**DUR Board Meeting**
**January 20, 2021**
**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.
Paula Podrazik, M.D.
James Magee, M.D.
Clint Boone, Pharm. D.
Michael Mancino, M.D.

**Medicaid Pharmacy Representatives Present**
Cinnamon Pearson, Pharm.D., Chair
Cynthia Neuhofel, Pharm.D. (DHS)
Karen Evans, P.D. (Magellan)
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
Brian King, Pharm.D
Elizabeth Pitman, J.D. (DHS)

Meeting held in a ZOOM webinar due to COVID-19. A quorum was present, and the chair called the meeting to order at 8:36 a.m.

# I. SPEAKERS

The Chair stated there were 2 speakers present to give public comment today on 3 medications:

a. Orilissa® (RoxAnn Dominguez, Pharm D from Abbvie)
b. Oriahnn™ (RoxAnn Dominguez, Pharm D from Abbvie)
c. Promacta® (Andrew Howe, Pharm D from Novartis)

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

d. Speakers available (no public comments but available for questions)
    1. Eardie Curry, PhD from Genentech
    2. Jim Musick from GSK

# 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. Reimbursement rates are based on WAC, FUL, or NADAC and do not include rebate information.
3. A complete review of the DUR bylaws will be conducted during the April 2021 meeting, and there will be a discussion of PA review process for new medications not yet reviewed by the DUR Board.
4. There is a new opioid information tab on the Magellan website for DUR educational purposes.
5. There has been updated information placed on the Magellan website for immunizations and vaccines.

B. **REVIEW MINUTES FROM THE OCTOBER 2020 QUARTERLY MEETING**
Motion by Dr. Bemberg to approve the minutes as written; Dr. Mancino 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 OCTOBER 21, 2020 DUR BOARD MEETING AND NOVEMBER 12, 2020 DRC MEETING**

**Preferred Drug List changes were effective January 1, 2021:** Angiotensin modulators (ACE inhibitors, ARBs, renin inhibitors, and combination products), calcium channel blockers, cytokine and CAM antagonists (targeted immune modulators), immunomodulators for asthma, stimulants and related agents, and thrombopoiesis stimulating proteins.

**DUR PA manual review drugs' criteria was effective immediately:** Palforzia™ (peanut allergy), Fasenra® (benralizumab) injection, Qinlock™ (ripretinib) tablet, Kynmobi™ (apomorphine hydrochloride) SL films, Fintepla® (fenfluramine) oral solution, Evyrsdi™ (risdiplam) powder, Enspryng™ (satralizumab) injection, Inqovi® (cedazuridine and decitabine) tablet, Oral CGRP antagonists (Ubrelvy™ and Nurtec™ ODT), and Dojolvi® (triheptanoin) liquid;

**Point-of-sale and claim edit updates:** CII stimulant update (effective February 10, 2021) and controlled drug early refill threshold update (effective January 20, 2021)

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

1. **ISOTRETINOIN**

Chair discussed estimated reimbursement rate, indication, information on severe recalcitrant nodular acne, treatment recommendations, iPLEDGE® program, dosing, and recommended approval/denial criteria.

**SUGGESTED CRITERIA:**

- Recipient must be ≥ 12 years of age; AND
- Prescriber must be a dermatologist; AND
- Recipient must have a diagnosis of severe recalcitrant nodular acne with many inflammatory nodules measuring a diameter of 5 mm or greater; AND
- Recipient has been unresponsive to conventional therapy, including 3 consecutive months using at least 2 of the following:
    - Oral antibiotics (e.g., doxycycline, minocycline)
    - Oral contraceptives (females only)
    - Oral spironolactone (females only)
    - Topical retinoids, topical antibiotics, and/or benzoyl peroxide
    - Combination of oral antibiotics with benzoyl peroxide

**Topical acne medications are not covered by Arkansas Medicaid per Social Security Act 1927.

- Prescriber, pharmacy, wholesaler, and recipient must all be registered with the iPLEDGE® Program. Pharmacy claims will not process without all registrations being active; AND
- Requests for Absorica 25 mg and 35 mg AND Absorica LD require medical necessity over other options; AND
- Prescriber must submit the following:
    - Current chart notes with documentation of severity of acne along with previous therapies including any OTC topical options; AND
    - Current labs including CBC, lipid profile, LFTs, and glucose; AND
    - Signed copy of iPLEDGE Informed Consent form for both male and female recipients. Female recipients must also sign the Pregnancy Prevention Consent form. If the recipient is under 18, the parent or guardian needs to sign the form in the blank provided. Only the patient is required to initial each item; AND
    - Documentation that female recipient of reproductive potential is taking two reliable forms of birth control (one of which must be a primary form—tubal sterilization, male vasectomy, IUD, hormonal contraception) beginning one month before starting isotretinoin and for one month after stopping treatment; AND
    - Initial prescription requires documentation of two negative blood or urine pregnancy tests for female recipients of reproductive potential. The first test may be obtained from the prescriber, and the second test must be performed by a CLIA-certified lab at least 19 days after first test. Check Patient Health Conditions to see if HCG test was done (may be used as confirmation if pregnancy tests results are not in the chart notes); AND
    - Requested dose (PA is dose specific); AND
- Initial PA will be approved for a maximum of 155 days; AND
- Requests for diagnoses other than acne will be reviewed by DHS clinical review team on a case-by-case basis.

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Prescriber is requesting more than two (2) courses of therapy; OR
- Recipient is pregnant; OR
- All required information is not provided; OR
- Recipient has uncontrolled hypertriglyceridemia.

**CONTINUATION CRITERIA:**

- Recipient has persistent or recurring severe nodular acne despite the initial 4 months of therapy; AND
- Recipient must have at least 8 weeks between the first and second course of therapy; AND
- Prescriber must submit the following:
    - Current chart notes; AND
    - Current labs; AND
    - Current pregnancy test results.

**QUANTITY EDITS:**

- #60/30 days for max of 4 months per authorization

**DISCUSSION:**
Dr. Johnson asked if we should be able to require topical retinoids, topical antibiotics, or benzoyl peroxide if not covered by the plan. The Chair stated that documentation of the use in the chart notes and prescribers attestation would be taken into consideration.

