Arkansas Medicaid DUR Board Meeting Minutes

Date / Time:	October 19, 2022 8:30 AM– 12:30 PM Central		**Location:**	ZOOM webinar	
Chair:	Cindi Pearson, Pharm.D.		**Reports:**	Lynn Boudreaux, Pharm.D. Magellan Karen Evans, P.D. Magellan	
		Panelist (voting members)		**Panelist (non-voting members)**	**Organization**
	x	Geri Bemberg, Pharm.D.	X	Barry Fielder, Pharm.D.	ATC
	X	Clint Boone, Pharm.D.		Shannon Burke, Pharm.D.	Empower
	X	Lana Gettman, Pharm.D.	X	Phuong Luu, Pharm.D.	Empower
		Florin Grigorian, M.D.	x	Lauren Jimerson, Pharm.D.	Summit
	X	Jill Johnson, Pharm.D.		Turkesia Robertson-Jones, Pharm.D.	CareSource
		Brian King, Pharm.D.		Jennifer Chapin, Pharm.D.	CareSource
	X	James Magee, M.D.		Elizabeth Pitman	DHS Director
	X	Michael Mancino, M.D.	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
	x	Laurence Miller, M.D.	X	Cynthia Neuhofel, Pharm.D.	DHS pharmacy
	X	Paula Podrazik, M.D.	X	William Golden, M.D.	DHS advisor
	X	Tonya Robertson, Pharm.D.	X	Shane David, Pharm.D.	ADH advisor
		Vacant M.D. position	X	Karen Evans, P.D.	Magellan
		Vacant M.D. position	X	Lynn Boudreaux, Pharm.D.	Magellan
		Vacant Pharm.D. position	X	Lesley Irons, Pharm.D.	Magellan
		Vacant Pharm.D. position	X	Ifeyinwa Onowu, Pharm.D.	CareSource
Call to order		Meeting held virtually by ZOOM webinar. A quorum was present, and the chair called the meeting to order at 8:40am.			
Public comments		1) John A. Flatt, M.D., MSL—Marinus Pharmaceuticals, Inc Ztalmy® 2) Jenna McGowan, Pharm.D., MPH—AbbVie Skyrizi® 3) Jenna McGowan, Pharm.D., MPH—AbbVie Rinvoq® 4) Andrew Delgado, Pharm.D., PhD—BMS Sotyktu® 5) Mariola Vazquez, Pharm.D., CDES—LEO Pharma Adbry™			
Announcements		1. There were no conflicts of interest by any voting Board member, Dr. Pearson, or Dr. Boudreaux. 2. Reimbursement rates are based on WAC, FUL or NADAC. Arkansas Medicaid Quarterly Newsletter (3. Quarterly provider newsletter-- 4. Board reviewed updated bylaws combining the Drug Utilization Review Board and Drug Review Committee. Motion to approve the bylaws as presented was made by Dr. Mancino, seconded by Dr. Podrazik. All voting members present voted to approve the bylaws as written. Motion passed.			
Minutes		Motion to approve July 2022 meeting minutes was made by Dr. Miller, seconded by Dr. Mancino. All voting members present voted to approve the minutes as written. Motion passed.			

Board Updates		1. Discussed updated POS edits for SGLT-2 inhibitors, GLP-1 receptor antagonists and thiazolidinediones 2. Discussed PA trends and Medicaid eligible trend 3. Medication Assisted Treatment utilization update 4. Re-review of Bylvay™--no change to criteria recommended
		1. Monoclonal Antibodies—immunomodulators **<u>PROPOSED APPROVAL CRITERIA FOR ASTHMA:</u>** **(Dupixent®, Fasenra®, Nucala®, Tezspire®, and Xolair®)** Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex® • Prescribed by or in consultation with specialist in pulmonology, allergy or immunology • Recipient must have a diagnosis consistent with FDA indications. (Current indications as of 10/5/2022.) o **NUCALA**—add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype o **FASENRA**—add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype o **DUPIXENT**—add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. o **TEZSPIRE**—add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype o **XOLAIR**—adults and pediatric patients 6 years of age and older with 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 have moderate to severe asthma as defined by at least **TWO** of the following: o Pre-bronchodilator FEV1 < 80% for ≥ 18 years of age **OR** FEV1 < 90% for < 18 years of age o 2 or more exacerbations despite compliance on ICS plus an additional controller medication in the last year. Exacerbation is defined as: ▪ Treatments with systemic corticosteroids ▪ Medical treatments (e.g., emergency room visits or hospitalizations) ▪ Combination of the 2 above o Documentation of functional impairment due to poor asthma control (e.g., impaired activities of daily living, continued dyspnea) • Recipient must be 100% compliant on at least two asthma maintenance medications for the last 12 months o One medication must be an inhaled corticosteroid at a maximized dose o ICS/LABA combination products count as two medications • Recipient has no therapeutic duplication with any other monoclonal antibodies • Recipient must be a non-smoker • Recipient with pre-existing helminth infection must be treated prior to beginning therapy • Prescriber must submit the following: o Current chart notes o Documentation of previous therapies tried for asthma with response o Baseline labs (must fall within the manufacturer's requirements in the package insert) ▪ Baseline blood eosinophil count for FASENRA, NUCALA, and DUPIXENT (if eosinophilic type) ▪ Baseline serum IgE levels, body weight, and completed form for XOLAIR o Baseline Asthma Control Questionnaire (ACQ-5) for all patients **OR** Asthma Quality of Life Questionnaire (AQLQ) scores for adults only o Current Pulmonary Function Test results o If the request is for a non-preferred product, provide a letter of medical necessity for requested product over the preferred monoclonal antibody (currently FASENRA) and other therapies outlined in treatment guidelines. **<u>CONTINUATION CRITERIA FOR ASTHMA:</u>** • Recipient is compliant on asthma controller medication (ICS or ICS/LABA) and immunomodulator injection

- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy after 12 months of treatment
  - Current PFTs
  - Current blood eosinophil count for FASENRA, DUPIXENT (if eosinophilic type), and NUCALA
  - Current serum IgE level and body weight for XOLAIR
  - Current Asthma Control Questionnaire (ACQ-5) for all patients **OR** Asthma Quality of Life Questionnaire (AQLQ) scores for adults only
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy as indicated by at least ONE (1) of the following:
  - Recipient must have an improvement in FEV1 over baseline after 12 months
  - Recipient must have fewer exacerbations
  - Recipient must have a decrease in blood eosinophil count **OR** serum IgE **OR** decrease in oral corticosteroid usage (depending on medication)
  - Recipient must have improved asthma control and quality of life scores

DISCUSSION:
No comments
ACTION:
Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Johnson. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR ATOPIC DERMATITIS (Dupixent®)

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- Recipient has a documented diagnosis of moderate to severe atopic dermatitis with at least TWO of the following (baseline at time of biologic request):
  - Baseline impacted body surface area (BSA) ≥ 10%
  - Baseline Eczema Area and Severity Index (EASI) total score of ≥ 16
  - Baseline weekly averaged peak pruritis Numeric Rating Scale (NRS) ≥ 7
  - Baseline Investigator's Global Assessment (IGA) score ≥ 3
  - Baseline Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- Recipient must have a trial and failure of both topical and systemic medications and at a minimum must include:
  - Trials of topical drugs (unless contraindicated or inappropriate for the patient's age)
    - At least **TWO** different topical corticosteroid entities over a minimum of 60 days use with at least one topical corticosteroids being "high" potency (Class-2) **OR** superpotent (Class-1) **OR** medium potency for children
    - At least **ONE** trial of a topical calcineurin inhibitor (TCI) with either pimecrolimus or tacrolimus over a minimum of 30 days
    - At least **ONE** trial of topical phosphodiesterase-4 inhibitor (crisaborole) over a minimum of 30 days after trial of TCI
  - At least **ONE** trial of systemic immunomodulatory therapy from the following unless contraindicated (for recipients ≥ 10 years of age):
    - Cyclosporine for a minimum of 6 weeks
    - Azathioprine for a minimum of 12 weeks
    - Methotrexate for a minimum of 12 weeks
- If BSA ≥ 50%, recipient may skip the topical and systemic medication requirement
- Prescriber must submit
  - Current chart notes

- Documentation of previous therapies with trial length of each medication
- BSA prior to topical/systemic therapies and current impacted BSA
- Baseline EASI, NRS, IGA and/or SCORAD and updated score with previous treatment
- Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
- Letter of medical necessity over other treatment options for atopic dermatitis

CONTINUATION CRITERIA FOR ATOPIC DERMATITIS:

- Recipient is compliant on this medication
- Recipient must show continued positive treatment response with each PA request for continued prior approval with at least one of the following compared to baseline
  - Decrease in severity scores; **OR**
  - Decrease in BSA impacted; **OR**
  - Decrease in need for systemic or topical rescue treatment
- Prescriber must submit
  - Current chart notes
  - Current BSA and EASI, NRS, IGA or SCORAD (compared to baseline severity score)

DISCUSSION:

Dr. Johnson recommended to remove the requirement for crisaborole since that is not indicated for moderate to severe AD. Dr. Magee asked if we would require a specialist, and Dr. Pearson confirmed. Dr. Magee also questioned BSA of 50%. Dr. Pearson stated that we see BSA documented in chart notes from dermatologists. Dr. Golden stated that many PA cases he has reviewed have extensive BSA. Dr. Podrazik commented on notification in UpToDate about treatment in children, and we should rely on the specialist to make the decision on immunosuppressant use. Dr. Golden stated the literature is becoming increasingly lenient in the use of Dupixent in children, and the literature may not be consistent with current guidelines. Dr. Johnson reviewed the ICER report which stated systemic immunosuppressants have limited benefits but potential side effects. Dr. Johnson recommended to remove the requirement for immunosuppressants but leave that decision with the specialist. Dr. Pearson stated that if the immunosuppressant requirement is removed, then the BSA requirement would need to be as well. We wouldn't expect someone with high BSA to use topical steroids only.

ACTION:

Motion made to approve the criteria amended was made by Dr. Johnson; seconded by Dr. Miller. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR NASAL POLYPS (Dupixent®, Nucala®, and Xolair®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must have a diagnosis of chronic rhinosinusitis with nasal polyposis
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Prescribed by or in consultation with specialist in pulmonology, allergy, or immunology
- Recipient must have a trial and failure of at least **TWO** of the following:
- Intranasal saline with nasal corticosteroids for three (3) months (e.g., fluticasone, beclomethasone, budesonide)
  - Nasal corticosteroids with antileukotriene (e.g., montelukast) for three (3) months
  - Oral corticosteroid therapy for 45 days consecutively
  - At least one prior nasal surgery followed by nasal corticosteroids
- Prescriber must submit the following:
  - Current chart notes with description of size/quantity of nasal polyps
  - Documentation of previous therapies tried
  - Requested dose
  - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
  - Current IgE and weight for Xolair® request
  - Medical necessity over nasal corticosteroids, antileukotrienes, and surgery

- Documentation that concomitant nasal corticosteroids are prescribed

CONTINUATION CRITERIA

- Recipient must demonstrate an improvement in size/quantity of polyps with an improvement of symptoms compared to baseline
- Recipient must be compliant on this medication and nasal corticosteroids
- Prescriber must submit the following:
  - Current chart notes with description of polyps
  - Current body weight for dose determination for Xolair®
  - Requested dose

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Johnson. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR EOE (Dupixent®)

- Recipient must be ≥ 12 years of age and at least 40 kg OR the minim age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must have a confirmed diagnosis of eosinophilic esophagitis (EOE) with an esophageal biopsy that indicates ≥15 eosinophils per high-power field (eos/hpf) and **ONE** of the following:
  - Symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, chest pain); **OR**
  - Endoscopy features consistent with eosinophilic esophagitis (e.g., stacked circular rings, esophageal strictures, linear furrows)
- Recipient must have at least a 12 week trial and failure of swallowed corticosteroids (e.g., fluticasone or budesonide) and proton pump inhibitors (e.g., pantoprazole or omeprazole)
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies including dietary restrictions, procedures, or pharmacological treatment
  - Baseline eos/hpf after corticosteroid and PPI trials
  - Baseline recipient determined Dysphagia Symptom Questionnaire (DSQ) score

