



## TennCare Pharmacy Advisory Committee (PAC Meeting)

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August 24, 2017

**Members in Attendance:** Shana Bush, PharmD, Co-Chairman Edward Capparelli, MD, David Collier, MD (TennCare), Brent Dunlap, PharmD, J. Rusty Hailey, PharmD, DPh, MBA, FAMCP (TennCare), James Johns, MD, Ernest Jones, MD, Rodney Poling, MD, Karen Rhea, MD, FAPA, FAAP, Christopher Schwerdt, PharmD

**Non-member present from TennCare:** Renee Williams, PharmD

**Non-members present from Magellan:** Leslie Pittman, PharmD, Tracey Lovett, PharmD

Dr. Hailey opened the meeting by welcoming the committee and guests. Dr. Hailey informed the committee that Dr. Capparelli who has been our longest tenured committee member will be serving as the Chairman for this meeting. Dr. Hailey thanked Dr. Capparelli for his willingness to serve. Dr. Hailey also recognized Dr. Dunlap who was appointed by Lt. Governor Randy McNally to replace Dr. Corley's position. Dr. Corley retired after his term ended on July 31st. Dr. Hailey made note that TennCare has a new logo and gave the background information that many people were unfamiliar with the term HCFA (Health Care Finance and Administration), thus the name was changed for the Bureau of TennCare to the Division of TennCare. Dr. Hailey turned the meeting over to Dr. Capparelli.

### INTRODUCTIONS

The meeting was called to order by Co-Chairman Edward Capparelli. Dr. Capparelli recognized Dr. Corley for his 24 years of service on the Pharmacy Advisory Committee (PAC) and stated that his participation will be missed. Dr. Capparelli passed along greetings and thoughts from Dr. Corley to the committee. Dr. Capparelli asked the members of the Committee to introduce themselves. In addition, Dr. Dunlap gave some information on his pharmacy practice background. Dr. Capparelli stated that committee members are volunteers, appointed according to public act (TCA 71-5-2401) establishing the Pharmacy Advisory Committee (PAC). Dr. Capparelli confirmed a quorum had been established and stated no disclosures related to conflict of interests for this meeting have been received.

### PAC MINUTES

The May 18, 2017 PAC meeting minutes were reviewed by the committee.

- Dr. Johns motioned to approve the minutes as written.
- Dr. Dunlap seconded the motion.
- Motion carried.

## TENNCARE UPDATE

Dr. Collier thanked the committee on behalf of the Division of TennCare for taking time out from their schedules to travel and attend the PAC committee and gave the TennCare update for the quarter.

**Immediate Postpartum Voluntary Reversible Long Acting Contraceptive (ipp vrLAC):** TennCare is continuing to work to make IUDs (intrauterine devices) and implants available to TennCare enrollees at hospitals for those female members who choose this form of contraceptive shortly following delivery. In the past there have been some issues providing the devices immediately following delivery. So TennCare is working through those issues to ensure members have access with this new initiative by placing the product in the provider's office and allowing replacement of the device following the medical procedure. The plan is to have this option fully operational by the end of the year.

Additionally, TennCare is trying to decrease Neonatal Abstinence Syndrome (NAS) incidence and the ipp vrLAC should help decrease the incidence of NAS infants being born. Women have babies that have been exposed to drug substances via the mother which causes withdrawal in the infants. Dr. Collier explained that year-to-date the numbers have decreased by 10 infants compared to last year. Dr. Collier stated this decrease is encouraging as prior years showed a steady increase in NAS born infants; but noted there is much work to do in this area and hope that we will soon see a flattening and reversal of this trend.

- Dr. Collier asked if that decrease was the average across the state. Dr. Collier stated this was not the number across the state and was not able to review the absolute numbers, but reviewed the percentages across the state. Dr. Collier stated the issue is more heavily concentrated in Northeastern Tennessee.

### Tennessee Healthcare Innovation Initiative

**Episodes of care:** Wave 8 TAGs (Technical Advisory Groups) will begin in September with 3 TAGs being planned which focus on: General Surgery, Gynecology and Internal Medicine.

- 1. General Hospitalist TAG:** will focus on acute seizure, syncope, hyponatremia/dehydration and acute lower respiratory infection/bronchiolitis in infants. The hospital will serve as the responsible party for reporting outcomes; which is referred to as the quarterback.
- 2. Gynecology TAG:** will focus on colposcopy and hysterectomy. The gynecologist will serve as the quarterback for this TAG.
- 3. General Surgery TAG:** will focus on G.I. Obstruction, appendectomy, and hernia procedures. Most of the G.I. obstruction cases are hospitalized; thus the quarterback will be the hospital. The quarterback for both appendectomy and hernia procedures will be the surgeon.

**PCMH/Health Link:** Wave 1 of PCMH (Patient-Centered Medical Home) began on January 1<sup>st</sup> with 29 primary care practices. Health Link began on December 1, 2016 with 19 behavioral health practices. Wave 2 of PCMH will begin on January 1, 2018, an additional 43 health practices will be added which will give us a total of 72 practices, this includes more than 1,000 practitioners, and more than 400,000 TennCare enrollees (approximately 1/3 of TennCare enrollees) will participate in the PCMH project.

The Health Link which handles the severely, persistently mentally ill population will not be adding additional health centers or PCMH. Dr. Collier explained that most of the community mental health centers are already participating. Thus there is not a need to add any additional centers. Dr. Collier stated that he believes there are approximately 19 homes currently participating.

- Dr. Johns asked if the episodes of care differentiated between pediatric and adult patients. Dr. Collier stated that he thinks they do; but did not know for certain. However, there is risk adjustment involved to make reasonable comparisons. But did make note that there would be some differences involved. Dr. Collier further explained that the Technical Advisory Groups (TAG) have representatives participating from appropriate areas. Dr. Collier stated the TAG groups are just getting started and he would mention this to Dr. Frigon, who works with the various TAG groups.

**Managed Care Final Rule:** Dr. Collier informed the committee that CMS (Centers for Medicare and Medicaid Services) promulgated new managed care rules that take effect January 1, 2018. TennCare has requested CMS consider our current appeals process as meeting the new managed care rules. This was reviewed by TennCare attorneys and the current appeals process meets the intent of the new managed care final rule that will go in effect in January. If TennCare has to comply with the rules as written it would require a major overhaul of the current system. The new rules state that the Managed Care Organizations (MCOs) have to handle the appeal process and currently TennCare handles the appeal process; while TennCare attorneys manage the appeal process and direct the response and reconsiderations. Dr. Collier explained that the MCOs do the reconsiderations in response to TennCare's request. Thus, CMS has approved our appeal process; so providers will not have to learn a new process nor TennCare members. Dr. Collier explained that TennCare has put in many years to ensure this process works appropriately to protect our members.

**TennCare Pharmacy Update:** Dr. Hailey gave a brief Pharmacy update.

**Long-Acting Reversible Contraceptive (LARC) Program:** Dr. Hailey stated that TennCare Pharmacy celebrated the 1 year anniversary of the outpatient LARC program that was implemented on August 1, 2016. Dr. Hailey explained that Dr. Lorraine Buerhaus will take the lead on this initiative for re-launch and assist with expanding the project. Dr. Hailey stated that TennCare has seen a lot of success with the program. Dr. Hailey stated that one concern was with members not returning for the office visit to insert the LARC devices. However, this program actually places product in the provider's office for use upon the patient's consent.

**Medication Therapy Management (MTM) Initiative:** Dr. Hailey recognized Dr. Renee Williams for her work on the MTM initiative that will be rolled out in January 2018, which the state has received funding from the legislature to implement a 2 year pilot program. The TennCare Pharmacy program has been working in conjunction with the pharmacy community to ensure products and services for this initiative will be available. Dr. Hailey stated there has been 3 TAG meetings to discuss the project and allow for a smooth implementation. TennCare has received wonderful input and our currently working with our MCO partners. This initiative has been met with much enthusiasm and energy. Dr. Hailey acknowledged Dr. Williams for her work on the initiative; as this program has a lot of moving parts (e.g. coding, billing, etc) associated with the implementation. TennCare will be monitoring the rate of investment (ROI) for the initiative and ensuring there is a positive outcome for the program. However, Dr. Hailey felt that the initiative will result in a positive outcome given the enthusiasm that has been

received from the stakeholders. In addition, the TennCare Pharmacy Program is working with the PCMH project; as the MTM program will tie into that initiative as well.

- Dr. Capparelli inquired about the cost information that should be reviewed by the PAC committee when making recommendations. Dr. Capparelli stated that the committee receives the pharmacy retail cost, but this does not reflect the net cost of the medications in question. Dr. Capparelli stated that he understands this information is proprietary and cannot be disclosed. However, with other states and MCOs a dollar sign notation has been utilized to indicate true cost as a means of comparing products within a drug class. Dr. Capparelli asked if for the next meeting this notation could be incorporated.
- Dr. Hailey stated that due to anti-trust legislation and from a legal perspective we are not able to discuss net price. Given this is a public meeting this request is not possible and are certain that the companies that TennCare contracts with would not want their competitors knowing the terms of the contract. Dr. Hailey acknowledged that **Dr. Capparelli made a valid point and stated as we have done in the past; they will take this recommendation and discuss internally and bring back as a follow-up item** (which was initiated by the PAC committee to discuss follow-up items as part of the agenda.) **at the next meeting**; but reiterated that the committee does receive cost; but understand this is not what the committee wants. Dr. Hailey informed the committee that TennCare always listens to the recommendations of the committee and actively considers those requests that have been brought forth.