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

## 2. GnRH RECEPTOR ANTAGONIST UPDATE (Orilissa® and Oriahnn™)

Chair discussed endometriosis, uterine leiomyomas, and information for Orilissa® and Oriahnn™--estimated reimbursement rate, indications, mechanism of action, and dosing.

**SUGGESTED CRITERIA:**
**APPROVAL CRITERIA for both ORILISSA and ORIAHNN unless specified:**

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has a diagnosis of moderate to severe pain associated with endometriosis for ORILISSA requests **OR** a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas/fibroids for ORIAHNN requests **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must be premenopausal; **AND**
- Attestation that recipient of reproductive potential will use effective non-hormonal contraception during treatment and for 1 week after discontinuing therapy; **AND**
- Recent dual-energy X-ray absorptiometry (DXA) scan results for documentation of baseline bone mineral density for patients at high risk of osteoporosis. Examples of high-risk patients include but are not limited to the following:
    - History of low-trauma fracture
    - Taking other medications that may decrease BMD (i.e., corticosteroids, anticonvulsants, PPIs)
    - Parent or sibling with osteoporosis
- Documentation of negative pregnancy status by one of the following:
    - Current negative pregnancy test results in patient with reproductive potential; **OR**
    - Documentation of beginning medication within 7 days of onset of menses; **OR**
    - Documentation of tubal ligation
- Provider must submit the following for **ORILISSA** requests:
    - Current chart notes documenting symptom history, all previous treatments for endometriosis, and that the pelvic pain is not due to other causes; **AND**
    - Current labs including CBC and LFTs; **AND**
    - Confirmation of endometriosis by pelvic exam results **AND** at least one of the following:
        - Transvaginal ultrasound; **OR**
        - Magnetic Resonance Imaging; **OR**
        - Laparoscopy or laparotomy; **OR**
        - Biopsy report confirming diagnosis.
    - Documentation that recipient has tried and failed **at least 2** medications in the following drug classes with at least a **3-month history** of each:

        - NSAID and/or acetaminophen usage
        - Contraceptives (Combined estrogen-progestin treatments include combined oral contraceptive pills, transdermal patches, and vaginal rings)
        - Progesterone-only therapy (e.g., medroxyprogesterone, norethindrone, dienogest)
        - Intrauterine device
    - Letter outlining the medical necessity of ORILISSA over other treatment options (i.e., OTC pain medications, hormonal contraception, progestin therapy, and surgery); **AND**
    - Recipient must use the lowest effective dose possible but may titrate taking into account severity of symptoms. Documentation of initial starting dose from one of the following:
        - 150 mg once daily for 24 months--Recipient has no hepatic impairment or dyspareunia
        - 200 mg twice daily for 6 months—Recipient has dyspareunia
        - 150 mg once daily for 6 months—Recipient has moderate hepatic impairment (Child-Pugh B)
- Provider must submit the following for **ORIAHNN** requests:
    - Current chart notes documenting symptom history and all previous treatments for uterine leiomyomas/fibroids with heavy menstrual bleeding/painful menstrual cycles; **AND**
    - Current labs including CBC and LFTs; **AND**
    - Confirmation of uterine fibroids by pelvic exam results **AND** at least one of the following:
        - Transabdominal or transvaginal ultrasound; **OR**
        - Magnetic Resonance Imaging; **OR**
        - Computerized Tomography scan; **OR**
        - Hysterosalpingogram or sonohysterogram; **OR**
        - Laparoscopy or hysteroscopy
    - Letter outlining the medical necessity of ORIAHNN over other treatment options (i.e., OTC pain medications, hormonal contraception, IUD, and surgery); **AND**
    - Documentation that recipient has tried and failed **at least 2** medications in the following drug classes with at least a **3-month history** of each:
        - NSAID and/or acetaminophen usage
        - Contraceptives (Combined estrogen-progestin treatments include combined oral contraceptive pills, transdermal patches, or vaginal rings)
        - Progesterone-only therapy (e.g., medroxyprogesterone, norethindrone, dienogest)
        - Intrauterine device
        - Tranexamic acid

**DENIAL CRITERIA for both ORILISSA and ORIAHNN unless specified:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is postmenopausal; **OR**
- Recipient has a diagnosis of osteoporosis or osteopenia (T-score < -1.0 SD); **OR**
- Recipient has history of major depression or PTSD in last 2 years **OR** history of major psychiatric disorder (i.e., schizophrenia or bipolar) **OR** history of suicide attempt in the last year; **OR**
- Recipient is pregnant; **OR**
- Recipient has severe hepatic impairment (Child-Pugh C), and dose modifications may be needed for moderate hepatic impairment; **OR**
- Recipient requires concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil); **OR**

- Prescriber requests for > 24 months of treatment for ORIAHNN and ORILISSA patients with no coexisting conditions; requests for > 6 months of treatment for ORILISSA patients with either dyspareunia or moderate hepatic impairment; **OR**

**DENIAL CRITERIA for both ORILISSA and ORIAHNN unless specified:**

- ORILISSA recipient has chronic pelvic pain that is not caused by endometriosis (e.g., pelvic inflammatory disease, inflammatory bowel disease, ovarian cysts); **OR**
- ORIAHNN recipient with any of the following:
    - Over 35 years of age **and** currently smokes; **OR**
    - History of breast cancer or other hormonally-sensitive malignancies; **OR**
    - History of or high risk for arterial, venous thrombotic or thromboembolic disorder; **OR**
        - Deep vein thrombosis or pulmonary embolism; **OR**
        - Vascular disease; **OR**
        - Thrombogenic valvular or thrombogenic rhythm disease of the heart; **OR**
        - Inherited or acquired hypercoagulopathies; **OR**
        - Uncontrolled hypertension; **OR**
        - Headaches with focal neurological symptoms or have migraine headaches with aura (over 35 years of age); **OR**
    - History of heavy bleeding associated with uterine fibroids that has not caused anemia (hemoglobin level ≤ 12 g/dL); **OR**
    - Undiagnosed abnormal uterine bleeding.