CONTINUATION CRITERIA FOR DUPIXENT®:

- Recipient demonstrates a positive response with one of the following after 6 months of treatment:
  - Achieved remission with ≤ 6 eos/hpf; **OR**
  - Decrease in DSQ score from baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current recipient determined DSQ score
  - Current eos/hpf

DISCUSSION:
No discussion since reviewed during the July 2022 DUR meeting
ACTION:
No vote

PROPOSED APPROVAL CRITERIA FOR EGPA (Nucala®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must be diagnosed with EGPA for at least 6 months based on the presence of asthma plus eosinophilia (>1.0×10^9 /Liter and/or >10% of leucocytes)
- Recipient has a history of relapsing or refractory disease with at least one confirmed EGPA relapse within the last 2 years while taking oral corticosteroids
- Recipient must be on a stable dose of oral prednisolone or prednisone of ≥7.5 mg/day for at least four (4) weeks
- If Recipient is receiving immunosuppressive therapy (excluding cyclophosphamide), the dosage must be stable for four (4) weeks
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®

- Recipient has no therapeutic duplication with any other monoclonal antibodies
- Recipient does not have life-threatening EGPA. Life-threatening EGPA would be defined as:
  - Severe alveolar hemorrhage or hemoptysis requiring transfusion or ventilation, or hemoglobin is <8 g/dL
  - Rapidly progressive glomerulonephritis with creatinine >2.5 mg/dL
  - Severe cardiac involvement including life-threatening arrhythmia, LVEF <20%, NUHA Class III/IV or acute myocardial infarction
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBCs and LFTs if on methotrexate or azathioprine
  - Baseline Birmingham Vasculitis Activity Score (BVAS)
  - Medical necessity over corticosteroids and/or immunosuppressive therapy

CONTINUATION CRITERIA FOR EGPA

- Recipient must be compliant on this medication
- Recipient must show a positive response to therapy with at least **ONE** of the following:
  - BVAS = 0 (no vasculitis); **OR**
  - Corticosteroid dose has been decreased to ≤4 mg/day
- Prescriber must submit the following:
  - Current chart notes
  - Current corticosteroid dose
  - Current BVAS

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Miller; seconded by Dr. Johnson. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR HYPEREOSINOPHILIC SYNDROME (Nucala®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must have a diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient has documented at least 2 HES flares within the past 12 months while on stable HES therapy with at least **TWO** of the following:
  - Chronic or episodic corticosteroids
  - Immunosuppressants
  - Cytotoxic therapy
- Recipient has a baseline blood eosinophil count of at least 1000 cells/µL
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried and response
  - Current labs including CBCs and LFTs if on methotrexate or azathioprine

CONTINUATION CRITERIA FOR HYPEREOSINOPHILIC SYNDROME

- Recipient must be compliant on this medication
- Recipient has a positive response with a decrease in HES flares and a decrease in blood eosinophil count
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBCs
  - Documentation of HES flares since beginning treatment

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed.

PROPOSED CRITERIA FOR CHRONIC SPONTANEOUS URTICARIA (Xolair®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must have a diagnosis of chronic spontaneous urticaria (CSU) while remaining symptomatic despite H1 antihistamine treatment. CSU was formerly called chronic idiopathic urticaria (CIU)
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient should minimize factors that can exacerbate CSU (i.e., NSAIDs, alcohol, stress, friction from clothing)
- Recipient's IgE level and XOLAIR form for asthma are not required
- Recipient's baseline Urticaria Activity Score-7 (UAS7) must be ≥ 16 despite previous treatment outlined below
- Recipient must have tried and failed the following:
    - Non-sedating H1-antihistamine (nsAH) for a minimum of 2 weeks; **AND**
    - nsAH at 4 times the normal daily dose for a minimum of 4 weeks; **AND**
    - Alternative nsAH at 4 times the normal daily dose for a minimum of 4 weeks OR H_2 antagonist; **AND**
    - Add a Leukotriene receptor antagonist to the nsAH or H_2 antagonist for a minimum of 4 weeks; **AND**
    - Add cyclosporine to the above treatment dosed at 4 mg/kg (based on ideal body weight) for a minimum of 8 weeks.
    - Hydroxyzine or doxepin??
- Prescriber must submit the following:
    - Current chart notes
    - Baseline description of urticaria
    - Baseline UAS7
    - Previous therapies tried with duration.
    - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
    - Letter of medical necessity over other treatment options

CONTINUATION CRITERIA

- Recipient must be compliant on this medication
- Recipient must have a positive response with a decrease in UAS7 and decrease in urticaria symptoms
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of current symptoms
    - Current UAS7

DISCUSSION:
Dr. Johnson reviewed 2014 trials which demonstrated that the addition of a first generation antihistamine for sleep is not supported. Dr. Golden noted that these urticaria cases are typically transient and spontaneously resolve so these treatment requirements would pertain to those with very persistent and disabling presentations. Dr. Johnson noted an article that supported the use of cyclosporine in these patients. Motion was made to remove the requirement for hydroxyzine or doxepin.
ACTION:
Motion made to approve the criteria as amended was made by Dr. Johnson; seconded by Dr. Mancino. All other members present voted for the motion. Motion passed.

