



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Bill J. Crouch
Cabinet Secretary

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Cynthia E. Beane
Commissioner

*Pharmaceutical and Therapeutics
Committee*
April 29, 2020

Location: WebEx only
Time: Executive Session 2:00 PM – 3:30 PM
Time: Open Session 3:30 PM – 5:00 PM
Charleston, WV 25301
(304) 558-1700

MINUTES

Committee Members Present:

Tom Kines, RPh, Chair
Chris Terpening, PharmD, PhD, Vice-Chair
Toni DiChiacchio, DNP
Philip Galapon, MD FAAFP
David Gloss, MD
Bradley Henry, MD
Kelli Lynn Jennings, PharmD
Steve Neal, RPh

Absent:

John Bernabei, RPh
Heather Jones, PA-C
Hani Nahza, MD
Charles Rohrbaugh, RPh

Division of Medicaid Staff Present:

Gail Goodnight, Rebate Manager
Bill Hopkins, Operations Manager
Lori Moles, Appeals Pharmacist
Priya Shah, DUR Coordinator
Doug Sorvig, Data Analyst
Brian Thompson, PharmD, MS, Director

Contract Staff Present:

Change Healthcare
Brent Breeding, RPh
Robert Dinwiddie, PharmD
Rusty Hailey, PharmD
Jacquelyn Hedlund, MD

Other Contract / State Staff Present:

I. Executive Session

The Committee convened for Executive Session at 2:00 PM.

II. Call to Order

Dr. Tom Kines, Chairman, called the meeting to order at 3:32 PM.

III. Welcome and Introductions

Dr. Kines welcomed all present to the committee meeting. Committee members, Bureau of Medical Services staff, and Change Healthcare staff introduced themselves.

IV. Administrative Items / Updates

A. Approval of the October 30, 2019 Minutes

The Committee moved to approve the October 30, 2019 Meeting minutes. All were in favor with no objections or revisions.

B. PDL Compliance / Generic Percent Report Updates

Dr. Breeding provided an explanation of the PDL Compliance and Generic Percent reports.

- Dr. Breeding reviewed the Generic Percent Report; overall generic utilization for Q1 2020 was 86.1%
- Dr. Breeding reviewed the PDL Compliance Report; overall compliance for Q1 2020 was 92.2%.

V. Public Comments

Public comments for this meeting were only accepted in writing. Written statements were provided to State and Committee members for review prior to this meeting, and are available to the public on the State's website.

- Sara Parambil of AstraZeneca provided written statement regarding Fasenra.
- A written statement was provided by Sanofi Genzyme regarding Dupixent.
- Bruce Wallace provided a written statement from Azurity Pharmaceuticals, Inc regarding Katerzia.
- A written statement and medication guide was provided by Neurelis, Inc. regarding Valtoco.
- A written statement was provided by UCB regarding Nayzilam.

- A written statement was provided by Abbvie regarding Rinvoq.
- Evan Loh, MD of Paratek Pharmaceuticals, Inc. provided a written statement regarding Nuzyra.
- A written statement was provided regarding Xolair.

VI. New Business

A. Therapeutic Class Review

i. Hypoglycemics, GLP-1 Agonists

HYPOGLYCEMICS, GLP-1 AGONISTS^{CL}

CLASS PA CRITERIA: Agents in this class will not be approved for patients with a starting A1C < 7%. Non-preferred agents are available only on appeal. Preferred agents in this class shall be approved in six (6) month intervals if the following criteria are met:

- Initial starts require a diagnosis of Type 2 Diabetes and an A1C taken within the last 30 days reflecting the patient's current and stabilized regimen.
- No agent in this class shall be approved except as add on therapy to a regimen consisting of at least one (1) other agent prescribed at the maximum tolerable dose for at least 90 days.
- Re-authorizations require continued maintenance on a regimen consisting of at least one (1) other agent at the maximum tolerable dose AND an A1C of $\leq 8\%$.

NOTE: GLP-1 agents will NOT be approved in combination with a DPP-4 inhibitor.