**CONTINUATION CRITERIA:**

- Recipient has been compliant on medication; **AND**
- Recipient has noted improvement of symptoms with noted reduction in endometriosis-associated pain in ORILISSA patients and decrease in heavy menstrual bleeding with improvement of hemoglobin level in ORIAHNN patients; **AND**
- Recipient remains free from hepatic impairment, osteoporosis, psychiatric disorders, and pregnancy; **AND**
- Recipient has not surpassed the maximum treatment durations; **AND**
    - ORIAHNN—has not exceeded 24 months total
    - ORILISSA—has not exceeded 24 months total for no coexisting condition **OR** has not exceeded 6 months in dyspareunia patients and those with moderate hepatic impairment
- Prescriber must submit the following:
    - Current chart notes with documentation of positive response to therapy; **AND**
    - Current labs including CBC and LFTs; **AND**
    - Documentation of negative pregnancy status; **AND**
- Attestation that recipient of reproductive potential will continue to use effective non-hormonal contraception during treatment.

**QUANTITY EDITS:**

**ORILISSA**

- **150 mg**--#28/28 days (max of 24 months)
- **200 mg**--#56/28 days (max of 6 months)

**ORIAHNN 300-1-0.5 mg/ 300 mg**

- #56/28 (max of 24 months)

**DISCUSSION:**

No discussion

**ACTION:**

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

**3. THROMBOPOIESIS STIMULATING PROTEINS (Promacta®, Mulpleta®, Doptelet®, and Tavalisse™)**

Chair discussed the estimated reimbursement rate for agents, indications for all agents, mechanism of action, information on chronic immune thrombocytopenia, information on thrombocytopenia with CLD, information of aplastic anemia, and dosing for all agents.

**SUGGESTED CRITERIA:**

**MULPLETA APPROVAL CRITERIA:**

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has thrombocytopenia with baseline platelet count of < 50,000/µL **AND** a diagnosis of chronic liver disease **AND** is scheduled to undergo a procedure **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must be scheduled for a procedure that would require a platelet transfusion to address risk of bleeding (i.e,. liver ablation/coagulation, transcatheter arterial chemoembolization, liver biopsy, gastrointestinal endoscopy, dental extraction, diagnostic paracentesis or laparocentesis, septoplasty, embolization of splenic artery aneurysm, bone marrow biopsy, removal of cervical polyp or inguinal hernia repair); **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of upcoming procedure and history of liver disease; **AND**
    - Prescriber must submit documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion); **AND**
    - Current labs including CBC and LFTs (must be within a week of PA request); **AND**
    - Type of procedure; **AND**
    - Date of procedure (Dosing must begin 8-14 days prior to procedure, and dosing should end 2-8 days prior to procedure); **AND**
    - Document if a platelet transfusion will be given prior to surgery; **AND**
    - If used previously, provide chart notes and labs with documentation of response.

**MULPLETA DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient platelet count is ≥ 50,000/µL at time of PA request; **OR**
- Recipient was a non-responder to previous therapy of either Doptelet or Mulpleta (Defined as not reaching a platelet count of at least 50,000/µL **AND** platelet count did not increase by at least 20,000/µL from baseline); **OR**

- Prescriber requesting more than a 7 days' supply; **OR**
- Prescriber is attempting to normalize platelet counts; **OR**
- Recipient has a history of arterial or venous thrombosis **OR** congenital or acquired thrombotic disease; **OR**
- Prescriber determines recipient will need a platelet transfusion for procedure prior to beginning therapy; **OR**
- Recipient is prescribed concomitant thrombopoietic agents or spleen tyrosine kinase inhibitor (i.e., eltrombopag, romiplostim, fotamatinib); **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient's procedure includes laparotomy, thoracotomy, open-heart surgery, craniotomy, or organ resection; **OR**
- Recipient has Child-Pugh C liver disease or uncontrolled hepatic encephalopathy.

**CONTINUATION CRITERIA:**

- No continuation as this is a 7-day course of therapy

**DOPTELET APPROVAL CRITERIA:**

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has a diagnosis of either thrombocytopenia due to chronic liver disease and scheduled for a procedure **OR** chronic immune thrombocytopenia with insufficient response to a previous treatment **OR** a diagnosis consistent with FDA indications; **AND**

**Chronic Liver Disease**

- Recipient with chronic liver disease requires dosing based on platelet count prior to procedure; **AND**
    - Platelet count < 40,000/µL—dose is 60mg once daily for 5 days
    - Platelet count ≥ 40,000/µL to < 50,000/µL—dose is 40mg once daily for 5 days
- Recipient must be scheduled for a procedure that would require a platelet transfusion to address risk of bleeding without this medication (i.e., liver ablation/coagulation, transcatheter arterial chemoembolization, liver biopsy, gastrointestinal endoscopy, dental extraction, diagnostic paracentesis or laparocentesis, septoplasty, embolization of splenic artery aneurysm, bone marrow biopsy, removal of cervical polyp or inguinal hernia repair); **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of upcoming procedure and history of liver disease; **AND**
    - Documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion); **AND**
    - Current labs including CBC and LFTs (must be within a week of PA request); **AND**
    - Type of procedure; **AND**
    - Date of procedure (Dosing must begin 10-13 days prior to procedure and end 5-8 days prior to procedure); **AND**
    - Document if a platelet transfusion will be given prior to surgery; **AND**
    - If used previously, provide chart notes and labs with documentation of response.