PROPOSED CRITERIA FOR PRURIGO NODULARIS (Dupixent®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication

- Recipient must have a diagnosis of prurigo nodularis with widespread or recalcitrant disease **OR** has a comorbidity of moderate to severe atopic dermatitis
- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient must have a trial and failure of both topical and systemic medications and at a minimum must include:
  - Trials of topical drugs (unless contraindicated or inappropriate for the patient's age)
    - At least **TWO** different topical corticosteroid entities over a minimum of 60 days use with at least **ONE** topical corticosteroids being "high" potency (Class-2) **OR** superpotent (Class-1) **OR** medium potency for children; **AND**
    - At least **ONE** trial of a topical calcineurin inhibitor (TCI) with either pimecrolimus or tacrolimus over a minimum of 30 days; **AND**
    - Intralesional corticosteroid use if a few large PN lesions
  - At least **ONE** trial of systemic immunomodulatory therapy from the following unless contraindicated (for recipients ≥ 10 years of age):
    - Cyclosporine for a minimum of 6 weeks
    - Azathioprine for a minimum of 12 weeks
    - Methotrexate for a minimum of 12 weeks
- Prescriber must submit the following:
  - Current chart notes
  - Description of current status for baseline (i.e., BSA of nodules, peak pruritis Numeric Rating Scale (NRS), Investigator's Global Assessment (IGA))
  - Previous therapies tried
  - If no history of atopic dermatitis, provide documentation that other systemic causes for pruritis have been ruled out (i.e., chronic kidney disease, liver disease)

CONTINUATION CRITERIA:

- Recipient must show continued positive treatment response with each PA request for continued prior approval with at least one of the following compared to baseline
  - Decrease in pruritis; **OR**
  - Decrease in BSA impacted; **OR**
  - Decrease in need for systemic or topical rescue treatment
- Prescriber must submit
  - Current chart notes
  - Current BSA and pruritis test scores (i.e., NRS, IGA)

DISCUSSION:
Dr. Johnson recommended that we keep the systemic immunomodulatory therapy requirement based on information from UpToDate.
ACTION:
Motion made to approve the criteria as presented was made by Dr. Johnson; seconded by Dr. Robertson. All other members present voted for the motion. Motion passed.

2. TARGET IMMUNOMODULATORS
There was discussion on whether Alopecia Areata is cosmetic only, and the consensus is that we consider it to be an immune-mediated disorder and not just cosmetic. Dr. Johnson wanted clarification on the products that would be included. Dr. Pearson commented that all TIMs with this indication will be required to follow this criteria, but the non-preferred options would require a failure or contraindication to a preferred option in addition to the criteria.

PROPOSED APPROVAL CRITERIA FOR PLAQUE PSORIASIS

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating plaque psoriasis
- Recipient has a documented diagnosis of moderate to severe plaque psoriasis

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Recipient must trial ≥ 6 months with at least **ONE** product from each of the following (6 months of topical and 6 months of systemic):
  - Topical drug therapy with corticosteroids, calcipotriene, calcitriol, tazarotene, roflumilast, or tapinarof
  - Systemic drug therapy with methotrexate, acitretin, or cyclosporine
- Recipient must have tried and failed phototherapy or have a contraindication
- Recipient continues to have symptoms after trial of conventional therapy with at least **ONE** of the following:
  - Involvement of ≥10% body surface area (BSA)
  - Psoriasis Area and Severity Index (PASI) score ≥12
  - Plaque location severely impacts quality of life (i.e., head/neck, palms, soles of feet, genitalia)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current psoriasis description with BSA and PASI score
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Johnson; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR PSORIATIC AND RHEUMATOID ARTHRITIS

- Prescribed by or in consultation with a rheumatologist or other specialist treating psoriatic arthritis
- Recipient has a documented diagnosis of psoriatic arthritis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with NSAIDs
- Trial and failure with ≥ 6 months of any of the following:
  - Hydroxychloroquine
  - Methotrexate
  - Sulfasalazine
  - Leflunomide
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current labs as baseline (e.g., Erythrocyte Sedimentation Rate, C-Reactive Protein level)
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
No discussion
ACTION:
No vote

PROPOSED APPROVAL CRITERIA FOR ULCERATIVE COLITIS

- Prescribed by or in consultation with a gastroenterologist
- Recipient has a documented diagnosis of moderate to severe ulcerative colitis as defined by **ONE** of the following:
  - Fecal calprotectin > 150 µg/g
  - Endoscopy Mayo subscore ≥ 2 or modified Mayo score (mMS) ≥ 5
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Trial and failure with ≥ 3 months of standard of care drug therapy with at least **TWO** of the following for induction or maintenance of remission:
  - Immunosuppressants (e.g., azathioprine, 6-mercaptopurine, cyclosporine)
  - Oral/rectal glucocorticoids (e.g., enteric coated budesonide, prednisone, hydrocortisone)
  - Oral/rectal 5-aminosalicyclic acid agents (e.g., mesalamine, sulfasalazine)
- Recipient has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current labs including inflammatory markers (i.e., fecal calprotectin, endoscopic Mayo subscore)
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.

CONTINUATION CRITERIA FOR UC:

- Recipient has documented positive response after 4 months with mucosal healing defined as ONE of the following:
  - Endoscopy Mayo subscore ≤ 1
  - Fecal calprotectin ≤ 150 µg/g
  - Recipient that does not meet either of the above but has no other pharmacological or non-pharmacological options available
- Recipient must be compliant on this medication
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with description of current symptoms
  - Current Mayo subscore and fecal calprotectin

DISCUSSION:

Dr. Johnson recommended that positive response be reduced to 8 weeks for continuation. After discussion of Crohn's, it was recommended to add acute hospitalization to the standard of care options for UC as well. Recommendation was made to decrease the trial length of standard of care options to 2 months.

ACTION:

Motion made to approve the criteria amended was made by Dr. Johnson; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR CROHN'S DISEASE

- Prescribed by or in consultation with a gastroenterologist
- Recipient has a documented diagnosis of moderate to severe Crohn's Disease confirmed by assessment of stool frequency, abdominal pain score, and Simple Endoscopic Score for Crohn's Disease (SES-CD). Information for diagnosis is based on endoscopy and imagining results as well as elevated CRP and fecal calprotectin.
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication

- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Trial and failure with ≥ 3 months of standard of care drug therapy with at least **TWO** of the following for induction or maintenance of remission:
  - Immunosuppressants (e.g., azathioprine, 6-mercaptopurine, cyclosporine)
  - Oral/rectal glucocorticoids (e.g., enteric coated budesonide, prednisone, hydrocortisone)
  - Oral/rectal 5-aminosalicyclic acid agents (e.g., mesalamine, sulfasalazine)
  - Methotrexate
- Recipient has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies and surgeries
  - Current labs including CBCs and inflammatory markers (i.e., fecal calprotectin, C-reactive protein)
  - Colonoscopy or imaging reports
  - Baseline stool frequency and abdominal pain score
  - Baseline Crohn's Disease Activity Index (CDAI) (clinical trials included patients with score ≥ 220) or Simple Endoscopic Score for Crohn's disease (SES-CD) (clinical trials included patients with score ≥ 6 or ≥4 for isolated ileal disease)
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.