## AE SUBCOMMITTEE

Dr. Leslie Pittman reported to the PAC committee there were three additions to existing categories on the Auto-Exemption (AE) List through 2Q2017. This included: KISQALI-FEMARA co-pack, sevelamer powder, and ZEJULA. Dr. Pittman stated that 2 of the agents are classified as oncology agents and 1 agent is a phosphorus depletor thus are in existing categories and do not require a vote.

- Dr. Capparelli inquired as to whether the generic SSRIs (e.g. fluoxetine, paroxetine, sertraline & citalopram) could be placed on the Auto-Exempt list. Dr. Capparelli felt these were fairly inexpensive agents that could be placed on the list. Dr. Capparelli explained that many on the committee are on MCO provider relations committees and it was discussed a couple meetings about the large number of SSRI requests. Dr. Capparelli stated there were over 1,000 PA requests for these agents within the drug class over the last quarter. Dr. Capparelli stated that it was felt this would be cost-effective and alleviate burdens on the provider. Dr. Williams asked Dr. Capparelli if he would like to open this up to the committee for further discussion and a vote on the recommendation. Dr. Capparelli stated that he did not want to place the entire drug class but would like to recommend that the generics specifically mentioned may be exempted from the script limit. Discussion continued regarding how to proceed with the recommendation. Dr. Rhea stated that many of these generics are on many pharmacies \$4 list. Dr. Pittman stated that to in order to add new categories it must be taken to the Auto-Exempt Subcommittee to discuss and vote on the recommendation. Dr. Hailey also clarified that a recommendation would have to be formally voted on by the committee to bring to the Auto-Exempt Subcommittee. Dr. Pittman stated

that the subcommittee will have to meet prior to the November PAC meeting. Dr. Bush discussed findings from the United Healthcare group regarding this agent. Discussion continued amongst the committee regarding allowing the entire class. However, it was later decided to just add the generic agents discussed within the class to the Auto-Exempt list.

- Dr. Jones motioned to take the recommendation of adding the specifically listed generic SSRIs to the Auto-Exempt list to the Auto-Exempt Subcommittee for consideration.
- Motion seconded by Dr. Bush.

## PAC FOLLOW-UP ITEMS

Dr. Lovett stated there were no follow-up items from the last meeting that needed to be addressed.

## PUBLIC TESTIMONY

Public testimony speakers were allowed 5 minutes to address the committee on their respective drug(s).

Public Testimony Speakers		
Speaker	Organization	Product
Helen Kim, PharmD	Synergy Pharmaceuticals	TRULANCE
Manuel Nunez	Sanofi-Genzyme	DUPIXENT
Maggie Murphy, PharmD	Teva Pharmaceuticals	AIRDUO Respiclick
Daniel Claassen, MD	Vanderbilt University	AUSTEDO
Syed Mahmud	PTC Therapeutics	EMFLAZA
Monica Guillory, PharmD	Neurocrine Biosciences	INGREZZA
Teresa Wild, PharmD /Collette Utley, FNP-BC	Pfizer	EUCRISA

- Dr. Capparelli asked if any other studies were conducted that compared TRULANCE with other agents outside of placebo. Dr. Kim stated the only studies conducted were compared with placebo.
- It was noted that the correct spelling for the representative speaking on behalf of Sanofi-Genzyme should be listed as Manuel Nunez. Dr. Capparelli asked for clarification on the response rate regarding DUPIXENT versus placebo. Dr. Capparelli commented that roughly there was about a 25% value added compared to placebo.
- Dr. Capparelli asked for clarification on the efficacy of AIRDUO Respiclick compared to other combination products. Dr. Murphy stated that for ADVAIR and FLOVENT specifically, studies showed similar efficacy compared to Airduo Respiclick. Dr. Capparelli applauded the company in regards to the price point of this agent compared to other agents within the class.

- Dr. Claassen, representative from Vanderbilt discussed Huntington's disease and the new treatment option, AUSTEDO that is currently now available. Dr. Capparelli asked Dr. Claassen if he felt that the drug would lose efficacy overtime with chronic use. Dr. Claassen stated that they are not seeing any signs that would indicate such. Verification that there were not other clinics available that would be able to treat this disease. Dr. Claassen stated that the Vanderbilt Huntington Clinics are the only clinics that offer interdisciplinary care for these patients which includes counseling, physical therapy, occupational therapy and palliative care, etc in one place.
- Representatives from PTC Therapeutics, Neurocrine Biosciences and Pfizer also gave public testimony for their respective drug agents.

## DRUG CLASS REVIEWS

The drug class review section of the meeting consisted of a Magellan Health Services presentation of background information and an overall recommendation for each therapeutic class as well as any proposed clinical criteria, step therapy or quantity limits. This presentation was followed by the Committee's discussion and a vote on the recommendation and any proposed restrictions.

For the purpose of the minutes, the section below reflects Magellan's proposed recommendations, the committee's discussion, the committee's vote on each recommendation, and criteria reviewed. For the complete background information provided by Magellan, please refer to the August 24, 2017 PAC review packet at:

[https://tenncare.magellanhealth.com/static/docs/Committee\\_Information/PAC\\_packet\\_20170824.pdf](https://tenncare.magellanhealth.com/static/docs/Committee_Information/PAC_packet_20170824.pdf)

## TENNCARE PHARMACY INITIATIVES

### NSAIDs

- It is recommended that at least 5 NSAID agents be available for use, one of which should be meloxicam. Additionally, at least one liquid formulation should be available for use. Clinical guidelines recommend topical NSAIDs over oral NSAIDs for patients who may be at risk of GI adverse events and can be useful in patients with difficulty swallowing with poor absorption, or who are at risk or experience adverse effects with systemic NSAIDs. Therefore, it is recommended that topical NSAID agents be available to those with swallowing, absorption difficulties or at increased risk for adverse events.

### Discussion:

- Dr. Johns motioned to accept the recommendation.
- Motion seconded by Dr. Bush.
- Motion carried.

### Current Criteria for diclofenac gel, diclofenac sodium topical soln., FLECTOR, PENNSAID, VOLTAREN gel, VOPAC MDS kit:

Approval will be granted for the following conditions:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Patient has failed an adequate trial of ORAL generic diclofenac AND at least 1 other preferred NSAID, OR



- Patient is unable to swallow/absorb PO medications
- Patients with hypersensitivity to NSAIDs will NOT be approved.

#### **Proposed Criteria for diclofenac gel, diclofenac sodium topical soln., FLECTOR, PENNSAID, VOLTAREN gel, VOPAC MDS kit :**

- Same as Current Criteria

#### **Discussion:**

- Dr. Capparelli voiced concern over bullet point 2 and 3 of the criteria; given that some patients have issues with the oral products. Drs. Lovett and Pittman explained that all the formulations listed in the first PA criteria are specifically for topical diclofenac agents. Discussion continued regarding the wording of bullet point 2.
- Dr. Schwerdt motioned to approve the criteria with modification that bullet point 2 reads “trial/failure, or has contraindication, or intolerance to oral generic diclofenac AND at least 1 other preferred NSAID”.
- Motion seconded by Dr. Jones.
- Motion carried.

#### **Current Criteria for SPRIX:**

Approval will be granted for the following conditions:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Patient has failed an adequate trial of ORAL generic ketorolac; OR
- Patient is unable to swallow/absorb PO medications

#### **Proposed Criteria for SPRIX:**

- Same as Current Criteria

#### **Discussion:**

- Dr. Poling motioned to approve the prior authorization criteria with modification that bullet point 2 reads “Patient has tried/failed, or has contraindication or intolerance to oral generic ketorolac”
- Motion seconded by Dr. Schwerdt.
- Motion carried.

#### **Current Criteria for TIVORBEX & ZORVOLEX:**

Will be approved for patients meeting **ALL** of the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Diagnosis of FDA-approved indication
- Provider must provide peer-reviewed medical literature documenting why the requested drug for the requested Indication is the only appropriate choice versus a preferred

#### **Proposed Criteria for TIVORBEX & ZORVOLEX:**

- Same as Current Criteria

### Discussion:

- The PAC committee asked for clarification on the formulations. Dr. Pittman explained that Tivorbex was indomethacin capsules and Zorvolex was a low dose diclofenac formulation available in 18mg and 35mg capsules. Discussion ensued about the indications and whether it should be included in the criteria.
- Dr. Schwerdt motioned to approve the prior authorization criteria as listed.
- Motion seconded by Dr. Johns.
- Motion carried.

### Current Criteria for VIVLODEX:

Approval will be granted for the following conditions:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Patient has failed an adequate trial of ORAL generic ketorolac; OR
- Patient is unable to swallow/absorb PO medications

### Proposed Criteria for VIVLODEX:

- Same as Current Criteria

### Discussion:

- Committee was given clarification that VIVLODEX was a meloxicam formulation.
- Dr. Schwerdt motioned to approve the prior authorization criteria as listed.
- Motion seconded by Dr. Rhea.
- Motion carried.

### Quantity Limits

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- |             |                   |
|-------------|-------------------|
| • FLECTOR   | 2 patches/day     |
| • Ketorolac | 20/60 days        |
| • SPRIX     | 5 bottles/60 days |
| • VIVLODEX  | 1/day             |
| • ZORVOLEX  | 3/day             |

### Discussion:

- Dr. Jones motioned to approve the quantity limits.
- Motion seconded by Dr. Dunlap.
- Motion carried.