**Chronic Immune Thrombocytopenia**

- Recipient with chronic immune thrombocytopenia has a baseline platelet count of < 50,000/µL; **AND**
    - Initiate dose at 20 mg once daily
    - Titrate dose to keep platelets ≥ 50,000/µL with a max dose of 40 mg once daily
- Recipients requiring concomitant moderate or strong dual inhibitors of CYP2C9 and CYP3A4 must start dose at 20 mg three times per week; **AND**
- Recipient requiring concomitant moderate or strong dual inducers of CYP2C9 and CYP3A4 must start dose at 40 mg once daily; **AND**
- Recipient has documented failure of two (2) or more prior chronic immune thrombocytopenia therapies (including, but not limited to corticosteroids, immunoglobulins, azathioprine, danazol, cyclophosphamide and/or rituximab) **AND** failure with eltrombopag; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of previous therapies tried; **AND**
    - Documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion, and Promacta (eltrombopag)); **AND**
    - Current labs including CBC and LFTs (must be within a week of PA request); **AND**
    - If used previously, provide chart notes and labs with documentation of response; **AND**
    - Documentation that other causes for low platelets have been ruled out including myelodysplastic syndrome; **AND**
- Initial PA for one month only.

**DOPTELET DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Prescriber is attempting to normalize platelet counts; **OR**
- Recipient has a history of arterial or venous thrombosis **OR** congenital or acquired thrombotic disease; **OR**
- Recipient is prescribed concomitant thrombopoietic agents or spleen tyrosine kinase inhibitor (i.e., eltrombopag, romiplostim, fotamatinib); **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient has a history of hepatocellular carcinoma, cirrhosis, portal hypertension, chronic active hepatitis, or uncontrolled hepatic encephalopathy; **OR**
- Recipient has a baseline platelet count of ≥ 50,000/µL.

**Chronic Liver Disease**

- Prescriber requesting more than a 5 days' supply; **OR**
- Recipient was a non-responder to previous therapy of either DOPTELET or MULPLETA (Defined as requiring a platelet transfusion or any rescue procedure for bleeding up to 7 days following the elective procedure); **OR**
- Prescriber determines recipient will need a platelet transfusion for procedure prior to beginning therapy; **OR**

- Recipient's procedure includes neurosurgical interventions, thoracotomy, laparotomy, or organ resection.

**Chronic Immune Thrombocytopenia**

- Recipient has platelet count <50,000/µL after 4 weeks at 40 mg once daily; **OR**
- Recipient has platelet count >400,000/µL after 2 weeks at 20 mg once weekly; **OR**
- Recipient has a history of myelodysplastic syndrome; **OR**
- Recipient has not received one or more prior chronic immune thrombocytopenia therapies (including, but not limited to corticosteroids, immunoglobulins, azathioprine, danazol, cyclophosphamide and/or rituximab) **AND** eltrombopag.

**CONTINUATION CRITERIA:**

- No continuation for CLD recipient as this is a 5-day course of therapy. See below for ITP requirements.

**TAVALISSE APPROVAL CRITERIA:**

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has a diagnosis of chronic immune thrombocytopenia and has had an insufficient response to a previous treatment **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient has a baseline platelet count of < 50,000/µL; **AND**
- Recipient has documented failure of two (2) or more prior chronic immune thrombocytopenia therapies (including, but not limited to corticosteroids, immunoglobulins, azathioprine, danazol, cyclophosphamide and/or rituximab) **AND** failure with eltrombopag; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of previous treatments; **AND**
    - Current labs including CBC and LFTs (must be within a week of PA request); **AND**
    - Current vital signs including blood pressure; **AND**
    - Documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion, and Promacta® (eltrombopag)); **AND**
    - If used previously, provide chart notes and labs with documentation of response; **AND**
    - Documentation that other causes for low platelets have been ruled out including myelodysplastic syndrome; **AND**
- Initial PA for one month only for first 3 months.

**TAVALISSE DENIAL CRITERIA**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient platelet count is ≥ 50,000/µL at time of PA request; **OR**
- Recipient cannot tolerate the minimum dose of 100 mg once daily; **OR**
- Prescriber is attempting to normalize platelet counts; **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient is in hypertensive crisis with blood pressure > 180/120 mmHg or >160/100 mmHg after 4 weeks of aggressive hypertensive treatment; **OR**
- Recipient has signs of hepatotoxicity with AST/ALT 3X ULN AND Total Bili > 2X ULN; **OR**

- Discontinue if platelet counts do not increase to a level sufficient to avoid clinically important bleeding after 12 weeks.

**CONTINUATION CRITERIA:**

- See below for requirements

**PROMACTA APPROVAL CRITERIA:**

- Recipient must have a diagnosis of thrombocytopenia with chronic immune thrombocytopenia with insufficient response to corticosteroids, immunoglobulin, or splenectomy, **OR** chronic hepatitis C in which thrombocytopenia prevents the initiation of interferon-based therapies, **OR** severe aplastic anemia in combination with standard immunosuppressive therapy as first-line therapy, **OR** severe aplastic anemia with insufficient response to immunosuppressive therapy, **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient has a baseline platelet count of < 50,000/µL; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of previous therapies tried with response; **AND**
    - Current labs:
        - LFTs prior to therapy initiation, every 2 weeks during dose adjustment, then monthly once dosing is stable (If abnormal, monitor weekly); **AND**
        - CBC with differential (including platelets) prior to therapy, every week until platelet count is stable, then monthly; **AND**
    - Documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion); **AND**
    - If used previously, provide chart notes and labs with documentation of response; **AND**
    - Documentation that other causes for low platelets have been ruled out including myelodysplastic syndrome; **AND**
    - Verify required dose—dose reductions may be needed for patients with mild, moderate or severe hepatic impairment and patients with Asian ancestry (such as Chinese, Japanese, Taiwanese, Korean, or Thai) with ITP or severe aplastic anemia; **AND**
- Initial PA for one month only.

**Chronic Immune Thrombocytopenia**

- Recipient must be ≥ 1 year of age; **AND**
- Dose requirements
    - 1-5 years of age begin with 25 mg once daily
    - ≥ 6 years of age begin with 50 mg once daily
    - Max of 75 mg daily
    - Asian ancestry **OR** hepatic impairment, begin with 25 mg once daily
    - Asian ancestry **AND** hepatic impairment, begin with 12.5 mg once daily

**Interferon treatment for Hepatitis C patients**

- Recipient must be ≥ 18 years of age; **AND**
- Dose requirements; **AND**

  - Begin with 25 mg once daily
  - Max of 100 mg once daily
- Recipient must be prescribed interferon-based therapies.