CONTINUATION CRITERIA FOR CD:

- Recipient has documented positive response after 4 months with documented remission that does not require continued use of corticosteroids and one of the following:
  - SES-CD at least a 50% reduction from baseline or ≤ 2 for isolated ileal disease
  - Fecal Calprotectin < 150 µg/g
  - CRP < 5mg/L
  - CDAI < 150
  - Recipient that does not meet any of the above but has no other pharmacological or non-pharmacological options available
- Recipient remains compliant on this medication
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with description of current symptoms
  - Current labs including CBCs and inflammatory markers

DISCUSSION:

Dr. Johnson commented that 3 months of a steroid would be a really long time, and the patient should see a response well before that time if the patient was going to respond. Dr. Golden stated that many of these patients will present initially with disease severe enough to be hospitalized (e.g., has fistulas). Does that bypass some criteria? Dr. Johnson agreed that acute hospitalization may warrant bypassing the typical stand of care drug therapy. Dr. Johnson posed the question if steroid days in hospital should count towards the total. Dr. Golden could see depending on severity of presentation being started on the biologics prior to other therapies. Dr. Pearson recommended modifying the standard of care bullet to include hospitalization due to acute Crohn's. Dr. Podrazik noted that UpToDate recommended 8 weeks of corticosteroid for induction. Dr. Johnson recommended to add in addition to hospitalization that the standard of care therapy may be waived if they have fistulizing disease.

ACTION:

Motion made to approve the criteria amended was made by Dr. Johnson; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS OR DEFICIENCY OF IL-1 RECEPTOR ANTAGONIST

- Prescribed by or in consultation with a rheumatologist or other specialist

- Recipient has a documented diagnosis of moderate to severe polyarticular or systemic juvenile idiopathic arthritis.
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with NSAIDs (unless contraindication or intolerance)
- Trial and failure with ≥ 3 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindication or intolerance):
  - Methotrexate
  - Leflunomide
  - Cyclosporine
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies with description of current symptoms
  - Current labs including CBCs and inflammatory markers
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
Dr. Pearson noticed a typo in the recommendation. Systemic JIA will be stricken from the 2nd bullet and DIRA will be added. A minimum age on DMARDs will not be added.
ACTION:
Motion made to approve the criteria as amended was made by Dr. Mancino; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR ANKYLOSING SPONDYLITIS OR NONRADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient has a documented diagnosis of either ankylosing spondylitis or nonradiographic axial spondyloarthritis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with ≥ 3 months of standard of care drug therapy (unless contraindication or intolerance) with nonsteroidal anti-inflammatory drugs at maximum doses (e.g., naproxen, celecoxib, ibuprofen)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Johnson. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR ATOPIC DERMATITIS

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis

- Recipient has a documented diagnosis of moderate to severe atopic dermatitis with at least **TWO** of the following (baseline at time of biologic request):
  - Baseline impacted body surface area (BSA) ≥ 10%
  - Baseline Eczema Area and Severity Index (EASI) total score of ≥ 16
  - Baseline weekly averaged peak pruritis Numeric Rating Scale (NRS) ≥ 7
  - Baseline Investigator's Global Assessment (IGA) score ≥ 3
  - Baseline Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- Recipient must have a trial and failure of both topical and systemic medications and at a minimum must include:
  - Trials of topical drugs (unless contraindicated or inappropriate for the patient's age)
    - At least **TWO** different topical corticosteroid entities over a minimum of 60 days use with at least **ONE** topical corticosteroids being "high" potency (Class-2) **OR** superpotent (Class-1) **OR** medium potency for children
    - At least **ONE** trial of a topical calcineurin inhibitor (TCI) with either pimecrolimus or tacrolimus over a minimum of 30 days
    - At least **ONE** trial of topical phosphodiesterase-4 inhibitor (crisaborole) over a minimum of 30 days after trial of TCI
  - At least **ONE** trial of systemic immunomodulatory therapy from the following (for recipients ≥ 10 years of age):
    - Cyclosporine for a minimum of 6 weeks
    - Azathioprine for a minimum of 12 weeks
    - Methotrexate for a minimum of 12 weeks
- If BSA ≥ 50%, recipient may skip the topical and systemic medication requirement
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies with trial length of each medication
  - BSA prior to topical/systemic therapies and current impacted BSA
  - Baseline EASI, NRS, IGA and/or SCORAD and change in score with previous treatment
  - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
  - Letter of medical necessity over other treatment options for atopic dermatitis

CONTINUATION CRITERIA FOR ATOPIC DERMATITIS:

- Recipient must show continued positive treatment response with each PA request for continued prior approval with at least one of the following compared to baseline
  - Decrease in severity scores; **OR**
  - Decrease in BSA impacted; **OR**
  - Decrease in need for systemic or topical rescue treatment
- Prescriber must submit
  - Current chart notes
  - Current BSA and EASI, NRS, IGA or SCORAD (compared to baseline severity score)

DISCUSSION:
Dr. Pearson noted to update criteria consistent with changes made during the Dupixent discussion.
ACTION:
Motion made to approve the criteria as amended was made by Dr. Johnson; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES

- Prescribed by or in consultation with a specialist in treating CAPS

- Recipient must have a diagnosis of cryopyrin-associated periodic syndromes (CAPS) or neonatal-onset multisystem inflammatory disease (NOMID)
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Prescriber must submit the following:
  - Current chart notes
  - Confirmation of the diagnosis with genetic test results if available
  - Baseline symptoms
  - Previous therapies tried
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
No comments
ACTION:
Motion made to approve the criteria as presented was made by Dr. Johnson; seconded by Dr. Mancino. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR GIANT CELL ARTERITIS (GCA)