### Combination products for NSAID/Anti-Ulcer Agents

- Due to the incidence of GI adverse reactions associated with NSAIDs, it is recommended that at least one NSAID/anti-ulcer combination agent should be available for use in patients with high risk for NSAID-related GI complications.



### Discussion:

- Dr. Lovett explained that labeling updates were placed on Duexis labeling against substituting Duexis with single-ingredient components. Dr. Rhea asked the reason for the labeling warnings. Discussion continued, however, it was noted that the Duexis formulation contained ibuprofen 800mg and famotidine 26.6 mg which is a slightly different dose than the single famotidine component and is considered an extended release famotidine formulation.
- Dr. Capparelli felt the recommendation was in opposition to the current PDL placement. Dr. Pittman stated that there are not any preferred agents within the class. However, the agents are available to those who are considered high risk through an auto look- back process. Dr. Lovett stated the idea was to prevent direct access to the agents unless you are actually considered a high risk patient. Discussion continued regarding the auto-look back process.
- Dr. Jones motioned to accept the recommendation.
- Motion seconded by Dr. Bush.
- Motion carried.

### Current Criteria for Non-Preferred Agents:

- For patients less than 60 years old:
  - Must be prescribed by a provider with a Tennessee Medicaid ID; AND
  - Will be approved for patients who are at high risk for GI side effects as indicated by ANY of the following:
    - History of peptic ulcer disease/GI bleed/NSAID gastropathy
    - GERD (gastroesophageal reflux disease) due to conventional NSAIDS
    - Patient on anticoagulants (warfarin/heparin/LMWH)
    - Patient on corticosteroids
    - History of platelet dysfunction or coagulopathy, including use of clopidogrel or aspirin
    - Patient on methotrexate
- PA not required for patient > 60 years old.

### PROPOSED Criteria for Non-Preferred Agents:

Will be approved if **ALL** the following is met:

- Must be prescribed by a provider with a Tennessee Medicaid ID; **AND**
- Patient is at high risk for GI side effects as indicated by **ANY** of the following:
  - History of peptic ulcer disease/GI bleed/NSAID gastropathy
  - GERD (gastroesophageal reflux disease) due to conventional NSAIDS
  - Patient on anticoagulants (warfarin/heparin/LMWH)
  - Patient on *chronic* corticosteroids
  - History of platelet dysfunction or coagulopathy, including use of clopidogrel or aspirin
  - Patient on methotrexate; **AND**
- *Trial/failure or intolerance to 2 preferred proton pump inhibitors (PPIs) in combination with a prescription dose NSAID*

### Discussion:

- Dr. Capparelli asked if there was value in adding the bullet point that indicates PA is not required for patients greater than 60 years of age. Dr. Capparelli felt that since it was previously added to the criteria; that it was important to place the age related bullet points back into the criteria. Discussion continued regarding the age related concerns of NSAID agents and placement of age related bullet points.

- Dr. Jones motioned to approve criteria with modification to add back the bullet point “PA not required for pt ≥ 60 years old “ and include listed PA criteria for patients less than 60 years of age. Additionally, to remove specific examples of anticoagulants.
- Dr. Rhea seconded the motion.
- Motion carried.

## Quantity Limits

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|------------------------------------|---|
| • Diclofenac-misoprostol/Arthrotec | 50mg/200mcg: 4/day; 75mg/200 mcg: 2/day |
| • DUEXIS                           | 3/day                                   |
| • VIMOVO                           | 2/day                                   |

## Discussion:

- Dr. Jones motioned to approve the quantity limits as presented.
- Dr. Dunlap seconded the motion.
- Motion carried.

## Anti-migraine: 5HT1 Receptor Agonists

- Therefore, it is recommended that at least two distinct triptans be available *in multiple dosage forms*, including at least one oral, one nasal, and one injectable dosage form. Furthermore, ~~since almotriptan is the only FDA triptan approved for those 12 to 17 years of age, it should be available for use in children.~~ at least one triptan agent FDA approved for children should be available for use.

## Discussion:

- Dr. Rhea inquired as to what children would do if they did not respond to almotriptan. Dr. Pittman explained that they would meet the non-preferred criteria.
- Dr. Johns motioned to accept the recommendation.
- Motion seconded by Dr. Jones.
- Motion carried.

## Current Criteria for almotriptan:

- PA will not be required for patients < 18 years of age

## Proposed Criteria for almotriptan:

- ~~• PA will not be required for patients < 18 years of age~~

## Discussion:

- Dr. Lovett stated that the PA criteria that was previously in place is being removed. Dr. Pittman further explained that there is now a preferred agent available for kids that does not require a PA; so this agent will pay at POS if the submitted claim is within the allowed quantity limit. Dr. Pittman stated that the auto-PA that was in place for almotriptan will be removed. Discussion continued regarding brand name agents.

- Dr. Jones motioned to accept the removal of prior authorization criteria for almotriptan.
- Motion seconded.
- Motion carried.

#### **Current Criteria for IMITREX kit/cartridge & sumatriptan kit:**

Will only be approved for patients with a clinically valid reason clinical reason the patient cannot use the injectable vials; **AND**

Must be prescribed by a provider with a Tennessee Medicaid ID

(NOTE: Patient convenience is NOT an approvable reason) Will be approved if the following criteria is met:

#### **Proposed Criteria for IMITREX kit/cartridge & sumatriptan kit:**

- Same as Current Criteria

#### **Discussion:**

- Dr. Johns motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Jones.
- Motion carried.

#### **Current Criteria for MIGRANOW kit:**

Will be approved for patients meeting **ALL** of the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID; **AND**
- Patient has a contraindication, allergic reaction, or serious adverse event to ALL preferred Antimigraine: Selective 5-HT<sub>1</sub> Agonists; **AND**
- Provider must provide documentation as to why the requested drug for the requested indication is the only appropriate choice versus the preferred agents

#### **Proposed Criteria for MIGRANOW kit:**

- Same as Current Criteria

#### **Discussion:**

- Dr. Poling motioned to accept the PA criteria as presented.
- Motion seconded.
- Motion carried.

#### **Current Criteria for ONZETRA XSAIL:**

Will be approved if ALL of the following are met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID; **AND**
  - Patient has an allergy to an inactive ingredient found in the preferred sumatriptan containing agents; **AND**
  - Patient has a contraindication, allergic reaction, or drug-drug interaction to preferred rizatriptan containing agents; **AND**
  - A clinically valid reason is given as to why the patient requires a nasal powder
- (NOTE: Patient convenience is NOT an approval reason)

#### **Proposed Criteria for ONZETRA XSAIL:**

- Same as Current Criteria

### Discussion:

- Dr. Rhea asked if nausea would be an appropriate reason to use this product. Dr. Lovett stated there is a preferred nasal spray available along with an ODT product. Discussion continued.
- Dr. Jones motioned to approve the PA criteria as presented.
- Dr. Johns second the motion.
- Motion carried.

### Current Criteria for SUMAVEL DOSEPRO:

PA will be approved if All the following are met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID; **AND**
- Will be approved for patients with a clinically valid reason for a needleless injection device  
(NOTE: Patient convenience is NOT an approval reason)

### Proposed Criteria for SUMAVEL DOSEPRO:

PA will be approved if **All** the following are met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID; **AND**
- *Patient has an allergy to an inactive ingredient found in the preferred sumatriptan containing agents; **AND***
- *Patient has a contraindication, allergic reaction, or drug-drug interaction to preferred rizatriptan containing agents;*
- Will be approved for patients with a clinically valid reason for a needleless injection device

(NOTE: Patient convenience is NOT an approval reason)

### Discussion:

- Dr. Johns motioned to approve the proposed criteria.
- Motion seconded by Dr. Bush.
- Motion carried.

### Current Criteria for ZEMBRACE SYMTOUCH:

Will be approved if **ALL** of the following are met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID; **AND**
- Patient has an allergy to an inactive ingredient found in the preferred sumatriptan containing agents; **AND**
- Patient has a contraindication, allergic reaction, or drug-drug interaction to preferred rizatriptan containing agents; **AND**
- A clinically valid reason is given as to why the patient requires an autoinjector device (**NOTE:** Patient convenience is NOT an approval reason)

### Proposed Criteria for ZEMBRACE SYMTOUCH:

- Same as Current Criteria

### Discussion:

Dr. Rhea asked for clarification on the auto-injector and needleless formulations. Dr. Pittman explained that the Sumavel agent does not contain a needle for delivery of the medication. Dr. Lovett explained that the auto-injector does contain a needle and has a button that pushes the needle out with the medication.