**Severe Aplastic Anemia**

- Recipient must be ≥ 2 years of age; **AND**
- Dose requirements; **AND**
  - First-line with immunosuppressive therapy—
    - 2-5 years of age begin with 2.5 mg/kg
    - 6-11 years of age begin with 75 mg daily
    - ≥ 12 years of age begin with 150 mg daily
    - Do not exceed the initial dose (above are beginning and max doses per age)
  - Refractory—
    - Begin with 50 mg once daily
    - Titrate based on platelet count
    - Max of 150 mg once daily
    - If no hematologic response after 16 weeks, discontinue PROMACTA
  - Asian ancestry or hepatic impairment—
    - ≥ 12 years of age begin with 75 mg daily
    - 6-11 years of age begin with 37.5 mg daily
    - 2-5 years of age begin with 1.25 mg/kg daily
    - Refractory begin with 25 mg once daily
- Treatment duration is maximum of 6 months.

**PROMACTA DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has a diagnosis of myelodysplastic syndrome; **OR**
- Hepatitis C recipient is not being treated for HCV infection or the recipient has been prescribed a direct-acting antiviral agent instead of interferon; **OR**
- Recipient platelet count is ≥ 50,000/µL at time of PA request; **OR**
- Recipient has a history of arterial or venous thrombosis **OR** congenital or acquired thrombotic disease; **OR**
- Platelet count is >400,000/µL after 2 weeks at lowest PROMACTA dose; **OR**
- Aplastic anemia recipient is not prescribed standard immunosuppressive therapy along with PROMACTA for first-line treatment; **OR**
- Prescriber has requested a dose >150 mg daily for aplastic anemia, or >75 mg daily for ITP, or >100 mg daily for interferon treatment of hepatitis C; **OR**
- Prescriber requests PROMACTA for longer than 6 months in aplastic anemia.

**CONTINUATION CRITERIA for all medications:**

- Recipient is compliant on therapy; AND

- Recipient maintains a platelet count of ≥50,000/µL on doses within manufacturer's recommendation; AND
- Prescriber must submit the following:
    - Current chart notes; AND
    - Current labs including CBC and LFTs and labs since last PA review (See approval criteria for lab frequency); AND
    - Documentation of response to therapy (Provide information on required corticosteroids, IVIG, or platelet transfusion during treatment, etc.); AND
    - Dose requested based on abnormal platelet counts; AND
- Hepatitis C recipient remains on Interferon therapy for PROMACTA request.

**QUANTITY EDITS** (quantities outside of edits below will be reviewed on a case-by-case basis):

**TAVALISSE**
- #62/31 days

**PROMACTA**
- 50 mg--#62/31 days; all other strengths--#31/31 days

**MULPLETA**
- #7 per claim/PA

**DOPTELET**
- #15 per claim/PA for platelet <40,000/µL (NDC 71369-0020-15)
- #10 per claim/PA for platelet 40,000-50,000/µL (NDC 71369-0020-10)
- #62/31 days (NDC 71369-0020-30)

**DISCUSSION:**
No discussion

**ACTION:**
Motion was made to accept criteria as presented by Dr. Podrazik; seconded by Dr. Gettman. All members present voted by roll call to accept as presented. Motion passed.

**4. IMMUNOMODULATORS FOR ASTHMA (Fasenra®, Dupixent®, Xolair®, and Nucala®)**

Chair discussed the estimated reimbursement rate for all products, indications for all products, and dosing for all products.

**SUGGESTED CRITERIA:**

**APPROVAL CRITERIA (Asthma diagnosis only--Criteria for other indications remain the same as previously discussed. PA requests for new indications will be reviewed manually on a case-by-case basis.):**

- Recipient must be at least the minimum age (allowed age will be updated if FDA indication changes); **AND**
    - NUCALA—≥ 6 years of age

  - FASENRA--≥ 12 years of age
  - DUPIXENT--≥ 12 years of age
  - XOLAIR—≥ 6 years of age
- Recipient must have a diagnosis consistent with FDA indications (current indication below); **AND**
  - NUCALA—add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype
  - FASENRA—add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype
  - DUPIXENT—add-on maintenance treatment in patients with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
  - XOLAIR—moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids
- Recipient must be compliant on at least two asthma maintenance medications for the last 12 months (one must be an inhaled corticosteroid); **AND**
- Recipient has no therapeutic duplication with any interleukins; **AND**
- Prescriber must be a board-certified Allergy and Immunology specialist; **AND**
- Recipient has 2 or more exacerbations despite compliance on ICS plus an additional controller medication in the last 12 months. Exacerbation is defined as requiring systemic corticosteroids, an emergency department visit, or hospitalization for asthma; **AND**
- Recipient ≥ 18 years of age must have a pre-bronchodilator FEV1 < 80%; Recipient < 18 years of age must have a pre-bronchodilator FEV1 < 90%; **AND**
- Recipient must meet manufacturer's recommendations at baseline for one (1) of the following:
  - Serum IgE (XOLAIR); **OR**
  - Blood eosinophil count (DUPIXENT, NUCALA, AND FASENRA); **OR**
  - Dependent upon oral corticosteroids if not eosinophilic type (DUPIXENT); **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous therapies tried for asthma with response; **AND**
  - Baseline blood eosinophil count for FASENRA, DUPIXENT (if eosinophilic type), AND NUCALA; Baseline serum IgE levels, body weight, and completed form for XOLAIR; **AND**
  - Baseline Asthma Control Questionnaire (ACQ-5) for all patients **OR** Asthma Quality of Life Questionnaire (AQLQ) scores for adults only; **AND**
  - Current Pulmonary Function Test results; **AND**
  - Letter of medical necessity for requested product over the preferred medication (currently FASENRA) and other therapies outlined in treatment guidelines.