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient has a confirmed diagnosis of giant cell arteritis based on clinical symptoms and **ONE** of the following:
  - Temporal artery biopsy
  - Ultrasound of vessels
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Prescriber must submit the following:
  - Current chart notes
  - Documentation to confirm diagnosis with biopsy results and/or ultrasound report along with labs (i.e., CRP, ESR)
  - Medical necessity over high dose corticosteroids
  - Treatment plan for potential discontinuation in the future

DISCUSSION:
Dr. Golden asked about the use of steroids. Dr. Johnson noted that biologics can be used with steroids for this indication.
ACTION:
Motion made to approve the criteria as presented was made by Dr. Miller; seconded by Dr. Mancino. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD)

- Prescribed by or in consultation with a rheumatologist, pulmonologist, or other specialist
- Recipient has a confirmed diagnosis of SSc-ILD based on clinical symptoms and the following:
  - PFTs indicate a decreased lung volume and decreased DLCO
  - High resolution CT indicates ground glass or reticular opacities
  - Lab work consistent with scleroderma
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of immunosuppressant therapy with mycophenolate or cyclophosphamide unless a contraindication or intolerance

- Prescriber must submit the following:
  - Current chart notes
  - Current PFTs
  - High resolution CT report
  - Current labs
  - Baseline 6 minute walk test
  - Medical necessity over immunosuppressant therapy +/- glucocorticoids
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Gettman. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR RECURRENT PERICARDITIS

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is diagnosed with recurrent pericarditis based on previous episode of acute pericarditis and has developed pleuritic chest pain. Lab work should support an inflammatory phenotype (elevated CRP, WBC, or ESR).
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Recipient should not receive this medication if not diagnosed with an inflammatory phenotype.
- Recipient should have trial and failure with ALL of the following (unless there is a contraindication):
  - Colchicine + NSAID or aspirin—first line therapy
  - Colchicine + glucocorticoid—second line therapy
  - Colchicine + glucocorticoid + aspirin—third line therapy
- Prescriber must submit the following:
  - Current chart notes
  - Previous treatment for acute pericarditis
  - Electrocardiogram and echocardiogram results
  - Current labs including CBC, ESR, and CRP
  - Treatment plan including taper

DISCUSSION:
Dr. Johnson stated that guidelines recommend colchicine first, so she would agree with this criteria.
ACTION:
Motion made to approve the criteria as presented was made by Dr. Johnson; seconded by Dr. Robertson. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR NEUROMYELITIS OPTICA SPECTRUM DISORDER

- Prescribed by a specialist experienced with NMOSD
- Recipient is diagnosed with neuromyelitis optica spectrum disorder (NMOSD) and is anti-aquaporin-4 (AQP4) antibody positive and confirmed with the following:
  - Test indicating recipient is seropositive for AQP4-IgG antibodies
  - Recipient has at least one core clinical characteristic (i.e., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions
  - Exclusion of alternative diagnoses (i.e., Lupus, multiple sclerosis, sarcoidosis, cancer, chronic infection like HIV)
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®

- Recipient must have history of at least one documented relapse (including first attack) in the last 12 months
- Recipient must have an Expanded Disability Status Scale (EDSS) score ≤ 6.5
- Recipient has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- Recipient is not prescribed medication for the treatment of multiple sclerosis
- Prescribed to prevent future attacks (not meant to treat an acute attack)
- Trial and failure of immunosuppressants (e.g., azathioprine, mycophenolate, methotrexate) unless there is a contraindication to their use
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies tried
    - Confirmation of NMOSD diagnosis
    - Baseline Expanded Disability Status Scale score
    - Medical necessity over the use of immunosuppressants
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
Dr. Johnson stated that this is not a new drug. Other products including Soliris and Ritixumab may work. Dr. Johnson suggested that this indication be tabled pending further review.
ACTION:
Table discussion for a later date.

PROPOSED APPROVAL CRITERIA FOR UVEITIS

- Prescribed by or in consultation with a rheumatologist, ophthalmologist, or other specialist for treating uveitis
- Recipient must be diagnosed with non-infectious intermediate, posterior, or panuveitis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with ALL of the following:
    - Topical glucocorticoid (e.g., prednisolone, triamcinolone)
    - Systemic glucocorticoid at the maximum indicated dose unless a contraindication or intolerance (e.g., prednisone)
    - Immunosuppressant (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine)
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies tried
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Bemberg; seconded by Dr. Johnson. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR TUMOR NECROSIS FACTOR RECEPTOR ASSOCIATED PERIODIC SYNDROME OR HYPERIMMUNOGLOBULIN D SYNDROME/MEVALONATE KINASE DEFICIENCY

- Prescribed by or in consultation with a rheumatologist or other rare disease specialist for treating TRAPS

- Recipient must be diagnosed with TNF Receptor Associated Periodic Syndrome (TRAPS) after infectious or neoplastic causes of recurrent fevers are excluded
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of NSAIDs and oral glucocorticoids at the maximum indicated dose unless a contraindication or intolerance
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of symptoms and criteria used for diagnosis
  - Previous therapies tried
  - Current weight for dose determination
  - Medical necessity for the use of this medication over NSAIDs and oral glucocorticoids
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Miller; seconded by Dr. Podrazik. Dr. Johnson abstained, and all other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR FAMILIAL MEDITERRANEAN FEVER

- Prescribed by or in consultation with a rheumatologist or other rare disease specialist for treating FMF
- Recipient must be diagnosed with Familial Mediterranean Fever (FMF)
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of colchicine unless a contraindication or intolerance (treatment recommended indefinitely)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of symptoms and criteria used for diagnosis
  - Previous therapies tried
  - Current weight for dose determination
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Johnson; seconded by Dr. Mancino. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR STILL'S DISEASE

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient must be diagnosed with active Still's Disease (either Adult-Onset Still's Disease (AOSD) or Systemic Juvenile Idiopathic Arthritis (SJIA))
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- New onset AOSD
  - Trial and failure of NSAIDs OR oral glucocorticoids at the maximum indicated dose unless a contraindication or intolerance for mild to moderate disease
  - If macrophage activation syndrome is suspected, a biologic is warranted (UpToDate recommends anakinra in these patients)

- Established AOSD still needing therapy
    - Trial and failure with ≥ 3 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindication or intolerance):
        - Methotrexate
        - Leflunomide
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of symptoms and criteria used for diagnosis
    - Previous therapies tried
    - Current weight for dose determination
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
Dr. Mancino asked which drugs had this indication.
ACTION:
Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Miller. All other members present voted for the motion. Motion passed.