OZEMPIC (semaglutide)

TRULICITY (dulaglutide)

VICTOZA (liraglutide)

ADLYXIN (lixisenatide)

BYDUREON (exenatide)

BYETTA (exenatide)

BYDUREON BCISE (exenatide)

RYBELSUS (semaglutide)

TANZEUM (albiglutide)

Discussion around recommended changes to this category was discussed later in conjunction with the discussion around the new drug, Rybelsus.

B. New Therapeutic Class

i. MAbs, anti-IL/IgE

MABS, ANTI-IL/IgE

CLASS PA CRITERIA:

CINQAIR (reslizumab)
DUPIXENT (dupilumab)
FASENRA (benralizumab)
FASENRA PEN (benralizumab)
NUCALA SYRINGE/VIAL (mepolizumab)
NUCALA AUTO INJECTOR (mepolizumab)
XOLAIR (omalizumab)

Recommending to add this class with all agents non-preferred. No discussion. There was a motion to approve the new therapeutic class of MAbs, Anti-IL/IgE as

recommended; the motion was seconded. All members were in favor and the motion was approved.

C. New Drug Reviews

i. Adhansia XR (methylphenidate)

STIMULANTS AND RELATED AGENTS		
CLASS PA CRITERIA: A PA is required for adults eighteen (18) years of age or older.		
Non-preferred agents require a thirty (30) day trial of at least one preferred agent in the same subclass and with a similar duration of effect and mechanism of action, unless one (1) of the exceptions on the PA form is present. NOTE: Non-preferred agents will NOT be “grandfathered” for adults. Children under the age of 18 may continue their current therapy until the end of the school year after which they will be required to switch to a preferred agent.		
NON-AMPHETAMINE		
APTENSIO XR (methylphenidate) atomoxetine clonidine IR dexmethylphenidate IR FOCALIN XR (dexmethylphenidate) guanfacine ER guanfacine IR methylphenidate IR METHYLIN SOLUTION (methylphenidate) QUILLICHEW ER (methylphenidate) QUILLIVANT XR (methylphenidate)	ADHANSIA XR (methylphenidate) clonidine ER CONCERTA (methylphenidate) COTEMPLA XR ODT (methylphenidate) DAYTRANA (methylphenidate) dexmethylphenidate XR FOCALIN IR (dexmethylphenidate) INTUNIV (guanfacine extended-release) JORNAY PM (methylphenidate) KAPVAY (clonidine extended-release) methylphenidate CD methylphenidate chewable tablets, solution methylphenidate ER methylphenidate ER (generic CONCERTA) methylphenidate LA RITALIN (methylphenidate) RITALIN LA (methylphenidate) STRATTERA (atomoxetine)*	* Strattera is limited to a maximum of 100 mg per day.

Steve Neal made a motion to approve the changes to the Stimulants and Related Agents category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

ii. **Aklief Cream (trifarotene)**

ACNE AGENTS, TOPICAL^{AP}

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of one (1) preferred retinoid and two (2) unique chemical entities in two (2) other subclasses, including the generic version of the requested non-preferred product, before they will be approved, unless one (1) of the exceptions on the PA form is present.

In cases of pregnancy, a trial of retinoids will *not* be required. For members eighteen (18) years of age or older, a trial of retinoids will *not* be required.
Acne kits are non-preferred.

Specific Criteria for sub-class will be listed below. NOTE: Non-preferred agents in the Rosacea sub-class are available only on appeal and require at least a 30-day trial of all preferred agents in that sub-class.

RETINOIDS

TAZORAC (tazarotene)
tretinoin cream, gel

adapalene
AKLIEF CREAM (trifarotene)
ALTRENO LOTION (tretinoin)
ATRALIN (tretinoin)
AVITA (tretinoin)
DIFFERIN (adapalene)
PLIXDA SOLUTION (adapalene)
RETIN-A (tretinoin)
RETIN-A MICRO (tretinoin)
tazarotene cream
tretinoin gel micro

In addition to the Class Criteria: PA required for members eighteen (18) years of age or older.