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has not been compliant with two asthma maintenance medications for at least 12 months including an inhaled corticosteroid (ICS or ICS/LABA); **OR**
- Recipient has approval for another asthma immunomodulator; **OR**

- Recipient has a baseline blood eosinophil level or baseline serum IgE level that falls outside of manufacturer's requirements; **OR**
- Recipient is a current smoker; **OR**
- Recipient has helminth infections. Pre-existing helminth infections should be treated prior to beginning therapy; **OR**
- If approved, recipient must remain compliant on asthma controller medications including inhaled corticosteroids and immunomodulator.

**CONTINUATION CRITERIA:**

- Recipient is compliant on asthma controller medication (ICS or ICS/LABA) and immunomodulator injection; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of response to therapy after 6 months of treatment; **AND**
    - Current PFTs; **AND**
    - Current blood eosinophil count for FASENRA, DUPIXENT (if eosinophilic type), and NUCALA; **AND**
    - Current serum IgE level and body weight for XOLAIR; **AND**
    - Current Asthma Control Questionnaire (ACQ-5) for all patients **OR** Asthma Quality of Life Questionnaire (AQLQ) scores for adults only; **AND**
- Recipient must have an improvement in FEV1 over baseline; **AND**
- Recipient must have fewer exacerbations; **AND**
- Recipient must have a decrease in blood eosinophil count **OR** serum IgE **OR** decrease in corticosteroid usage; **AND**
- Recipient demonstrates an improvement in ACQ-5 and/or AQLQ scores.

**QUANTITY EDITS:**

**FASENRA--**#1 pen/vial per 8 weeks (will need quantity override for first 3 months)
**DUPIXENT--**#5 syringes per 50 days
**NUCALA--**#3 prefilled syringes/autoinjectors per 28 days (based on other indications)
**XOLAIR--**#8 150 mg prefilled syringe/vial per 28 days; #1 75 mg prefilled syringe per 28 days

**DISCUSSION:**

Dr. Johnson asked to define compliance. The Chair stated that the clinical team may not require 12 fills in 12 months, but at least 75% compliant. Dr. Johnson stated that before moving to an immunomodulator, the ' patient should maximize ICS dose. Dr. Johnson asked how long the PA was good for. The Chair stated that typically initial PAs are 3 months, but we would want to see a response by 6 months. Dr. Johnson stated that this group of drugs is not good for asthma, therefore the patient must be watched longer to see an improvement concerning exacerbations. None of the drugs caused an improvement in quality of life corresponding to a significant improvement in ACQ-5 or AQLQ score. Dr. Johnson suggested that we remove the requirement of improved scores for continuation and require a longer review period when considering exacerbations (at least 12 months). Chair asked the Board their thoughts on compliance with ICSs. Dr. Magee recommended that full compliance with monthly claims (or less depending on how dosed) would be ideal.

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

**5. XPOVIO® (selinexor)**

Chair discussed the estimated reimbursement rate, FDA indications, information on multiple myeloma, information on diffuse large B-cell lymphoma, NCCN guidelines for both indications, and dosing information.

**SUGGESTED CRITERIA:**

**APPROVAL CRITERIA:**

- Recipient must be ≥ 18 years of age; AND
- Recipient must have a diagnosis of multiple myeloma **OR** diffuse large B-cell lymphoma **OR** a diagnosis consistent with FDA indications; AND
- Recipient with multiple myeloma requires one of the following:
    - Recipient must have at least one prior therapy and will take XPOVIO in combination with bortezomib and dexamethasone; **OR**
    - Recipient with relapsed or refractory disease has received at least four prior therapies and disease is refractory to at least two proteasome inhibitors (e.g., bortezomib, ixazomib and carfilzomib), at least two immunomodulatory agents (e.g.,lenalidomide, pomalidomide and thalidomide), and an anti-CD38 monoclonal antibody (e.g., daratumumab) and will take XPOVIO in combination with dexamethasone
- Recipient with relapsed or refractory diffuse large B-cell lymphoma requires a failure of at least 2 lines of systemic therapy; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of diagnosis and previous therapies; **AND**
    - Current labs including CBC with differential, complete metabolic panel, and LFTs; **AND**
    - Required dosage since dose adjustments are required for thrombocytopenia, neutropenia, anemia, extreme nausea/vomiting, diarrhea, hyponatremia, and ocular toxicity (refer to manufacturer's package insert); **AND**
    - Verification that recipient has been prescribed concomitant 5-HT3 receptor antagonists or other anti-nausea agents; **AND**
    - Treatment plan for potential nausea and dehydration; **AND**
- PA's approved month-to-month until stable due to significant thrombocytopenia and neutropenia risks.

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipients with DLBCL that had an autologous hematopoietic stem cell transplantation; **OR**
- Recipient cannot tolerate the following minimum dosages; **OR**
    - 40 mg weekly for multiple myeloma in combination with bortezomib and dexamethasone

  - 60 mg weekly for multiple myeloma in combination with dexamethasone
  - 40 mg weekly for diffuse large B-cell lymphoma
- Recipient is pregnant or breastfeeding; **OR**
- Multiple myeloma recipients are not prescribed the required concomitant therapy based on FDA indications; **OR**
- Recipient has active smoldering multiple myeloma; **OR**
- Recipient has active plasma cell leukemia; **OR**
- Recipient has documented systemic amyloid light chain amyloidosis; **OR**
- Recipient has active CNS multiple myeloma; **OR**
- Recipient with DLBCL has not failed at least two prior therapies; **OR**
- Recipient with relapsed or refractory multiple myeloma has not failed at least four prior therapies.

**CONTINUATION CRITERIA:**

- Recipient has no disease progression or unacceptable toxicity; **AND**
- Recipient with multiple myeloma continues to take bortezomib **and/or** dexamethasone; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy; **AND**
  - Current labs including CBC with differential and complete metabolic panel (especially need neutrophil count, platelets, hemoglobin, and sodium); **AND**
  - Current weight; **AND**
  - Current required dose; **AND**
- Once stable, PA's may be approved 3 months at a time.

**QUANTITY EDITS:**

- #32/ 28 days

**DISCUSSION:**

Dr. Johnson stated that the B-cell lymphoma trials were single-arm trials and only showed durable response. Therefore, there is a question of medical necessity. She also stated that this drug is ranked no higher than clinical trials for B-cell lymphoma. No criteria changes were recommended from those presented.