PROPOSED APPROVAL CRITERIA FOR ALOPECIA AREATA

- Prescribed by or in consultation with a dermatologist
- Recipient has a documented diagnosis of alopecia areata with >50% scalp hair loss or refractory disease
- Recipient does not have another cause of hair loss (i.e., androgenetic alopecia, chemotherapy-induced hair loss, or causes of hair loss other than alopecia areata)
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of topical and/or intralesional corticosteroids
- Trial and failure with ≥ 6 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindicated):
    - Methotrexate
    - Leflunomide
    - Cyclosporine
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies tried with duration
    - Medical necessity over intralesional corticosteroids, topical steroids, and DMARDs
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
Dr. Johnson recommended to add that therapy should not be combined with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants. Dr. Johnson wanted to question whether this product is cost effective for this disease state. Dr. Golden suggested to add the requirement of documentation of impact of condition for psychosocial status and indications for treatment beyond cosmetic.
ACTION:
Motion made to approve the criteria as amended was made by Dr. Mancino; seconded by Dr. Gettman. All other members present voted for the motion. Motion passed.

		3. UPDATE TO MEDICATIONS FOR ADHD ADULTS
		PROPOSED APPROVAL CRITERIA FOR CII STIMULANTS AND NON-STIMULANTS FOR ADULTS
		• Completed CII stimulant form is required for recipients ≥19 years of age
		• Currently, atomoxetine does not require a prior authorization
		• Recipient with ADHD
		  o Recipient must have signs/symptoms in 2 or more settings using a standardized rating scale with at least one of the following:
		  ▪ Currently attends school (high school, college, or vocational)
		  ▪ Currently employed
		  ▪ Currently searching for employment (approval for maximum of 3 months without documentation of employment)
		  o Recipient must have multiple symptoms of inattention and/or hyperactivity/impulsivity from the DSM-5 documented on the form for initial approval
		  o Recipient with co-morbid conditions of bipolar disorder or schizophrenia must be controlled and adherent with appropriate medication therapy, or prescriber must provide adequate documentation as to why the co-morbid condition is no longer being treated
		  o Prescriber must submit the following:
		  ▪ Completed CII stimulant form
		  ▪ Current chart notes
		  ▪ Documentation needed to support the diagnosis of ADHD
		• Recipient without ADHD may be approved for one of the following: (each request is reviewed on a case-by-case basis for medical necessity)
		  o Narcolepsy with sleep study results confirming diagnosis
		  o Traumatic Brain Injury (TBI)
		  o Fatigue due to underlying illness (i.e., cancer or multiple sclerosis)
		  o Binge Eating Disorder (BED)—Vyvanse only
		
		DISCUSSION:
		Dr. Pearson asked Dr. Miller to make a comment about our PA reviews.
		ACTION:
		Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Johnson. All other members present voted for the motion. Motion passed.

New Business		**1. ZTALMY® (ganaxolone)**
		PROPOSED APPROVAL CRITERIA:
		• Recipient must be ≥2 years of age
		• Recipient must have a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
		• Recipient's seizures are refractory to current antiepileptic therapy with at least 2 previous trials with different MOA
		• Recipients requiring a CYP3A4 inducer should avoid this medication. If unavoidable, the ZTALMY dose should be increased.
		• Prescriber must order a dose titration and should not order a dose that exceeds the dose supported in the FDA approved package insert or MicroMedex®:
		  o Weight ≤28 kg: maximum dose is 63 mg/kg/day
		  o Weight >28 kg: maximum dose is 1,800 mg/day
		• Prescriber must submit **ALL** of the following:
		  o Current chart notes
		  o Current weight
		  o Genetic testing results confirming the presence of the CDKL5 mutation
		  o Previous therapies tried with response
		  o Baseline average daily seizure count
		  o Attestation that the recipient/caregiver has been educated on titration schedule
		
		CONTINUATION CRITERIA:

- Recipient demonstrates a positive response with a decrease in seizure frequency
- Prescriber must submit the following:
    - Current chart notes
    - Current dose (must be within manufacturer's guidance)
    - Response to therapy

DISCUSSION:
No comment
ACTION:
Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Bemberg. All other members present voted for the motion. Motion passed.

2. VIVJOA™ (oteseconazole)
PROPOSED APPROVAL CRITERIA:
- Recipient is an adult, female with a history of recurrent vulvovaginal candidiasis (RVVC) defined as ≥4 episodes of vulvovaginal candidiasis in a 12-month period **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient must **NOT** be of reproductive potential as defined by one of the following:
    - Postmenopausal; **OR**
    - Permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy)
- Recipient with severe renal impairment/ESRD **OR** moderate-severe hepatic impairment should avoid this medication
- Prescriber must submit **ALL** of the following:
    - Current chart notes
    - History of symptomatic vulvovaginal candidiasis with previous treatment
    - Vaginal discharge culture or microscopy report
    - Note which therapy will be initiated
        - VIVJOA-only; **OR**
        - Fluconazole/VIVJOA
- PA will be approved for a maximum of 12 weeks

CONTINUATION CRITERIA:
None—therapy should be a maximum of 12 weeks per the manufacturer's package insert

QUANTITY EDITS:
#18 for full course over 12 weeks

DISCUSSION:
Dr. Golden asked if literature for this product discusses uncontrolled diabetes, and he asked if the hemoglobin A1c is high (e.g., 12) does this preclude the effectiveness of this medication. Dr. Golden suggested that diabetes control be considered in the criteria. Dr. Johnson commented about the clinical trial comparing 150 mg of fluconazole every 72 hours the first week with 2 high dose oteseconazole. Typically, if there is recurrence, there is MIC creep which would require an increased fluconazole dose. There is concern that the active trial was against a too low dose of fluconazole. Dr. Pearson asked if there was something that could be added to the criteria to remedy this situation. Dr. Golden asked if we could table this discussion. Dr. Podrazik agreed with Dr. Golden on the need to consider tight diabetes control.
ACTION:
Discussion was tabled for the next DUR meeting.

