medications in their administration as opposed to this oral agent. Chair stated that based on WAC pricing alone, Evrysdi would be cheaper than Spinraza per year of treatment. The Chair asked for Dr. Neuhofel's opinion. She stated that a patient with transportation problems would have a reason to start oral therapy. Dr. Johnson disagreed based on Sunfish 1 and Sunfish 2 trials. Spinraza had Cherish data that did find statistically significant difference with RCT. Dr. Johnson felt that changing to Evrysdi just to get an oral option would be a waste of Medicaid money and a poor decision clinically. Dr. Johnson stated that we would need to define intolerance. Dr. Mancino stated that it would have to be a medically documented adverse reaction. Dr. Johnson asked if we should only allow Evrysdi for SMA type 1 patients. Dr. Podrazik referenced UptoDate which did not have great data either. Dr. Podrazik asked about other state trends. Chair stated that the polled states were a mixed bag. No polled states only allowed Type 1 patients. Chair asked Elizabeth Pitman about legality of only allowing Type 1 at this time. She stated we would need to discuss with Office of Chief Counsel. Dr. Golden stated that as a non-voting member he could not make a motion, but he suggested that Type 1 be included and Type 2 and 3 be deferred to a later meeting when more data is available that shows benefit for these patients. Dr. Johnson agreed and made a proposed amendment to reflect that Type 2 and 3 should not be included at this time. Dr. Johnson also stated that concurrent use of Spinraza in Type 1 patients should not be approved.

ACTION:

Motion was made to accept criteria as amended by Dr. Johnson; seconded by Dr. King. Dr. Bemberg was not available for voting. All members present voted by roll call to accept as written. Motion passed.

7. ENSPRYNG™ (satralizumab) injection

Chair discussed neuromyelitis optica spectrum disorder, symptoms of NMOSD, treatment options for NMOSD, and dosing requirements for Enspryng.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of neuromyelitis optica spectrum disorder and anti-aquoporin-4 (AQP4) antibody positive **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have **one** core clinical characteristics from the following:
    - Optic neuritis; **OR**
    - Acute myelitis; **OR**
    - Area postrema syndrome (unexplained hiccups or nausea and vomiting); **OR**
    - Acute brainstem syndrome; **OR**
    - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions; **OR**
    - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
- Recipient has an Expanded Disability Status Scale (EDSS) score between 0-6.5; **AND**
- Recipient has clinical evidence of at least 1 relapse in the previous 12 months; **AND**

- Prescriber must submit the following:
  - Current chart notes with documentation of symptoms of inflammation; **AND**
  - Current labs including CBCs, lipids, and LFTs; **AND**
  - Current Hepatitis B test results including surface antigen (HBsAg) and anti-HBV tests (HBcAb); **AND**
  - Current tuberculosis test results for active and latent infections; **AND**
  - Documentation of previous therapies trialed (i.e. corticosteroids, immunosuppressants, plasma exchange); **AND**
  - Documentation of AQP4 antibody tests results; **AND**
  - MRI results if needed for confirmation of diagnosis.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has an active Hepatitis B infection; **OR**
- Recipient has active or untreated latent tuberculosis; **OR**
- Recipient has a known active infection (excluding fungal infections of nail beds) within 4 weeks prior to initiation of therapy; **OR**
- Medical necessity over immuno-suppressive therapy has not been established; **OR**
- ALT or AST is > than 5X ULN with an elevation in bilirubin; if no elevation in bilirubin, the recipient may continue ENSPRYNG after AST and ALT return to normal. If that takes longer than 12 weeks, recipient must restart with loading dose.

CONTINUATION CRITERIA:

- Recipient has been compliant on therapy; **AND**
- Recipient must show improvement in symptoms associated with optic nerve, spinal cord, and brainstem inflammation; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including CBCs, lipids, and LFTs (LFTs should be monitored every 4 weeks for the first 3 months then every 3 months; Neutrophils should be monitored every 4-8 weeks.)

QUANTITY EDITS:

#1/ 28 days (first month will require a quantity override to allow 3 injections)

DISCUSSION:

Dr. Johnson states that Soliris has the same indication and both products have similar efficacy. She states that Soliris is more expensive, and we should consider updating Soliris criteria for this indication to require Enspryng first. No changes to presented criteria.

ACTION:

Motion was made to accept criteria as presented by Dr. Johnson; seconded by Dr. Gettman. Dr. Bemberg was not available for voting. All members present voted by roll call to accept as written. Motion passed.