**ACTION:**

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

# III. NEW BUSINESS

## 1. GAVRETO™ (pralsetinib)

Chair discussed the estimated reimbursement rate for both Gavreto™ and Retevmo™, the FDA approved indications, information on NSCLC, information on medullary thyroid cancer, mechanism of action, dosing and NCCN guidelines.

**SUGGESTED CRITERIA:**

**APPROVAL CRITERIA:**

- Recipient must be ≥ 18 years of age if diagnosed with NSCLC and ≥ 12 years of age for thyroid cancer; **AND**

- Recipient must be diagnosed with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC), advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy, or advanced/metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have non-resectable disease; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of diagnosis with lab work confirming the presence of a RET gene fusion or gene mutation; **AND**
    - Current labs including CBC with differential, complete metabolic panel, calcitonin levels for medullary thyroid cancer; **AND**
    - Current blood pressure (hypertension must be controlled); **AND**
    - Documentation of previous therapies including radioactive iodine in RET fusion-positive thyroid cancer; **AND**
        - NSCLC—may be used first-line, but many patients start on platinum therapy
        - MTC—may have used cabozantinib, vandetanib, or naïve to both agents
        - TC—failure of standard therapy with radioactive iodine and sorafenib and/or lenvatinib
    - Attestation that recipients of reproductive potential are not pregnant and counseled to use effective non-hormonal contraception; **AND**
- Initial approval will be three (3) months

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has no documentation of RET gene fusion or RET gene mutation; **OR**
- Recipient cannot tolerate the minimum dose of 100 mg once daily; **OR**
- Recipient has recurrent interstitial lung disease/pneumonitis (grade 1 or 2) **OR** grade 3 or 4 reaction; **OR**
- Recipient has uncontrolled hypertension (180/100 mmHg)—HTN therapy may be required; **OR**
- Recipient has a history of severe or life-threatening hemorrhage; **OR**
- Recipient has moderate or severe hepatoxicity (may require dose decrease initially); **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient requires concomitant strong CYP3A inhibitor or combined P-gp and strong CYP3A inhibitor (e.g., clarithromycin, ketoconazole, ritonavir); **OR**
- Recipient baseline labs
    - Platelets < 75 X $10^9$/L
    - ANC < 1.0 X $10^9$/L
    - Hb < 9 g/dL
    - CrCl < 40 ml/min
    - Total serum phosphorus > 5.5 mg/dL

**CONTINUATION CRITERIA:**

- Recipient has no evidence of disease progression or unacceptable toxicity; **AND**
- Prescriber must submit the following:

- Current chart notes; **AND**
- Current labs including CBC with differential and complete metabolic panel (LFTs should be monitored every 2 weeks during the first 3 months) and calcitonin level (will increase with medullary thyroid cancer recurrence); **AND**
- Current blood pressure; **AND**
- Attestation that recipient with reproductive potential is not pregnant and continues to use effective non-hormonal contraception.

**QUANTITY EDITS:**

- #120/30 days

**DISCUSSION:**

Dr. Johnson noted that this is not a category 1 drug in NCCN guidelines and lacks data for efficacy. Data came from a non-randomized registrational data set. If they failed previous platinum therapy, then Dr. Johnson could understand trying this medication. Dr. Johnson stated that if we are forced to review this drug, then the proposed criteria is fine.

**ACTION:**

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

## 2. ONGENTYS™ (opicapone)

Chair discussed the estimated reimbursement rate for Ongentys™ and generic Stalevo®, FDA indication, information on "off" episodes of Parkinson's Disease, mechanism of action, and dosing.

**SUGGESTED CRITERIA:**

**APPROVAL CRITERIA:**

- Recipient must be ≥ 18 years of age; AND
- Recipient must have a diagnosis of Parkinson's Disease for at least 3 years and experiencing "off" episodes while compliant on levodopa/carbidopa OR a diagnosis consistent with FDA indications; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including LFTs and renal function; AND
- Recipient should be in Parkinson's Disease stages 2 to 4 in the OFF state in the modified Hoehn and Yahr Scale; AND
- Recipient must be on levodopa/carbidopa for at least one year with a stable dose at least 4 weeks prior to starting ONGENTYS; AND
- Recipient must be taking at least 3 doses of levodopa per day; AND
- Recipient must take ONGENTYS in combination with levodopa/carbidopa; AND
- Recipient must be experiencing at least 2 hours of OFF time per day excluding in the morning prior to first dose of the day; AND
- If taking other PD medications along with levodopa/carbidopa, recipient must be on a stable dose for at least 4 weeks prior to starting ONGENTYS (e.g., COMT inhibitors, MAO-B inhibitors, anticholinergics, and/or amantadine); AND
- Prescriber must provide the medical necessity over the increase in levodopa/carbidopa dose, changing to extended-release formulations, and changing to Stalevo/entacapone + levodopa/carbidopa.

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is diagnosed with severe hepatic impairment (Child-Pugh C); **OR**
- Recipient is diagnosed with end stage renal disease; **OR**
- Recipient has a history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms; **OR**
- Recipient takes concomitant non-selective monoamine oxidase (MAO) inhibitors; **OR**
- Recipient is diagnosed with a major psychotic disorder in the last year (i.e., major depressive disorder, bipolar, psychosis, generalized anxiety disorder); **OR**
- Recipient has < 2 hours a day of OFF time; **OR**
- Recipient has a diagnosis of atypical parkinsonism or secondary parkinsonism variants; **OR**
- Recipient is pregnant or breastfeeding.

**CONTINUATION CRITERIA:**

- Prescriber must submit the following:
  - Current chart notes indicating the patient has responded to therapy indicated by the reduction in "off" episodes and an increase in "on" episodes compared to baseline; **AND**
  - Chart notes monitoring for the absence of adverse effects during treatment including new or worsening dyskinesia, development of impulse control disorders, hallucinations and other symptoms of psychosis; **AND**
- Recipient must continue and be compliant with levodopa/carbidopa as well as ONGENTYS.