Steve Neal made a motion to approve the changes to the Acne Agents, Topical category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

iii. **Beser Lotion (fluticasone propionate)**

STEROIDS, TOPICAL

CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of one (1) form of **EACH** preferred unique active ingredient in the corresponding potency group before they will be approved, unless one (1) of the exceptions on the PA form is present.

MEDIUM POTENCY

fluticasone propionate cream,
ointment
mometasone furoate
triamcinolone acetonide 0.025%
and 0.1% cream

ARISTOCORT (triamcinolone)
BESER LOTION (fluticasone)
BETA-VAL (betamethasone valerate)
betamethasone valerate foam
CLODERM (clocortolone pivalate)
clocortolone cream
CORDRAN/CORDRAN SP (flurandrenolide)
CUTIVATE (fluticasone propionate)
DERMATOP (prednicarbate)
ELOCON (mometasone furoate)
fluocinolone acetonide cream, ointment,
solution
fluticasone propionate lotion
hydrocortisone butyrate cream
hydrocortisone butyrate ointment, solution
hydrocortisone valerate
LOCOID (hydrocortisone butyrate)
LOCOID LIPOCREAM (hydrocortisone
butyrate/emollient)
LUXIQ (betamethasone valerate)
MOMEXIN (mometasone)

STERIODS, TOPICAL

CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of one (1) form of **EACH** preferred unique active ingredient in the corresponding potency group before they will be approved, unless one (1) of the exceptions on the PA form is present.

MEDIUM POTENCY

PANDEL (hydrocortisone probutate) prednicarbate TOPICORT LP (desoximetasone) TRIDERM (triamcinolone acetonide) WESTCORT (hydrocortisone valerate)

Steve Neal made a motion to approve the changes to the Steroids, Topical category as recommended; the motion was seconded by Philip Galapon. All members were in favor and the motion was approved.

iv. Drizalma (duloxetine)

NEUROPATHIC PAIN

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent in the corresponding dosage form (oral or topical) before they will be approved, unless one (1) of the exceptions on the PA form is present.

capsaicin OTC duloxetine gabapentin lidocaine patch pregabalin capsule	CYMBALTA (duloxetine) DRIZALMA SPRINKLE (duloxetine) GRALISE (gabapentin)* HORIZANT (gabapentin) IRENKA (duloxetine) LIDODERM (lidocaine) LYRICA CR (pregabalin)** LYRICA SOLUTION (pregabalin)** NEURONTIN (gabapentin) ^{AP} QUTENZA (capsaicin) SAVELLA (milnacipran)*** ZTLIDO PATCH (lidocaine) LYRICA CAPSULE (pregabalin)	*Gralise will be authorized only if the following criteria are met: <ol style="list-style-type: none"> 1. Diagnosis of post herpetic neuralgia and 2. Trial of a tricyclic antidepressant for a least thirty (30) days and 3. 90-day trial of gabapentin immediate release formulation (positive response without adequate duration) and 4. Request is for once daily dosing with 1800 mg maximum daily dosage. **Lyrica CR and Lyrica Solution require medical reasoning beyond convenience as to why the need cannot be met using preferred pregabalin capsules. ***Savella will be authorized for a diagnosis of fibromyalgia only after a 90-day trial of one preferred agent
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Steve Neal made a motion to approve the changes to the Neuropathic Pain category as recommended; the motion was seconded by Kelli Jennings. All members were in favor and the motion was approved.

v. Duaklir Pressair (aclidinium/formoterol)

COPD AGENTS

CLASS PA CRITERIA: Non-preferred agents require a sixty (60) day trial of one preferred agent from the corresponding sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

ANTICHOLINERGIC-BETA AGONIST COMBINATIONS^{AP}

ANORO ELLIPTA (umeclidinium/vilanterol) albuterol/ipratropium nebulizer solution BEVESPI (glycopyrrolate/formoterol) COMBIVENT RESPIMAT (albuterol/ipratropium) UTIBRON (indacaterol/glycopyrrolate)	DUAKLIR PRESSAIR (aclidinium/formoterol) DUONEB (albuterol/ipratropium) STIOLTO RESPIMAT (tiotropium/olodaterol)*	*In addition to the Class PA criteria, Stiolto Respimat requires a sixty (60) day trial of Anoro Ellipta.
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Chris Terpening made a motion to approve the changes to the COPD Agents category as recommended; the motion was seconded by Kelli Jennings. All members were in favor and the motion was approved.

vi. Evekeo ODT (amphetamine)

STIMULANTS AND RELATED AGENTS

CLASS PA CRITERIA: A PA is required for adults eighteen (18) years of age or older.