## Quantity Limits

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• sumatriptan nasal/IMITREX Nasal	6 units/month
• rizatriptan, rizatriptan ODT, MAXALT, MAXALT MLT	12 tablets/month
• MIGRANOW Kit	1kit per 30 days
• ONZETRA XSAIL	4/30 days
• RELPAX	6 tablets/month
• sumatriptan injectable, IMITREX inj	8 vials/month
• sumatriptan tabs, IMITREX	9 tablets/month
• naratriptan, AMERGE	9 tablets/ month
• almotriptan, AXERT	12 tablets/ month
• frovatriptan, FROVA	9 tablets/month
• sumatriptan kit/ IMITREX kit/Cartridge	4/ month
• ALSUMA Auto Injector, SUMAVEL DOSEPRO	4 mL/30 days
• TREXIMET	10 tablets/ month
• ZEMBRACE SYMTOUCH	2 mL/30 days
• zolmitriptan, ZOMIG, ZOMIG ZMT	6 tablets/ month
• ZOMIG Nasal Spray	6 units/ month

## Discussion:

- Dr. Collier asked why some of the products go by monthly quantity limits and others by day. Dr. Williams stated that typically the quantity limits are pulled from the package insert; so it's based on the manufacturer's specifications. Dr. Lovett and Pittman further clarified that the packaging and the number of migraines you can treat per month is also factored into the quantity limit. Discussion continued regarding the day supply and 85% utilization threshold.
- Dr. Poling asked if a PA was required for Treximet if the amount they received was within the quantity limit allowed. Dr. Pittman stated that non-preferred agents require a PA, if it does not have a superscript, the standard non-preferred PA criteria of trial/failure of 2 preferred agents applies. Discussion continued.
- Dr. Jones motioned to accept the quantity limits.
- Motion seconded by Dr. Dunlap.
- Motion carried.

## Anti-Migraine: Ergotamine Derivatives

- Therefore, it is recommended that at least ergotamine be available as an alternative therapy for patients experiencing acute headaches.

## Discussion:

- Dr. Capparelli commented on the fact that some patients who experience migraines are unable to take anything by mouth due to the effects of the migraine and a nasal spray is a really good option. Dr. Capparelli also commented that perhaps the recommendation should indicate that "at least one ergotamine product be available".

- Dr. Pittman discussed the fact that Ergomar was not commercially available for a long time; but since that time has just recently been placed back on the market as a sublingual agent. Dr. Lovett commented that there was only 1 patient in the past quarter that has used the product. Dr. Jones commented that the agent was available as a sublingual agent when it was previously on the market. Discussion continued. Dr. Capparelli commented that dihydroergotamine nasal spray was very expensive.
- Dr. Jones motioned to approve the recommendation with modification that it reads “at least one ergotamine agent be available”.
- Motion seconded by Poling.
- Motion carried.

#### Current Criteria for Non-preferred agents:

Will be approved for patients with contraindication or therapeutic failure to TWO preferred products in ANY of the following categories:

- Triptans
- RX NSAIDS
- Migraine combination product; AND
- Must be prescribed by a provider with a Tennessee Medicaid ID

#### Proposed Criteria for Non-preferred agents:

Same as Current Criteria

#### Discussion:

- Dr. Poling motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Jones.
- Motion Carried

#### Quantity Limits

- |  |                 |
|--|-----------------|
| • Dihydroergotamine nasal spray/MIGRANAL | 8 mL/30 days    |
| • ERGOMAR                                | 20 tabs/30 days |

#### Discussion:

- Dr. Poling motioned to accept the quantity limits.
- Motion seconded by Dr. Dunlap.
- Motion Carried.

#### Anti-Migraine: Combo Agents

- Therefore, it is recommended that ~~at least three~~ migraine combination products be available for use in the management of headaches, *which includes including* at least one ergotamine-containing product, at least one ASA-containing product, and at least one APAP-containing product. *Additionally, given the safety concern regarding butalbital containing agents and upon recommendation of our DUR Board Committee the quantity limit on butalbital containing products*

*should be limited to 20 tablets per month with requests over this limit subject to prior authorization criteria.*

#### Discussion:

- Dr. Rhea inquired about frovatriptan indications. Dr. Pittman commented that it has a prophylactic indication for menstrual headaches.
- Dr. Jones commented that the FDA is allowing multiple combination products on the market. Discussion ensued.
- Dr. Capparelli commented on the number of patients that are willing to pay for the remaining amount of medication that is not covered by TennCare
- Dr. Jones motioned to approve the recommendation as presented.
- Motion seconded by Dr. Poling.
- Motion carried.

#### Current Criteria for Quantity Limit Override on Butalbital-Containing Products:

Requests for butalbital-containing products for quantities greater than 20 per 30 days will be approved for patients meeting the following criteria:

- Trial and failure of at least 2 prophylactic headache treatments: a tricyclic antidepressant (unless contraindicated) **PLUS** at least one of the following: divalproex sodium, sodium valproate, topiramate, frovatriptan or beta-blocker

#### Proposed Criteria for pilocarpine:

- Same as Current Criteria

#### Discussion:

- Dr. Jones motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Rhea.
- Motion Carried.

#### Quantity Limits

• butalbital/ <b>APAP combo products</b>	Max Qty: 20 tabs/caps of butalbital containing products per 30 days ** Max: 4 g APAP/day
• butalbital/ASA combo products	Max Qty: 20 tabs/caps of butalbital containing products per 30 days**
• CAFERGOT	30 tabs/30 days
• Isomethept/caffeine/APAP	8/day Max: <b>4 gm APAP/day</b>
• Isometheptene/dichloralphenazone/APAP	8/ day Max: <b>4 gm APAP/day</b>
• MIGERGOT	15 SUPP/30 DAYS
• VANATOL LQ	300 ML/30 DAYS

#### Discussion:

- Dr. Lovett noted the limit on the APAP combination products. Dr. Capparelli stated that it is very hard to limit the amount of APAP that a patient may use once they pick up the prescription, given the APAP products are available over the counter that may be used in conjunction with the prescription products.



- Dr. Jones motioned to accept the quantity limits.
- Motion seconded by Dr. Johns.
- Motion Carried

## DUR Board Recommendations

### Androgens

- Due to its unique indications, it is recommended that danazol should be available for use. Additionally, it is recommended at least one topical testosterone gel product should be available for use. Due to the potential for abuse as an anabolic agent, as well as to prevent use in erectile dysfunction not associated with hypogonadism, it is recommended all agents in this class (with the exception of danazol) should be subject to clinical criteria.

#### Discussion:

- Dr. Pittman also reviewed the DUR Board recommendations regarding androgens. Dr. Capparelli noted that testosterone levels decrease during the day; so exceptions for shift workers should be considered. Dr. Capparelli also noted that normal testosterone levels differ by age. Dr. Pittman stated that the PA criteria does not specifically list a testosterone level and made note about the shift worker concern. It was also stated that “a low free testosterone level” should be clarified.
- Dr. Rhea voiced concerns regarding using levels based on age. Dr. Rhea stated that she typically tries to treat based on a normal healthy individual level. Dr. Poland commented that one of the common problems with low testosterone is obesity. Dr. Capparelli stated that smoking should tie into that as well. Discussion continued regarding the laboratory norm levels and the proposed PA criteria.
- Dr. Pittman asked if clarification should be included as to who should be required to submit a PSA level. Dr. Capparelli commented that the PSA criteria level is great and should be included. Discussion continued regarding the PSA level that should be listed.
- Dr. Jones motioned to accept the recommendation.
- Motion seconded.
- Motion Carried.

### Current Criteria for Preferred Products:

Preferred androgen products will be approved for recipients meeting **ALL** of the following criteria:

- Documentation of lab results confirming diagnosis of hypogonadism
- Recipient must be MALE
- Must be prescribed by a provider with a Tennessee Medicaid Provider ID

**Note:** Requests for renewal requires documentation of low or normal lab results from previous 12 months.

### Proposed Criteria for Preferred Products:

Preferred androgen products will be approved for recipients meeting **ALL** of the following criteria:

*Initial Requests:*

- ~~Documentation of lab results confirming~~ Diagnosis of hypogonadism *as confirmed by 2 baseline fasting testosterone levels drawn between 8-10 AM demonstrating low testosterone*
- ~~Recipient must be MALE~~

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- *Baseline hematocrit*
- *Baseline Luteinizing Hormone*
- *Requests for diagnosis of gender dysphoria will be referred to the state on a case-by-case basis for determination*

#### *Renewal Requests:*

- Documentation of low or normal fasting *testosterone level* lab results from previous 12 months
- *Hematocrit  $\leq 50\%$*
- *PSA level  $< 3$  ng/mL*

### Discussion:

- Committee discussed adding wording that specifies testosterone levels should be taken on 2 separate days. The committee discussed if free testosterone or total testosterone should be specified. The committee decided to not specify which testosterone level should be utilized. Discussion continued around the timing of drawing testosterone levels.
- The committee discussed criteria specifics. Dr. Pittman stated she would check on the PA duration during lunch. The committee continued to discuss requests from women. It was decided that recipient must be male would be added for those with a diagnosis of hypogonadism. Dr. Rhea voiced concern with requests from children. Dr. Pittman stated that all gender dysphoria cases are reviewed by the state on a case by case basis.
- The committee motioned to accept the prior authorization criteria with modification that documentation of lab results confirming diagnosis of hypogonadism as confirmed by 2 baseline fasting testosterone levels are drawn in the AM on separate dates , recipient must be male, must be prescribed by a provider with a TN Medicaid Provider ID, patient has a baseline hematocrit that is  $\leq 50\%$ , patient has a baseline luteinizing hormone and a PSA level  $< 3$  ng/mL and requests for a diagnosis of gender dysphoria are referred to the state on a case-by case basis for determination, For Renewal requests, documentation of low or normal fasting testosterone level lab results from the previous 12 months, a hematocrit  $\leq 50\%$  and a PSA level  $< 3$  ng/mL.
- Motion seconded
- Motion Carried.