**QUANTITY EDITS:**

- #30/30

**DISCUSSION:**
No discussion

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

## 3. ONUREG® (azacitidine)

Chair discussed estimated reimbursement rate, FDA indication, information on azacitidine for injection, information on acute myeloid leukemia, mechanism of action, dosing, and NCCD guidelines.

**SUGGESTED CRITERIA:**
**APPROVAL CRITERIA:**

- Recipient must be ≥ 55 years of age; AND
- Recipient must have the diagnosis of acute myeloid leukemia and either achieved first complete remission OR complete remission with incomplete blood count recovery after intensive induction chemotherapy and are not able to compete intension curative therapy OR a diagnosis consistent with FDA indication; AND
- Recipient should not be substituting ONUREG for IV or subcutaneous azacitidine at the same doses; AND
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies and response; AND

  - Current labs including CBC with differential and LFTs (delay therapy cycle if ANC <0.5 Gi/L); AND
  - Required dosage since dose adjustments are required for neutropenia, thrombocytopenia, and gastrointestinal toxicity; AND
- Recipient must not be a candidate for hematopoietic stem cell transplant; AND
- Recipient must be prescribed an antiemetic for use during the first 2 cycles; AND
- PA's approved month-to-month until stable due to significant thrombocytopenia and neutropenia risks.

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient has not received recent intensive induction chemotherapy; OR
- Recipient is pregnant or breastfeeding; OR
- Recipient cannot tolerate the minimum dose of 200 mg per day with a reduced treatment duration of 7 days; OR
- Recipient has a diagnosis of myelodysplastic syndrome; OR
- Recipient has moderate to severe hepatic impairment (total bilirubin >1.5 to 3 X ULN); OR
- Recipient had a prior bone marrow or stem cell transplantation.

**CONTINUATION CRITERIA:**

- Recipient continues to have no disease progression and has no unacceptable toxicity; AND
- Prescriber must submit the following:
  - Current chart notes with documented response to treatment; AND
  - Current labs including CBC with differential and LFTs (CBCs should be monitored every other week for the first 2 cycles and prior to start of each cycle thereafter).

**QUANTITY EDITS:**

- #14/28 days for each strength

**DISCUSSION:**

The Chair asked the Board to make an input on the age requirement. According to Dr. Podrazik, AML tends to be a disease of elderly with disease commonly no younger than 50 years of age. The Chair stated that if a request is made for a patient slightly outside of this limit, the request will still be reviewed. The Chair asked for thoughts on documentation of transplant eligibility. No recommendations for a change in criteria was made.

**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 presented. Motion passed.

## 4. ZOKINVY (lonafarnib)

Chair discussed the estimated reimbursement rate and notified the Board that this product is not rebateable at this point. Chair also discussed the FDA indication, mechanism of action, information on Hutchinson-Gilford Syndrome, and dosing.

**SUGGESTED CRITERIA:**

**APPROVAL CRITERIA:**

- Recipient must be ≥ 12 months of age; AND
- Recipient has a diagnosis of Hutchinson-Gilford Progeria Syndrome or processing-deficient Progeroid Laminopathies with either heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutation OR a diagnosis consistent with FDA indication; AND
- Prescriber must submit the following:
    - Current chart notes; AND
    - Genetic mutational analysis results confirming the diagnosis with a LMNA mutation, or a ZMPSTE24 mutation; AND
    - Current labs including CBC with differential and complete metabolic panel; AND
    - Current body surface area (BSA); AND
    - Most recent DXA scan for bone mineral density (if applicable); AND
    - Documentation of symptoms associated with the disease specific for this recipient (i.e., cardiovascular disease, osteoporosis, loss of muscle mass); AND
    - Chart notes relevant to the recipient's comorbidities from other specialists.

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient's BSA is < 0.39/$m^2$; **OR**
- Recipient requires concomitant moderate or strong CYP3A inhibitors or inducers; **OR**
- Recipient requires concomitant midazolam; **OR**
- Recipient requires concomitant HMG CoA reductase inhibitors ("statins"); **OR**
- Recipient is pregnant.

**CONTINUATION CRITERIA:**

- Recipient must remain compliant on ZOKINVY; **AND**
- Recipient has no intolerable side effects to this therapy; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current BSA; **AND**
    - Current labs including CBC with differential and complete metabolic panel.

**QUANTITY EDITS:**

- 50mg—#120/30
- 75mg—#120/30

**DISCUSSION:**

Dr. Johnson requested that the drug be tabled until more data is available as medical necessity is in question. The Chair stated she could not find data on how this drug would impact the patient. Dr. Podrazik asked what the information is we want to see that would be helpful. The Chair stated that we may not get this data. Dr. Miller suggested that the drug be tabled.

**ACTION:**

Motion was made to table the review of this medication by Dr. Johnson; seconded by Dr. Miller. All members present voted to table the discussion until more information becomes available. Motion passed.

# IV. REPORTS

## A. ProDUR Report

Dr. Karen Evans from Magellan gave the ProDUR reports for October-December 2020. The percentage of total overrides remained roughly the same. Approximately 75.4% 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 1st quarter of SFY2021 (July-September 2020). The PASSEs had a combined 257,166 paid claims with 40,336 ProDUR alerts resulting in 21,529 cancelled claims or 53.4% of alerts cancelled at POS.

## B. RDUR Report

Dr. Lynn Boudreaux from Magellan presented intervention letter data for October-December 2020, the quarterly lock-in report, and potential intervention criteria to be discussed by the DUR board for February 2021, March 2021, and April 2021. Dr. Boudreaux discussed that the October and November intervention letters will have to be resent to providers with patient names and dates of birth included. The Board made recommendations to perform intervention review on the following:

February 2021—Heart failure diagnosis without ACEI/ARB and BB
March 2021—Diabetics ages 40-75 with no statins
April 2021—DPP-4 and SGLT-2 inhibitors—FDA warnings

- Motion to accept the recommended intervention criteria was made by Dr. Bemberg; seconded by Dr. Podrazik. All other members present voted by roll call to accept as presented. Motion passed.

**C.** Meeting adjourned at 11:37 a.m.