8. INQOVI® (cedazuridine and decitabine) tablet

Chair discussed mechanism of action for Inqovi, information on myelodysplastic syndrome, treatment options on MDS, and dosing requirements for Inqovi.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient is ≥ 18 years of age; **AND**
- Recipient has a documented diagnosis of myelodysplastic syndrome (MDS) **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including CBC with differential, BMP, and LFTs; **AND**
    - Female recipients of childbearing potential must have a negative pregnancy test prior to beginning Inqovi® **OR** has documentation of contraception usage; **AND**
    - Documentation of prior therapies with response; **AND**
- Recipient has an absolute neutrophil count (ANC) > 1,000/µL and platelets > 50,0000/µL; **AND**
- Recipient has Total or direct bilirubin ≤2 × upper limit of normal (ULN); AST/SGOT and ALT/SGPT ≤2.5 × ULN; **AND**
- Recipient has serum creatinine ≤1.5 × ULN or calculated creatinine clearance or glomerular filtration rate >50 mL/min/1.73 m^2; **AND**
- Prior authorizations will be approved for only one (1) month at a time.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient does not meet lab approval criteria; **OR**
- Recipient is taking concomitant IV decitabine; **OR**
- Recipient had cytotoxic chemotherapy or prior azacitidine or decitabine within 4 weeks of first dose; **OR**
- Recipient has rapidly progressive or highly proliferative disease (total white blood cell count of >15 × 10^9/L) or other criteria that render the subject at high risk of requiring intensive cytotoxic chemotherapy within the next 3 months; **OR**
- Recipient has a life-threatening illness or severe organ system dysfunction, such as uncontrolled congestive heart failure or chronic obstructive pulmonary disease, or other reasons including laboratory abnormalities, which could compromise the recipient's safety, interfere with absorption or metabolism.

CONTINUATION CRITERIA:

- Recipient has no disease progression or unacceptable toxicity; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of response to therapy; **AND**
    - Current labs including CBC with differential, BMP, and LFTs (CBCs must be drawn prior to every cycle); **AND**
    - Female recipients of childbearing potential must have a negative pregnancy test prior to PA renewal **OR** has documentation of contraception usage.

QUANTITY EDITS:

#5 tablets/ 28 days

DISCUSSION:

Dr. Johnson stated that the published data with a single arm trial hasn't shown the rationale for this combination product over IV decitabine alone. Dr. Johnson requested the addition of medical necessity of Inqovi over IV decitabine.

ACTION:

Motion was made to accept criteria as amended by Dr. Johnson; seconded by Dr. Podrazik. Dr. Bemberg was not available for voting. All members present voted by roll call to accept as written. Motion passed.

9. ORAL CGRP ANTAGONISTS

Chair discussed the dosing requirements for both Ubrelvy and Nurtec ODT.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of acute migraines with or without auras **OR** a diagnosis consistent with FDA indication; **AND**
- Recipient must have a failure of **at least TWO** (2) preferred $5HT_{1B/1D}$ receptor agonists using two (2) different chemical agents not just different dosage forms (sumatriptan tablets, Imitrex nasal spray, rizatriptan tablets, or Zomig nasal spray) at maximally tolerated doses unless recipient has one of the following contraindications:
    - 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
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of migraine frequency and severity/duration; **AND**
    - List of all therapies trialed with timeframes; **AND**
    - Attestation that the beneficiary has been evaluated for severe hepatic impairment and severe renal impairment and made the appropriate dose adjustment if necessary.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient requires continued use of a strong CYP3A4 inhibitor (i.e. ketoconazole, itraconazole, clarithromycin, etc.) or a strong CYP3A4 inducer (rifampin) for both UBRELVY and NURTEC ODT; recipient requires concomitant use of P-gp (i.e. amiodarone, carvedilol, macrolides) or BCRP inhibitors (i.e. statins) for NURTEC ODT; **OR**
- Recipient has end stage renal disease (CLcr <15 mL/min); **OR**
- NURTEC ODT recipient has severe hepatic impairment (Child-Pugh Class C); **OR**
- UBRELVY recipient is requesting 100 mg and has severe hepatic impairment (Child-Pugh Class C) or severe renal impairment (CLcr 15-29 mL/min); **OR**
- Recipient does not have improvement while on the oral CGRP agonist.

CONTINUATION CRITERIA:

- Recipient demonstrates a positive response with a decrease in the severity/duration of migraines; **AND**
- Recipient must submit the following:
    - Current chart notes; **AND**
    - Documentation of current migraine frequency and severity/duration.

QUANTITY EDITS:
UBRELVY
#10 pills / 30 days (both strengths)—Package size is #10

NURTEC ODT
#8 pills / 30 days—Package size is #8

DISCUSSION:
Dr. Johnson asked if there is a possibility to add this class to the PDL. Chair stated that was a possibility, but we are waiting for potential new products to become available. Waiting would ensure fair opportunity for PDL placement. No changes to criteria were suggested.

ACTION:
Motion was made to accept criteria as presented by Dr. Johnson; seconded by Dr. Miller. Dr. Bemberg was not available for voting. All members present voted by roll call to accept as written. Motion passed.