### Current Criteria for Non-Preferred Topical Products:

Non-preferred topical androgen products will be approved for patients meeting the following criteria:

- Documentation of lab results confirming diagnosis of hypogonadism
- Recipient must be MALE
- Trial and failure, intolerance, or contraindication to at least ONE preferred topical testosterone product
- Must be prescribed by a provider with a Tennessee Medicaid Provider ID

### Proposed Criteria for Non-Preferred Topical Products:

Non-preferred topical androgen products will be approved for patients meeting ALL of the following criteria:

#### *Initial requests:*

- ~~Documentation of lab results confirming~~ Diagnosis of hypogonadism *as confirmed by 2 baseline fasting testosterone levels drawn between 8-10 AM demonstrating low testosterone*
- ~~Recipient must be MALE~~
- Must be prescribed by a provider with a Tennessee Medicaid Provider ID

- *Baseline hematocrit*
- *Baseline Luteinizing Hormone*
- ~~Trial and failure~~, Intolerance, or contraindication to an inactive ingredient in all preferred testosterone products that is not in requested product
- *Requests for diagnosis of gender dysphoria will be referred to the state on a case-by-case basis for determination*

**Renewal Requests:**

- Documentation of low or normal fasting *testosterone level* lab results from previous 12 months
- *Hematocrit ≤50%*
- *PSA level <3ng/mL*

**Discussion:**

- Dr. Jones motioned to accept the prior authorization criteria with the same modifications made to the PA criteria for preferred products.
- Motion seconded by Dr. Dunlap.
- Motion Carried.

**Current Criteria for DELATESTRYL, DEPO-TESTOSTERONE (excluding 200 mg/mL 1 mL vial), testosterone cypionate, and testosterone enanthate:**

Non-preferred androgen products will be approved for patients meeting the following criteria:

- Documentation of lab results confirming diagnosis of hypogonadism
- Recipient must be MALE
- Trial and failure, intolerance, or contraindication to at least ONE preferred testosterone product
- Must be prescribed by a provider with a Tennessee Medicaid Provider ID

Note: Requests for renewal requires documentation of low or normal lab results from previous 12 months

**Proposed Criteria for DELATESTRYL, DEPO-TESTOSTERONE (excluding 200 mg/mL 1 mL vial), testosterone cypionate, and testosterone enanthate:**

Non-preferred androgen products will be approved for patients meeting ALL of the following criteria:

**Initial requests:**

- ~~Documentation of lab results confirming~~ Diagnosis of hypogonadism *as confirmed by 2 baseline fasting testosterone levels drawn between 8-10 AM demonstrating low testosterone*
- ~~Recipient must be MALE~~
- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- *Baseline hematocrit*
- *Baseline Luteinizing Hormone*
- Trial and failure, intolerance, or contraindication to at least ONE preferred testosterone product
- *Requests for diagnosis of gender dysphoria will be referred to the state on a case-by-case basis for determination*

**Renewal Requests:**

- Documentation of low or normal fasting *testosterone level* ~~lab results~~ from previous 12 months
- *Hematocrit ≤50%*
- *PSA level <3ng/mL*

**Discussion:**

- Dr. Pittman noted that the previous changes could be made to these agents as well. The only other change is the non-preferred criteria which requires trial and failure, intolerance or contraindication to at least ONE preferred testosterone product.

- Dr. Poling motioned to accept the prior authorization criteria with modifications previously made.
- Motion seconded.
- Motion Carried.

#### Current Criteria for ANDROID, ANDROXY, METHITEST, methyltestosterone, and TESTRED:

Non-preferred androgen products will be approved for patients meeting the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Trial and failure, intolerance, or contraindication to at least ONE preferred topical testosterone product
- Note: Methyltestosterone and fluoxymesterone will also be approved for the treatment of advancing, inoperable metastatic mammary cancer in women who are 1 to 5 years post-menopausal.

#### Proposed Criteria for ANDROID, ANDROXY, METHITEST, methyltestosterone, and TESTRED:

Will be approved for patients meeting the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID; AND
- Treatment of advancing, inoperable metastatic mammary cancer in women who are 1 to 5 years post-menopausal; OR
- *Diagnosis of hypogonadism as confirmed by 2 baseline fasting testosterone levels drawn between 8-10 AM demonstrating low testosterone; AND*
  - ~~Recipient must be MALE~~
  - Baseline hematocrit
  - Baseline Luteinizing Hormone
  - Trial and failure, intolerance, or contraindication to at least ONE preferred testosterone product
- *Requests for diagnosis of gender dysphoria will be referred to the state on a case-by-case basis for determination*

*Renewal Requests for diagnosis of hypogonadism:*

- Documentation of low or normal fasting testosterone level from previous 12 months
- Hematocrit ≤50%
- PSA level <3ng/mL

#### Discussion:

- Dr. Jones motioned to accept the prior authorization criteria with modifications that the changes previously made are included.
- Motion seconded by Dr. Dunlap
- Motion Carried.

#### Quantity Limits

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• DEPO-TESTOSTERONE	4mL/30 days
• DELATESTRYL	4 mL/30 days
• testosterone cypionate	4 mL/30 days
• testosterone enanthate	4 mL/30 days

#### Discussion:

- Dr. Pittman stated the quantity limits listed are for the injectable testosterone products.

- Dr. Capparelli asked for clarification that a quantity limit override could be obtained if a patient needs more than the requested quantity limit
- Dr. Poling motioned to accept the quantity limits.
- Motion seconded by Dr. Dunlap.
- Motion Carried.

Dr. Hailey recognized Dr. Ray McIntire, Director of Pharmacy Operations for his 8th year anniversary with TennCare.

Committee members were dismissed for lunch.

All committee members returned with the exception of Dr. Collier.

## NEW DRUG APPROVALS

### fluticasone/salmeterol (AIRDUO Resplick)

#### Prior Authorization Criteria

##### Interim Criteria:

Will be approved for patients meeting following criteria:

- For the treatment of asthma or the treatment of other reversible airway disease(s) where optimal doses of inhaled steroids are being used and breakthrough symptoms require frequent use of inhaled short-acting bronchodilators; AND
- Trial and failure, contraindication or intolerance of 2 preferred agents

##### Proposed Criteria:

Same as Interim Criteria

##### Discussion:

- Dr. Jones motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Poling.
- Motion Carried.

## Quantity Limits

- 
- fluticasone/salmeterol (AIRDUO Resplick) 1/30 days

##### Discussion:

- Dr. Poling motioned to accept the quantity limits.
- Motion seconded by Dr. Schwerdt.
- Motion Carried.

## AUSTEDO

### Prior Authorization Criteria

##### Interim Criteria:

Will be approved for patients meeting following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Patient is diagnosed with chorea related to Huntington's disease; AND
- Trial and failure of tetrabenazine; AND

Patients meeting the following criteria will **NOT** be approved:

- History of untreated or inadequately depression
- Suicidal ideation, untreated or inadequately treated depression
- Concurrent therapy with tetrabenazine, reserpine, or MAOIs
- Hypersensitivity to deutetrabenazine
- Pregnancy
- Hepatic impairment

#### Proposed Criteria:

Will be approved for patients meeting following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Patient is diagnosed with chorea related to Huntington's disease; **AND**
- ~~Trial and failure~~ Contraindication or intolerance to tetrabenazine; **AND**

Patients meeting the following criteria will **NOT** be approved:

- History of untreated or inadequately depression, suicidal ideation, or untreated or inadequately treated depression *due to a boxed warning that it increases the risk of depression and suicidal thoughts and behavior*
- Concurrent therapy with tetrabenazine, reserpine, or MAOIs
- Hypersensitivity to deutetrabenazine
- Pregnancy
- Hepatic impairment

#### Discussion:

- Dr. Capparelli commented on the disease progression associated with this condition. Dr. Pittman also noted the depression issues and the concern that the medicine itself may add to the depression. Dr. Rhea interjected that the drug should not be dismissed for its quality of life benefits. The committee and Dr. Williams discussed genetic testing and associated pharmacokinetic issues.
- Dr. Johns inquired about a step through with tetrabenazine. Dr. Williams stated that after receiving the additional information regarding AUSTEDO; it appears both agents have a similar safety profile. Dr. Williams commented that if they wanted to reverse removal of the trial/failure of tetrabenazine; The Pharmacy Program would be open to the recommendation. Discussion continued regarding the agents place in therapy.
- Dr. Capparelli asked if there was value in addition to requiring provider must have TN Medicaid Provider ID; that a provider must also have experience in treating Huntington disease, for example provider is from a center of excellence. Dr. Hailey agreed with Dr. Capparelli's comment. Discussion continued.
- Dr. Capparelli motioned to approve the criteria with modification that a bullet point is added that requires the provider to be associated with a center of excellence or the provider is experienced in the treatment of Huntington's disease and to add back in the trial/failure on the 3rd bullet point.
- Motion seconded by Dr. Jones.
- Motion Carried.

#### Quantity Limits

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- AUSTEDO 4/day

#### Discussion:

- Dr. Jones motioned to accept the quantity limits.

- Motion seconded by Dr. Rhea.
- Motion Carried.