3. RADICAVA ORS (edaravone)
PROPOSED APPROVAL CRITERIA:
- Recipient must be ≥18 years of age
- Recipient must have a diagnosis of amyotrophic lateral sclerosis (ALS) **OR** a diagnosis consistent with any updated FDA approved indications
- Recipient must have disease duration ≤ 2 years
- Recipient must have FVC ≥80% at baseline
- Recipient must have a baseline ALSFRS-R score ≥ 24

- Recipient must be receiving the standard of care concomitantly (multidisciplinary care +/- riluzole)
- Prescriber must submit **ALL** of the following:
    - Current chart notes
    - Baseline ALS Functional Rating Scale score (ALSFRS-R)
    - Duration since first symptoms
    - Current Pulmonary Function Test

CONTINUATION CRITERIA:
- Recipient remains compliant on therapy
- Prescriber must submit the following:
    - Current chart notes
    - Current Pulmonary Function Test
    - Updated ALS Functional Rating Scale score

QUANTITY EDITS:
50 mL bottle--#1 per 28 days
70 mL bottle--#1 per 28 days

DISCUSSION:
Dr. Johnson stated the current therapies would probably be used together, and Radicava ORS is not even close to being cost effective since it is priced at $171,000 per year but considered cost effective at $3200 per year. Edaravone has minimal impact on disease progression, but it has no impact on mortality. Dr. Johnson suggested that we table this discussion until we bring Relyvrio to the Board.
ACTION:
Discussion was tabled for the next DUR meeting.

4. ZORYVE™ (roflumilast) and VTAMA® (tapinarof)
PROPOSED APPROVAL CRITERIA:
- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating plaque psoriasis
- Recipient has a documented diagnosis of moderate to severe plaque psoriasis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must trial ≥6 months of topical drug therapy with either corticosteroids, calcipotriene, calcitriol, tazarotene, or a combination
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies tried with duration and response
    - Current BSA
    - Current Investigator's Global Assessment (IGA) score
    - Current Worst Itch-Numeric Rating Score (WI-NRS)
    - Medical necessity over all other topical treatment options

CONTINUATION CRITERIA:
- Recipient has a VTAMA/ZORYVE claim on Medicaid profile in the last 60 days
- Recipient has a documented improvement in symptoms (i.e., decreased BSA, reduced IGA score, or WI-NRS)
- Prescriber must submit the following:
    - Current chart notes
    - Current BSA, IGA score, and WI-NRS

QUANTITY EDITS:
1 tube (60 gm)/ 30 days

DISCUSSION:
No comment
ACTION:

Motion made to approve the criteria as presented was made by Dr. Johnson; seconded by Dr. Robertson. All other members present voted for the motion. Motion passed.

5. AMVUTTRA™ (vutrisiran)

PROPOSED APPROVAL CRITERIA:

- Prescribed by or in consultation with a neurologist or other specialist that treats polyneuropathy due to hATTR
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is diagnosed with polyneuropathy due to hereditary transthyretin-mediated (hATTR) amyloidosis **OR** a diagnosis consistent with any updated FDA approved indications
- Recipients with multisystem symptoms and/or family history must have the diagnosis confirmed with **ONE** of the following:
    - Confirmation of a TTR variant by genetic testing
    - Tissue biopsy confirming the presence of amyloid deposits
- Recipient does not have any of the following:
    - Severe renal impairment or end-stage renal disease
    - Moderate or severe hepatic impairment
- Prescriber must submit the following:
    - Current chart notes
    - Medical necessity over preferred neuropathic pain agents
    - Attestation that Vitamin A is being monitored for possible supplementation
    - Baseline modified Neuropathy Impairment Score +7 (mNIS+7)
    - Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score
    - Previous therapies tried
    - Current labs including LFTs and BMP
- Renewal requires prescriber to submit updated notes and labs with documentation of a positive response to therapy

QUANTITY EDITS:

1 syringe every 3 months

DISCUSSION:

No comment

ACTION:

Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Miller. Drs. Bemberg and Robertson abstained, and all other members present voted for the motion. Motion passed.

6. XACIATO™ (clindamycin)

PROPOSED APPROVAL CRITERIA:

- Recipient is a female 12 years of age and older **OR** updated age allowance if indication changes
- Recipient has a confirmed diagnosis of bacterial vaginosis with the following:
    - Off-white vaginal discharge
    - Clue cells > 20% of total epithelial cells
    - Discharge pH >4.5
    - Positive whiff test
- Prescriber must submit the following:
    - Current chart notes
    - Previous therapies tried
    - Medical necessity over other treatment options available without a PA (e.g., oral or vaginal metronidazole, oral or vaginal clindamycin)

QUANTITY EDITS:

1 tube (8 gm)/ 30 days

DISCUSSION:

No comment

		ACTION: Motion made to approve the criteria as presented was made by Dr. Johnson; seconded by Dr. Robertson. All other members present voted for the motion. Motion passed.

Reports		• Dr. Pearson gave the ProDUR report for the PASSEs
		• Dr. Evans from Magellan gave the fee-for-service ProDUR report
		• Dr. Boudreaux from Magellan gave the fee-for-service RDUR report
		  ○ November 2022—criteria 8046 with GLP1 without a diabetes diagnosis (unless not enough for review)
		  ○ December 2022—7734 Diabetics without an ACEI or ARB in history
		  ○ January 2023—will choose later
		ACTION: Motion was made by Dr. Mancino for the above criteria; seconded by Dr. Bemberg. All other members present voted for the motion. Motion passed.

Adjourn		Meeting adjourned at 12:31pm.