Non-preferred agents require a thirty (30) day trial of at least one preferred agent in the same subclass and with a similar duration of effect and mechanism of action, unless one (1) of the exceptions on the PA form is present.

NOTE: Non-preferred agents will NOT be “grandfathered” for adults. Children under the age of 18 may continue their current therapy until the end of the school year after which they will be required to switch to a preferred agent.

AMPHETAMINES

amphetamine salt combination ER amphetamine salt combination IR dextroamphetamine ER dextroamphetamine IR VYVANSE CHEWABLE (lisdexamfetamine) VYVANSE CAPSULE (lisdexamfetamine)	ADDERALL (amphetamine salt combination) ADDERALL XR (amphetamine salt combination) ADZENYS XR ODT (amphetamine) ADZENYS ER SUSP (amphetamine) DESOXYN (methamphetamine) DEXEDRINE ER (dextroamphetamine) DEXEDRINE IR (dextroamphetamine) dextroamphetamine solution DYANAVEL XR SUSP (amphetamine) EVEKEO (amphetamine) EVEKEO ODT (amphetamine) methamphetamine MYDAYIS (dextroamphetamine/amphetamine salt)* PROCENTRA solution (dextroamphetamine) ZENZEDI (dextroamphetamine)	In addition to the Class Criteria: Thirty (30) day trials of at least three (3) antidepressants are required before amphetamines will be authorized for depression. *Mydayis requires a 30-day trial of at least one long-acting preferred agent in this subclass and a trial of Adderall XR.
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Philip Galapon made a motion to approve the changes to the Stimulants and Related Agents category as recommended; the motion was seconded by Steve Neal. All members were in favor and the motion was approved.

vii. Ezallor Sprinkle (rosuvastatin)

LIPOTROPICS, STATINS^{AP}		
CLASS PA CRITERIA: See below for individual sub-class criteria.		
STATINS		
atorvastatin lovastatin pravastatin rosuvastatin simvastatin*	ALTOPREV (lovastatin) CRESTOR (rosuvastatin) EZALLOR (rosuvastatin) ^{NR} EZALLOR SPRINKLE (rosuvastatin) fluvastatin fluvastatin ER LESCOL (fluvastatin) LESCOL XL (fluvastatin) LIPITOR (atorvastatin) LIVALO (pitavastatin) MEVACOR (lovastatin) PRAVACHOL (pravastatin) ZOCOR (simvastatin)* ZYPITAMAG (pitavastatin)	Non-preferred agents require twelve (12) week trials of two (2) preferred agents, including the generic formulation of the requested non-preferred agent, before they will be approved, unless one (1) of the exceptions on the PA form is present. *Zocor/simvastatin 80mg tablets will require a clinical PA.

Philip Galapon made a motion to approve the changes to the Lipotropics, Statins category as recommended; the motion was seconded by Steve Neal. All members were in favor and the motion was approved.

viii. Jornay PM (methylphenidate)