## EMFLAZA

### Interim Criteria:

#### Prior Authorization Criteria

Will be approved for an initial request for 6 months for patients meeting ALL of the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient must have documentation of a confirmed diagnosis of Duchenne muscular dystrophy (DMD); **AND**
  - Age ≥5 years; **AND**
  - Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
  - Patient should be receiving physical therapy; **AND**
  - Patient has experienced at least 1 of the following unacceptable adverse reactions directly attributable to previous therapy with prednisone:
    - Patient has experienced significant weight gain (e.g., crossing 2 percentiles and/or reaching 98th percentile for age and sex)
    - Patient has manifested significant behavioral changes negatively impacting function at school, home, day care, etc.; **OR**

Requests for continuation after the initial PA will be approved for patients meeting the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient continues to receive physical therapy; **AND**
- Patient has received benefit from therapy, which may include 1 or more of the following:
  - Stability or slowing of decline in motor function
  - Stability or slowing of decline in respiratory function
  - Stability or slowing of decline in sequelae related to diminished strength of stabilizing musculature (e.g., scoliosis, etc.)
  - Quality of Life

### Proposed Criteria:

Same as Interim Criteria

### Discussion:

- Dr. Capparelli asked for clarification on bullet point that reads “Patient retains meaningful voluntary motor functions...” Dr. Pittman explained that these are merely examples and it does not mean they have to meet all motor functions listed.
- Dr. Capparelli informed the committee that the recommendation is not up for vote; only the PA criteria for EMFLAZA is being voted on today.
- Dr. Johns motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Rhea.
- Motion Carried.

## EUCRISA

- It is recommended topical PDE-4 inhibitors should be subject to prior authorization.



## Discussion:

- Dr. Rhea motioned to accept the recommendation.
- Motion seconded by Dr. Bush.
- Motion carried.

## Prior Authorization Criteria for EUCRISA

### Interim Criteria

Will be approved if all of the following are met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient is  $\geq 2$  years of age; **AND**
- Diagnosis of atopic dermatitis; **AND**
- Trial and failure of 2 Topical Corticosteroids and 1 Topical Calcineurin Inhibitor (e.g., Pimecrolimus or Tacrolimus); **OR**
- Trial and failure of either class (Topical Corticosteroids or Topical Calcineurin Inhibitors) and there is a clinical situation where therapy is not preferred with the other class:
  - Steroids:
    - of sensitive areas (face, anogenital, skin folds)
    - Steroid Induced Atrophy
    - Long-term Uninterrupted use
  - Topical Calcineurin Inhibitors:
    - Severely impaired skin barrier (Netherton Syndrome)
    - Risk/Presence of malignancy

### Proposed Criteria:

Will be approved if all of the following are met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient is  $\geq 2$  years of age; **AND**
- Diagnosis of atopic dermatitis; **AND**
- Trial and failure of 2 Topical Corticosteroids and 1 Topical Calcineurin Inhibitor (e.g., Pimecrolimus or Tacrolimus); **OR**
- Trial and failure of either class (Topical Corticosteroids or Topical Calcineurin Inhibitors) **AND** there is a clinical situation *patient has one of the following conditions* where therapy is not preferred with the other class:
  - *Conditions that preclude use of Steroids:*
    - Treatment of sensitive areas (face, anogenital, skin folds)
    - Steroid Induced Atrophy
    - Long-term uninterrupted use
  - *Conditions that preclude use of Topical Calcineurin Inhibitors:*
    - Severely impaired skin barrier (Netherton Syndrome)
    - Risk/Presence of malignancy

## Discussion:

- The committee discussed use of this product to primarily those areas that are sensitive (e.g. face, around eyes, neck) and using a steroid agent for the other parts of the body. Dr. Capparelli stated that when we get to quantity limits we may want to evaluate the amount allowed. Dr. Pittman commented that the proposed quantity limit allows 1 tube per 28 days. Discussion continued regarding the specific areas and percentage of the body that may be affected.
- Dr. Johns motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Dunlap.
- Motion Carried.

## Quantity Limits

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- Eucrisa 1 tube/28 days

### Discussion:

- The committee discussed the proposed quantity limit and it was noted that 1 tube allowed 60 grams of the medication. However, the committee agreed that this would not allow use for the entire body.
- Dr. Johns motioned to accept the quantity limit.
- Motion seconded by Dr. Jones.
- Motion Carried.

## INGREZZA

### Prior Authorization Criteria

#### Interim Criteria

Will be approved if **ALL** of the following are met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient age ≥ 18 years; **AND**
- Diagnosis of tardive dyskinesia; **AND**
- Documentation that AIMS test has been completed (e.g., score or copy of AIMS assessment); **AND**
- Prescribed by or in consultation with a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; **AND**
- Documentation or claims history of current or former chronic patient use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc).

**Patients with either of the following will be denied:**

- Concurrent use of MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc); **OR**
- Use for other movement disorders that are not TD (e.g., chorea, Parkinson's disease).

#### Proposed Criteria:

Same as Interim Criteria

### Discussion:

- Dr. Johns inquired if this agent needed a drug class recommendation. Dr. Pittman stated that this agent will not specifically be listed on the PDL, but would be listed under the category: "Agents not listed on the PDL", thus it will not require a class recommendation and will be listed with just the criteria. Discussion continued regarding possible placement on the PDL. However, Dr. Williams stated that given Ingrezza and Austedo have the same mechanism of action; they have 2 different indications. Dr. Poling voiced concern with using the phrase "other mental health provider" and who would fall under this title. Dr. Poling recommended removing this phrase and just leave psychiatrist. Dr. Capparelli voiced concerns over "reasonable access". Discussion continued.
- Dr. Bush suggested for patients who continue to have symptoms after the 12-16 week time frame listed in the package insert, adding another bullet point that states continuation of symptoms following dose reduction, tapering or discontinuation of the offending agent or patient is not a candidate of dose reduction or discontinuation. Committee discussion ensued. Dr. Bush proposed to withdraw the recommendation.
- Dr. Poling motioned to accept the prior authorization criteria with modification that the same "or other mental health provider" phrase is removed.
- Motion seconded by Dr. Jones.
- Motion Carried.

## Quantity Limits

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- INGREZZA 2/day

### Discussion:

- Dr. Poling motioned to accept the quantity limit.
- Motion seconded by Dr. Rhea.
- Motion Carried.

## KISQALI

### Prior Authorization Criteria

#### Interim Criteria

Will be approved if the following is met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient has a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive; **AND**
- Human epidermal growth factor receptor 2 (HER2)-negative; **AND**
- Is being used in combination with an aromatase inhibitor; **AND**
- Female patient is postmenopausal as defined by 1 of the following:
  - Prior bilateral oophorectomy
  - Age > 60 years
  - Age < 60 years and amenorrhea for ≥ 12 months (in the absence of chemotherapy, tamoxifen, toremifene or ovarian suppression) and FSH and estradiol levels in the postmenopausal range

Renewal Criteria:

- Patient continues to meet initial review criteria; **AND**
- Tumor response with stabilization of disease OR decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug at current dosage level

### Proposed Criteria:

Same as Interim Criteria

### Discussion:

- Dr. Jones motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Johns.
- Motion Carried.

## KISQALI-FEMARA Co-pack

### Prior Authorization Criteria

#### Interim Criteria

Will be approved if the following is met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient has a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive; **AND**
- Human epidermal growth factor receptor 2 (HER2)-negative; **AND**
- Is being used in combination with an aromatase inhibitor; **AND**

- Female patient is postmenopausal as defined by 1 of the following:
  - Prior bilateral oophorectomy
  - Age > 60 years
  - Age < 60 years and amenorrhea for ≥ 12 months (in the absence of chemotherapy, tamoxifen, toremifene or ovarian suppression) and FSH and estradiol levels in the postmenopausal range

#### Renewal Criteria:

- Patient continues to meet initial review criteria; **AND**
- Tumor response with stabilization of disease OR decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug at current dosage level

#### Proposed Criteria:

Same as Interim Criteria

#### Discussion:

- Dr. Pittman stated that the 4<sup>th</sup> bullet point should be removed as it is packaged with an aromatase inhibitor.
- Dr. Schwerdt motioned to accept the prior authorization criteria with modification that the 4<sup>th</sup> bullet point will be removed.
- Motion seconded by Dr. Jones.
- Motion Carried.

#### Quantity Limits

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- |                          |                               |
|--------------------------|-------------------------------|
| • KISQALI                | 63 tabs/28 days               |
| • KISQALI-FEMARA co-pack | 200mg: 1 pk (tabs)/28 days    |
|                          | 400mg: 1 pk (70 tabs)/28 days |
|                          | 600mg (91tabs)/28 days        |

#### Discussion:

- Dr. Schwerdt motioned to accept the quantity limit.
- Motion seconded.
- Motion Carried.

#### Rhofade

##### Prior Authorization Criteria

##### Interim Criteria

Will be approved if the following is met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient age at least 18 years of age, but less than 21 years of age; **AND**
- Patient has a diagnosis rosacea or erythema; **AND**
- Unless contraindicated, have tried and failed at least 2 of the following: brimonidine (MIRVASO), ivermectin (SOOLANTRA) tetracycline, minocycline, doxycycline, erythromycin, clindamycin, benzoyl peroxide; **AND**
- Trial/failure of 2 preferred topical agents for rosacea

#### Proposed Criteria:

Same as Interim Criteria

#### Discussion:

- Dr. Rhea inquired about the formulation of this agent and if there was a nasal spray available that contains the same active ingredient. Dr. Pittman stated this was a cream. Dr. Lovett stated it was

available as a nasal spray, called AFRIN which is an over the counter product. The committee discussed the fact that rosacea products are only covered for children; as this indication is considered cosmetic.

- Dr. Schwerdt motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Poling.
- Motion Carried.