10. DOJOLVI™ (triheptanoin) liquid

Chair discussed the mechanism of action for Dojolvi, information on long-chain fatty acid oxidation disorders, and dosing requirements for Dojolvi.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient has a confirmed diagnosis of long-chain fatty acid oxidation disorder; **AND**
- Recipient is under the care of a clinical specialist knowledgeable in appropriate disease-related dietary management based upon current nutritional recommendations; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation confirming the diagnosis of LC-FAOD with one of the following:
        - Acylcarnitine profiles from a newborn screen; **OR**
        - Fatty acid oxidation probe studies in cultured fibroblasts (low enzyme activity); **OR**
        - Mutation analysis containing one of the following mutations—CPT2, ACADVL, HADHA, or HADHB;
    - Total daily dose based on required daily caloric intake (DCI) X target % of DCI; **AND**
    - Documentation of symptoms; **AND**
    - Documentation of diet plan; **AND**
    - Baseline echocardiogram with documented left ventricular ejection fraction.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has pancreatic insufficiency; **OR**
- Recipient requires concomitant pancreatic lipase inhibitors (e.g. orlistat); **OR**
- Recipient is receiving another medium-chain triglyceride product; **OR**
- Recipient has a feeding tube manufactured of polyvinyl chloride (PVC).

CONTINUATION CRITERIA:

- Recipient demonstrates an improvement in symptoms; **AND**

- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current total daily dose; **AND**
    - Documentation of current symptoms if applicable.

QUANTITY EDITS:
No edits as volume required is not consistent between recipients.

DISCUSSION:
Dr. Johnson stated that there is a medium chain product OTC (Beta-qik). Dr. Johnson stated that the efficacy seems to be the same, but the OTC product is much cheaper. The suggestion was made to require the medical necessity of Dojolvi over the OTC product. Dr. Mancino stated that the disease state involves long-chain fatty acid but not medium-chain. The chair asked the Dojolvi speaker to address this discrepancy. Dr. Johnson asked for the endpoints in the trial. The speaker stated that increased energy and improvement in certain cardiac parameters. The chair stated that we cannot force the requirement of Beta-qik as this OTC product would not be covered by Medicaid. Dr. Boudreaux clarified that Beta-qik is not a rebateable product. Dr. Johnson discussed results from a trial for seizures. Dr. Johnson abstained from voting. Chair stated that we can ask for the medical necessity over other available options.

ACTION:
Motion was made to accept criteria as amended by Dr. Mancino; seconded by Dr. Podrazik. Dr. Johnson abstained from voting. Dr. Bemberg was not available for voting. All other members present voted by roll call to accept as amended. Motion passed.

IV. REPORTS

A. ProDUR Report

Dr. Karen Evans from Magellan gave the ProDUR reports for July-September 2020. The percentage of total overrides remained roughly the same. Approximately 75% of alerts were cancelled at POS. Due to temporary removal of early refill edits due to COVID, values have changed slightly. High Dose, Drug-Drug Interaction, Early Refill, Incorrect Duration and Therapeutic Duplication overrides were similar to the previous quarter with small differences. Despite the removal of edits due to COVID, incorrect duration and high dose overrides returned to near normal levels based on pharmacist overrides in POS system. The ProDUR system appears to have aided pharmacists in making appropriate decisions on overrides.

Dr. Cinnamon Pearson gave the combined PASSE ProDUR report for 4th quarter of SFY2020. The PASSEs had a combined 240,465 paid claims with 40,497 ProDUR alerts resulting in 22,398 cancelled claims or 55.3% of alerts cancelled at POS.

B. RDUR Report

1. Dr. Scott Donald from HID gave a presentation on the department's Retrospective Drug Utilization Review Report for second quarter of calendar year 2020 (April 2020-June 2020) including a Case Summary Report, Program Evaluation Report, Lock-In Program Report, Cost Report by Category, and Cost Report by Claim. Data received for calculations ended in May 2020 due to conversion of services to Magellan. This report will be the final report for HID.

2. Dr. Lynn Boudreaux from Magellan presented intervention letter data for July-September 2020, the quarterly lock-in report, and potential intervention criteria to be discussed by the DUR board for

November 2020, December 2020, and January 2021. The Board made recommendations to perform intervention review on the following:

November 2020—criteria 7980; Member 18 or older with stimulant type ADHD meds and no ADHD diagnosis
December 2020—criteria 15142; Statin non-compliance 60-day gap
January 2021—criteria 7828; Use of triptan without a migraine prevention medication

- Motion to accept the recommended intervention criteria was made by Dr. Miller; seconded by Dr. Boone. Dr. Magee, Dr. Mancino, Dr. Bemberg were not available for voting. All other members present voted by roll call to accept as presented. Motion passed.

C. Meeting adjourned at 12:07 p.m.