STIMULANTS AND RELATED AGENTS		
CLASS PA CRITERIA: A PA is required for adults eighteen (18) years of age or older.		
Non-preferred agents require a thirty (30) day trial of at least one preferred agent in the same subclass and with a similar duration of effect and mechanism of action, unless one (1) of the exceptions on the PA form is present. NOTE: Non-preferred agents will NOT be “grandfathered” for adults. Children under the age of 18 may continue their current therapy until the end of the school year after which they will be required to switch to a preferred agent.		
NON-AMPHETAMINE		
APTENSIO XR (methylphenidate) atomoxetine clonidine IR dexmethylphenidate IR FOCALIN XR (dexmethylphenidate) guanfacine ER guanfacine IR methylphenidate IR METHYLIN SOLUTION (methylphenidate) QUILLICHEW ER (methylphenidate) QUILLIVANT XR (methylphenidate)	ADHANSIA XR (methylphenidate) clonidine ER CONCERTA (methylphenidate) COTEMPLA XR ODT (methylphenidate) DAYTRANA (methylphenidate) dexmethylphenidate XR FOCALIN IR (dexmethylphenidate) INTUNIV (guanfacine extended-release) JORNAY PM (methylphenidate) KAPVAY (clonidine extended-release) methylphenidate CD methylphenidate chewable tablets, solution methylphenidate ER methylphenidate ER (generic CONCERTA) methylphenidate LA RITALIN (methylphenidate) RITALIN LA (methylphenidate) STRATTERA (atomoxetine)*	* Strattera is limited to a maximum of 100 mg per day.

Steve Neal made a motion to approve the changes to the Stimulants and Related Agents category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

ix. Katerzia Suspension (amlodipine)

CALCIUM CHANNEL BLOCKERS^{AP}		
CLASS PA CRITERIA: Non-preferred agents require fourteen (14) day trials of each preferred agent within the corresponding sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.		
LONG-ACTING		
amlodipine diltiazem ER felodipine ER nifedipine ER verapamil ER	ADALAT CC (nifedipine) CALAN SR (verapamil) CARDENE SR (nicardipine) CARDIZEM CD, LA (diltiazem) COVERA-HS (verapamil) diltiazem LA KATERZIA SUSPENSION (amlodipine) MATZIM LA (diltiazem) nisoldipine NORVASC (amlodipine) PLENDIL (felodipine) PROCARDIA XL (nifedipine) SULAR (nisoldipine) TIAZAC (diltiazem) verapamil ER PM VERELAN/VERELAN PM (verapamil)	

Steve Neal made a motion to approve the changes to the Calcium Channel Blockers category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

x. Minolira (minocycline)

TETRACYCLINES		
CLASS PA CRITERIA: Non-preferred agents require ten (10) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
doxycycline hyclate capsules doxycycline hyclate 100 mg tablets doxycycline monohydrate 50, 100 mg capsules minocycline capsules	ADOXA (doxycycline monohydrate) demeclocycline* DORYX (doxycycline hyclate) doxycycline hyclate 75, 150 mg tablets doxycycline hyclate tablet DR 75, 100, 150, 200 mg doxycycline hyclate tablet DR 50 mg doxycycline monohydrate 40, 75, 150 mg capsule doxycycline monohydrate tablet doxycycline monohydrate suspension DYNACIN (minocycline) MINOCIN (minocycline) minocycline ER capsules minocycline tablets MINOLIRA ER (minocycline) MORGIDOX KIT (doxycycline) ORACEA (doxycycline monohydrate) SOLODYN (minocycline) tetracycline VIBRAMYCIN CAPSULES, SUSPENSION, SYRUP (doxycycline) XIMINO (minocycline)	*Demeclocycline will be authorized for conditions caused by susceptible strains of organisms designated in the product information supplied by the manufacturer. A C&S report must accompany this request. Demeclocycline will also be authorized for SIADH.

Kelli Jennings made a motion to approve the changes to the Tetracyclines category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

xi. Nayzilam Spray (midazolam)

ANTICONVULSANTS

CLASS PA CRITERIA: For a diagnosis of seizure disorder, non-preferred agents require a fourteen (14) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present; patients currently on established therapies shall be grandfathered.

For all other diagnoses, non-preferred agents require a thirty (30) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

In situations where AB-rated generic equivalent products are available, "Brand Medically Necessary" must be handwritten by the prescriber on the prescription for the brand name product to be reimbursed.