### Quantity Limits

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- RHOFAD 60 grams/30 days

### Discussion:

- The committee discussed the quantity limit and thought it was available as a 30 gram tube. **Dr. Pittman stated they would double check the packaging and confirm the quantity limit.**
- Dr. Schwerdt motioned to accept the quantity limit with modification to allow only 1 tube.
- Motion seconded by Dr. Jones.
- Motion Carried.

### SILIQ

#### Prior Authorization Criteria

#### Interim Criteria

Will be approved for patients meeting ALL of the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient has a diagnosis of moderate to severe plaque psoriasis; **AND**
- Patient has failed an adequate trial of at least TWO topical treatments (corticosteroids, calcipotriene, coal tar, tazarotene) **AND**
- Patient has tried/failed at least ONE oral treatment (SORIATANE, methotrexate, cyclosporine) unless contraindicated; **AND**
- Patient has a contraindication, drug-drug interaction, or adverse reaction to ALL preferred immunomodulator agents with same indication (e.g., ENBREL, HUMIRA); **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Patient does not have a history of Crohn's disease; **AND**
- Prescriber and patient have met the requirements of the Siliq REMS program

**Length of authorization:** Initial PA of 6 months, and yearly thereafter if medication is well tolerated. For continuation of therapy after the initial PA, a 50% reduction of total Psoriasis Area Severity Index (PASI) score must be achieved.

### Proposed Criteria:

Same as Interim Criteria

### Discussion:

- Dr. Jones voiced concern that it is hard to prevent a patient from getting live vaccines as patients are able to receive vaccines from the local clinics and/or pharmacies without the provider ever knowing. Committee continued to discuss the PA requirements and how it related to the criteria for other non-preferred agents. Dr. Pittman stated that the first-half was similar to the other criteria, but the other requirements (live vaccines, Crohn's disease and REMs were specific to this agent.
- The committee also discussed the suicide risk associated with this agent. As a result, Dr. Bush recommended making the initial PA duration 4 months to determine if an adequate response has been seen within the 12-16 week time frame listed in the package insert. The committee also discussed modifying the reduction percentage in the total PASI score. Dr. Poling commented that all the other requirements are addressed in the REMS program.
- Dr. Rhea asked if this drug was more dangerous or due to the fact that drugs are being approved much faster. Dr. Pittman commented that several immunomodulators have come to the market recently and this is the only one that has had this many warnings in addition to the REMs program. Discussion continued around drug approvals.
- Dr. Poling motioned to accept the prior authorization criteria with modification to change the PA duration to 4 months.
- Motion seconded by Dr. Schwerdt.
- Motion Carried.

## Quantity Limits

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SILIQ 2 syringes/28 day

### Discussion:

- Dr. Poling motioned to accept the quantity limit.
- Motion seconded by Dr. Rhea
- Motion Carried.

## TRULANCE

### Prior Authorization Criteria

#### Interim Criteria

Will be approved for patients meeting ALL of the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient has diagnosis of chronic idiopathic constipation (CIC); **AND**
- Trial and failure of both PEG and Lactulose (as confirmed by paid claims by TennCare), **AND**
- Trial and failure to ONE agent in each of the following:
  - Bulk forming agents (i.e., fiber, psyllium)
  - Stimulant laxatives (i.e., bisacodyl); **AND**
- Trial and failure of, or contraindication or intolerance to, BOTH AMITIZA and LINZESS

**Note:** Safety and efficacy has not been established in patients < 18 years of age; and is contraindicated in patients less than 6 years of age.

### Proposed Criteria:

Same as Interim Criteria

### Discussion:

- Dr. Capparelli stated that the requirement requesting confirmation by paid TennCare claims was unnecessary and should be removed. Dr. Schwerdt asked if removing this statement would affect Linzess and Amitiza. Dr. Pittman stated this statement was included in the criteria for Linzess and Amitiza. Dr. Capparelli suggested removing it across the board for all 3 agents. Discussion continued.
- Dr. Johns asked for clarification on allowing the agent for patients less than 6 years of age. Thus, due to the safety issues recommended adding a bullet point that patient should be 6 years of age or older. Discussion continued.
- Dr. Johns motioned to accept the prior authorization criteria with modification that TennCare remove the statement “as confirmed by paid claims by TennCare” and adding a bullet point that patient must be age 6 years of age or older.
- Motion seconded by Dr. Jones.
- Motion Carried.

### Discussion:

- The committee asked for a separate motion to remove the statement “As confirmed by paid claims by TennCare” from the other agents within the class.
- Dr. Schwerdt motioned to request TennCare consider removing the statement “As confirmed by paid claims by TennCare” from the other agents within the class.
- Motion seconded by Dr. Jones.
- Motion carried.

### Quantity Limits

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TRULANCE	1/day
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### Discussion:

- Dr. Jones motioned to accept the quantity limit.
- Motion seconded.
- Motion Carried.

### TYMLOS

#### Prior Authorization Criteria

#### Interim Criteria

Will be approved for patients meeting ALL of the following criteria:

#### Initiation:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient has diagnosis of post-menopausal osteoporosis; **AND**
- Confirmation patient is receiving calcium and vitamin D supplementation if dietary intake is inadequate; **AND**



- Documented Hip bone densitometry (femoral neck or total hip) or lumbar spine T-score -2.5 (standard deviations) or below; **AND**
- Patient is at a high risk for fractures; **AND**
- Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone, bone metastases or skeletal malignancies, etc.); **AND**
- Patient has not received therapy with parathyroid hormone analogs (e.g., teriparatide) in excess of 24 months in total; **AND**
- Documented treatment failure, contraindication, or ineffective response to a minimum 12 month trial on previous therapy with oral bisphosphonates (e.g., alendronate, risedronate, ibandronate)

#### Renewal:

- Disease response (absence of fractures); **AND**
- Absence of unacceptable toxicity from the drug (e.g., osteosarcoma, orthostatic hypotension, hypercalcemia, hypercalcuria and urolithiasis, etc.); **AND**
- Total length of therapy has not exceeded 2 years

#### Proposed Criteria:

Same as Interim Criteria

#### Discussion:

- Dr. Capparelli commented on the 2 year treatment limit and what options are available after that time frame. Discussion continued regarding the benefits and risks of using PTH receptor- 1 agonists.
- Dr. Jones motioned to accept the prior authorization criteria with modification regarding clarification that the total lifetime limit should not exceed 2 years is added to the PA criteria.
- Motion seconded.
- Motion Carried.

#### Quantity Limits

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TYMLOS	1/30 days
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#### Discussion:

- Dr. Bush motioned to accept the quantity limit.
- Motion seconded.
- Motion Carried.

#### VEMLIDY

#### Prior Authorization Criteria

#### Interim Criteria

Will be approved for patients meeting ALL of the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient has inadequate treatment response (detectable HBV DNA level after 24 weeks of therapy), virologic breakthrough, resistance, intolerance or contraindication to entecavir OR tenofovir disoproxil fumarate (VIREAD); **AND**

- Patient is not using tenofovir alafenamide fumarate (VEMSIDY) as monotherapy if (HIV)-1 positive. (must have additional antiviral therapy if HIV-1 positive for coverage of both disease states)
- Note: Will not be approved for patients with decompensated liver disease

#### Proposed Criteria:

Same as Interim Criteria

#### Discussion:

- Dr. Poling motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Jones.
- Motion Carried.

#### XADAGO

#### Prior Authorization Criteria

#### Interim Criteria

Will be approved for patients meeting ALL of the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient has Parkinson's disease; **AND**
- Patient is receiving concomitant therapy with carbidopa/levodopa; **AND**
- Patient is experiencing "off episodes" with monotherapy using carbidopa/levodopa; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Score > 9); **AND**

Patient is not taking any of the following:

- Dextromethorphan
- other MAO-I inhibitors or other drugs that are potent inhibitors of monoamine oxidase (e.g., linezolid)

#### Proposed Criteria:

Will be approved for patients meeting ALL of the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient has Parkinson's disease; **AND**
- Patient is receiving concomitant therapy with carbidopa/levodopa; **AND**
- Patient is experiencing "off episodes" with monotherapy using carbidopa/levodopa; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Score > 9); **AND**
- Patient is not taking any of the following:
  - Dextromethorphan
  - other MAO-I inhibitors or other drugs that are potent inhibitors of monoamine oxidase (e.g., linezolid)
  - other serotonergic drugs (e.g., SNRIs, SSRIs, TCAs, St. John's wort, cyclobenzaprine)
  - opioid drugs (e.g., meperidine, methadone, propoxyphene, tramadol)
  - sympathomimetic medications (e.g., methylphenidate, amphetamine); **AND**
- *Trial and failure, contraindication, or intolerance to preferred MAO-B inhibitor*

#### Discussion:

- Dr. Poling motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Jones.
- Motion Carried.

#### Quantity Limits

XADAGO

1/day

#### Discussion:

- Dr. Johns motioned to accept the quantity limit.
- Motion seconded by Dr. Jones.
- Motion Carried.