BENZODIAZEPINES^{AP}

clonazepam diazepam rectal gel diazepam tablets NAYZILAM NASAL SPRAY (midazolam) VALTOCO NASAL SPRAY (diazepam)	clobazam* clonazepam ODT DIASTAT (diazepam rectal) KLONOPIN (clonazepam) ONFI (clobazam)* ONFI SUSPENSION (clobazam)* SYMPAZAN (clobazam film)*	*Onfi shall be authorized as adjunctive therapy for treatment of Lennox-Gastaut Syndrome without further restrictions. Off-label use requires an appeal to the Medical Director. NOTE: generic clobazam is preferred over brand ONFI.
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Philip Galapon made a motion to approve the changes to the Anticonvulsants category as recommended; the motion was seconded by Steve Neal. All members were in favor and the motion was approved.

xii. Nourianz (istradefylline)

ANTIPARKINSON'S AGENTS

CLASS PA CRITERIA: Patients starting therapy on drugs in this class must show a documented allergy to all preferred agents in the corresponding sub-class, before a non-preferred agent will be authorized.

OTHER ANTIPARKINSON'S AGENTS

amantadine* ^{AP} APOKYN (apomorphine) bromocriptine carbidopa/levodopa levodopa/carbidopa/entacapone selegiline	AZILECT (rasagiline) carbidopa ELDEPRYL (selegiline) GOCOVRI ER (amantadine) INBRIJA (levodopa) levodopa/carbidopa ODT LODOSYN (carbidopa) NOURIANZ (istradefylline) OSMOLEX ER (amantadine) PARCOPA (levodopa/carbidopa) PARLODEL (bromocriptine) rasagiline RYTARY (levodopa/carbidopa) SINEMET (levodopa/carbidopa) STALEVO (levodopa/carbidopa/entacapone) XADAGO (safinamide) ZELAPAR (selegiline)	*Amantadine will not be authorized for the treatment or prophylaxis of influenza.
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ANTIPARKINSON'S AGENTS

CLASS PA CRITERIA: Patients starting therapy on drugs in this class must show a documented allergy to all preferred agents in the corresponding sub-class, before a non-preferred agent will be authorized.

OTHER ANTIPARKINSON'S AGENTS

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Steve Neal made a motion to approve the changes to the Antiparkinson's Agents category as recommended; the motion was seconded by Philip Galapon. All members were in favor and the motion was approved.

xiii. ProAir Digihaler (albuterol)

BRONCHODILATORS, BETA AGONIST^{AP}

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each chemically distinct preferred agent in their corresponding sub-class unless one (1) of the exceptions on the PA form is present.

INHALERS, SHORT-ACTING

PROAIR HFA (albuterol)	MAXAIR (pirbuterol)	
PROAIR RESPICLICK (albuterol)	PROAIR DIGIHALER (albuterol)	
PROVENTIL HFA (albuterol)	VENTOLIN HFA (albuterol)	
	XOPENEX HFA (levalbuterol)	

Philip Galapon made a motion to approve the changes to the Bronchodilators, Beta Agonist category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

xiv. Relafen DS (nabumeton)

NSAIDS^{AP}

CLASS PA CRITERIA: See below for sub-class PA criteria.

NON-SELECTIVE

diclofenac (IR, SR)	CATAFLAM (diclofenac)	Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.
flurbiprofen	CLINORIL (sulindac)	
ibuprofen (Rx and OTC)	DAYPRO (oxaprozin)	
INDOCIN SUSPENSION (indomethacin)	diflunisal	
indomethacin	DUEXIS (famotidine/ibuprofen)	
ketoprofen	etodolac IR	
ketorolac	etodolac SR	
meloxicam tablet	FELDENE (piroxicam)	
nabumetone	fenoprofen	
naproxen sodium tablet	INDOCIN SUPPOSITORIES (indomethacin)	
naproxen sodium DS tablet	indomethacin ER	
naproxen suspension	ketoprofen ER	
EC-naproxen DR tablet	meclufenamate	
piroxicam	mefenamic acid	
sulindac	meloxicam suspension	
	MOBIC TABLET (meloxicam)	
	NALFON (fenoprofen)	
	NAPRELAN (naproxen)	
	NAPROSYN (naproxen)	
	naproxen CR	
	oxaprozin	
	PONSTEL (meclufenamate)	

NSAIDS^{AP}

CLASS PA CRITERIA: See below for sub-class PA criteria.