#### XERMELO

#### Prior Authorization Criteria

#### Interim Criteria

Will be approved for patients meeting ALL of the following criteria:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Patient has a carcinoid/neuroendocrine tumor and has been diagnosed with carcinoid syndrome; **AND**
- Patient has been receiving therapy with the FDA-approved maximum (or highest tolerated) dose of a somatostatin analog therapy (e.g. octreotide I/R or LAR, lanreotide depot) for at least 3 months; **AND**
- Patient has tried and received an inadequate response to antidiarrheals (e.g., loperamide); **AND**
- Patient has at least 4 bowel movements per day

#### Proposed Criteria:

Same as Interim Criteria

#### Discussion:

- Dr. Bush commented that a bullet point should be added to indicate that it should be used in combination with a somatostatin. Dr. Pittman stated this could be added.
- Dr. Jones motioned to accept the prior authorization criteria with modification that a bullet point is added to indicate that the agent should be used in combination with a somatostatin.
- Motion seconded by Dr. Johns.
- Motion carried.

#### Quantity Limits

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XERMELO

3/day

#### Discussion:

- Dr. Capparelli ask for verification that the drug was to be taken daily. Dr. Pittman stated yes.
- Dr. Jones motioned to accept the quantity limit.
- Motion seconded by Dr. Rhea.
- Motion Carried.

#### DUPIXENT

#### RECOMMENDATION

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## Anti-inflammatory: Systemic IL-4 Antagonist

- It is recommended systemic IL-4 antagonists for atopic dermatitis should be subject to prior authorization.

### Discussion:

- Dr. Schwerdt motioned to accept the recommendation.
- Motion seconded by Dr. Jones.
- Motion carried.

## Prior Authorization Criteria for Dupixent

### Interim Criteria

Will be approved for patients meeting ALL of the following criteria:

#### Initiation:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID, **AND**
- Be  $\geq 18$  years of age; **AND**
- Have a diagnosis of moderate to severe atopic dermatitis with  $\geq 1$  of the following:
  - Involvement of at least 10% of body surface area (BSA); OR
  - Scoring Atopic Dermatitis (SCORAD) score of 20 or more; OR
  - Investigator's Global Assessment (IGA) with a score  $\geq 3$ ; OR
  - Eczema Area and Severity Index (EASI) score of  $\geq 16$ ; OR
  - Incapacitation due to AD lesion location (e.g., head and neck, palms, soles, or genitalia); **AND**
- Have a prior trial and failure (documented by claims) or contraindication to 1 topical corticosteroids of medium to high potency (e.g., mometasone, fluocinolone) **AND** 1 topical calcineurin inhibitor; **AND**
- Not have responded adequately (or have contraindication) to a 3 month minimum trial of at least 1 immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.); **AND**
- Not have responded adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (e.g., psoralens with UVA light [PUVA], UVB, etc) provided patient has reasonable access to photo treatment; **AND**
- Is not pregnant; **AND** Is not concurrently receiving a live vaccine

#### Renewal Criteria:

Patient must:

- Continue to meet above criteria; **AND**
- Documented response compared to baseline as measured by measures used to qualify moderate to severe AD at baseline (e.g., pruritus, BSA involvement, EASI, IGA, SCORAD).

### Proposed Criteria:

Same as Interim Criteria

### Discussion:

- Dr. Capparelli inquired about the statement "reasonable access" and who determines. Dr. Pittman stated she was unsure but it could be removed if needed. Dr. Capparelli stated he did not want to take out reasonable access. The committee discussed that TennCare provides medical transportation. The committee felt that could be considered reasonable access. Discussion continued.
- The committee discussed the live vaccines limit wording and the PA criteria and decided to change wording to match the previous criteria reviewed.

- Dr. Johns motioned to accept the prior authorization criteria with modification to define reasonable access as reasonable access within range of TennCare provided transportation area and to modify the wording for the live vaccine limitation bullet point to read “patient will not receive live vaccines during treatment.
- Motion seconded by Dr. Jones.
- Motion Carried.

## Quantity Limits

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DUPIXENT

2 syringes/28 days

### Discussion:

- Dr. Pittman explained this is the maximum maintenance dose. The patient will require an initial loading dose which will be allowed when the PA is initially entered.
- Dr. Poling motioned to accept the quantity limit.
- Motion seconded by Dr. Jones.
- Motion Carried.

## NEW INDICATIONS

### Prior Authorization Criteria

#### Proposed Criteria for TROKENDI XR:

Will be approved if the following criteria has been met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Diagnosis of Lennox-Gastaut syndrome:
  - Will be approved for use as adjunctive therapy when used in combination with at least one other anticonvulsant; AND
  - Allergy to inactive ingredient in immediate release product that is not in requested product; AND
  - Trial and failure of topiramate ER
- Diagnosis of all other seizure types or epilepsy:
  - Allergy to inactive ingredient in immediate release product that is not in requested product; AND
  - Trial and failure of topiramate ER
- *Migraine Prophylaxis:*
  - *Allergy to inactive ingredient in immediate release product that is not in requested product; AND*
  - *Trial and failure of topiramate ER*

### Discussion:

- Dr. Rhea asked for the generic name for TROKENDI. Dr. Pittman stated it was topiramate.
- Dr. Johns motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Dunlap.
- Motion Carried.

## Proposed Criteria for TECHNIVIE

Will be approved for patients who meet the following:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Diagnosis of Chronic Hepatitis C, **genotype 4** (Initial authorization: 8 weeks pending HCV RNA at treatment week 4, then 4 additional weeks of therapy for a total duration of 12 weeks);
  - Patients *with compensated cirrhosis* or without cirrhosis
  - Will be used in combination with weight-based ribavirin
- Prior Authorization is being requested by a physician specialist with experience in the treatment of hepatitis C infection (e.g., Hepatology, Infectious Disease or Gastroenterology)
- Documentation of Disease Severity (patient **MUST** have evidence of one of the following):
  - Liver biopsy showing Metavir score of F2-F4; **OR**
  - Ultrasound based transient elastography (Fibroscan) score  $\geq 7.1$  kPa; **OR**
  - Evidence of any TWO of the following:
    - Fibrotest (FibroSure) score of  $\geq 0.49$
    - Fibrosis-4 index (FIB-4)  $> 1.45$
    - Aspartate aminotransferase/platelet ratio index (APRI) score of  $> 0.5$
- If the patient has a prior history of substance or alcohol abuse, then confirmation the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as a part of HCV treatment **AND** has been free of substance and alcohol abuse for previous 6 months.
- Patient must not be pregnant
- Patient **should not** be receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., simeprevir [OLYSIO]).
- Patient **has been evaluated** for potential clinically significant drug interactions, including the following:
  - Concomitant therapy with the following strong inducers of CYP3A with Technivie® is contraindicated: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol-containing medications such as combined oral contraceptives, St. John's wort, lovastatin, simvastatin, pimozide, efavirenz, and sildenafil (when dosed as Revatio® for the treatment of pulmonary arterial hypertension), triazolam, and orally-administered midazolam.
  - Concomitant therapy with the following medications could increase the concentration of Technivie®: lopinavir/ritonavir, and atazanavir or atazanavir/ritonavir.
  - Concomitant therapy with Technivie® could increase concentrations of the following interacting medications: digoxin, amiodarone, bepridil, disopyramide, flecainide, lidocaine (systemic), mexiletine, propafenone, quinidine, ketoconazole, quetiapine, amlodipine, fluticasone, furosemide, rilpivirine, pravastatin, cyclosporine, tacrolimus, salmeterol, buprenorphine/naloxone, and alprazolam.
  - Concomitant therapy with Technivie® could decrease concentrations of the following interacting medications: voriconazole, darunavir, and omeprazole
- **Criteria for continuation of Prior Authorization:**
  - Confirmation the patient has been compliant with drug therapy regimen (per pharmacy paid claims history); **AND**
  - HCV RNA levels at pre-defined treatment weeks must be  $< 25$  IU/mL

## Discussion:

- Dr. Capparelli commented that Genotype 4 is fairly rare. Dr. Pittman stated that Tennessee has a huge immigrant population.
- Dr. Poling motioned to accept the prior authorization criteria.
- Motion seconded.
- Motion Carried.

### Proposed Criteria for KALYDECO

Will be approved if ALL of the following have been met:

- Must be prescribed by a provider with a Tennessee Medicaid Provider ID
- Must be prescribed by a provider at a CF Center of Excellence
- Age ≥ 2 years old
- Lab documentation confirming patient has *one* mutation in the CFTR gene *that is responsive to ivacaftor*
- Patient has received baseline liver function tests (ALT and AST)
- Patient has received baseline FEV1
- Baseline ophthalmic examinations for patients 2 to 18
- NOTE: will NOT be approved for homozygous F508del mutation in the CFTR gene

Duration of Initial PA approval: 6 months

Renewal of prior authorization will be approved for patients meeting the following criteria:

- Improvement in at least one of the following compared to baseline:
  - Stable or improved FEV1
  - Decreased pulmonary exacerbations compared to pretreatment baseline
  - Improvement in BMI

Duration of Renewal PA approval: 12 months

### Discussion:

- Dr. Johns asked for clarification on the note regarding homozygous F508del mutation. Dr. Pittman explained it wouldn't be approved if they had 2 copies of the same F508del mutation gene.
- Dr. Jones motioned to accept the prior authorization criteria.
- Motion seconded by Dr. Poling.
- Motion Carried.

### REVIEW OF MAY PAC MEETING DECISIONS

Magellan reviewed TennCare's decisions from the May 18, 2017 meeting and there were no decisions for which TennCare did not accept the Committee's recommendations. Therefore, further clarification was not required.

Next meeting will be November 14, 2017 at Brentwood Public Library. Dr. Pittman informed the committee that Dr. Williams handed out a copy of the 2018 PAC meetings which will all be held at the Brentwood Public Library.

Meeting Adjourned.