NON-SELECTIVE

RELAFEN DS (nabumetone) SPRIX (ketorolac) TIVORBEX (indomethacin) tolmetin VIVLODEX (meloxicam) VOLTAREN (diclofenac) ZIPSOR (diclofenac potassium) ZORVOLEX (diclofenac)

Steve Neal made a motion to approve the changes to the NSAIDS category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

xv. Rinvoq (upadacitinib)

CYTOKINE & CAM ANTAGONISTS^{CL}

CLASS PA CRITERIA: Non-preferred agents require ninety (90) day trials of both Humira and Enbrel unless one (1) of the exceptions on the PA form is present. For FDA-approved indications, an additional ninety (90) day trial of Cosentyx will also be required. *Patients stabilized for at least 6-months on their existing non-preferred regimen shall be grandfathered (provided the current therapy is for a labeled indicaton). All off-label requests require review by the Medical Director.*

OTHERS

COSENTYX (secukinumab)*	ACTEMRA subcutaneous (tocilizumab) ENTYVIO (vedolizumab) ILARIS (canakinumab) ILUMYA (tildrakizumab) KEVZARA (sarilumab) KINERET (anakinra) OLUMIANT (baricitinib) ORENCIA subcutaneous (abatacept) OTEZLA (apremilast) RINVOQ ER (upadacitinib) SILIQ (brodalumab) SKYRIZI (risankizumab) STELARA subcutaneous (ustekinumab) TALTZ (ixekizumab) TREMIFYA (guselkumab) XELJANZ (tofacitinib) XELJANZ XR (tofacitinib)	*Cosentyx will be authorized for treatment of plaque psoriasis, psoriatic arthritis and ankylosing spondylitis only after inadequate response to a ninety (90) day trial of one preferred agent.
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Philip Galapon made a motion to approve the changes to the Cytokine & CAM Antagonists category as recommended; the motion was seconded by Kelli Jennings. All members were in favor and the motion was approved.

xvi. Rybelsus (semaglutide)

HYPOGLYCEMICS, GLP-1 AGONISTS^{CL}

CLASS PA CRITERIA: Agents in this class will not be approved for patients with a starting A1C < 7%. Non-preferred agents are available only on appeal. Preferred agents in this class shall be approved in six (6) month intervals if the following criteria are met:

- Initial starts require a diagnosis of Type 2 Diabetes and an A1C taken within the last 30 days reflecting the patient’s current and stabilized regimen.
- No agent in this class shall be approved except as add on therapy to a regimen consisting of at least one (1) other agent prescribed at the maximum tolerable dose for at least 90 days.
- Re-authorizations require continued maintenance on a regimen consisting of at least one (1) other agent at the maximum tolerable dose AND an A1C of ≤8%.

NOTE: GLP-1 agents will NOT be approved in combination with a DPP-4 inhibitor.

OZEMPIC (semaglutide)	ADLYXIN (lixisenatide)
TRULICITY (dulaglutide)	BYDUREON (exenatide)
VICTOZA (liraglutide)	BYETTA (exenatide)
	BYDUREON BCISE (exenatide)
	RYBELSUS (semaglutide)
	TANZEUM (albiglutide)

Recommendation was made to move Trulicity to Preferred and move Byetta and Bydureon to Non-Preferred. Recommendation was made to add Rybelsus to the category as Non-Preferred.

Philip Galapon made a motion to approve the changes to the Hypoglycemics, GLP-1 Agonists category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

xvii. Sunosi (solriamfetol)

STIMULANTS AND RELATED AGENTS

CLASS PA CRITERIA: A PA is required for adults eighteen (18) years of age or older.

Non-preferred agents require a thirty (30) day trial of at least one preferred agent in the same subclass and with a similar duration of effect and mechanism of action, unless one (1) of the exceptions on the PA form is present. **NOTE:** Non-preferred agents will NOT be “grandfathered” for adults. Children under the age of 18 may continue their current therapy until the end of the school year after which they will be required to switch to a preferred agent.

NARCOLEPTIC AGENTS

armodafinil ^{CL}	NUVIGIL (armodafinil)	* Sunosi is approvable only with documentation of treatment failure after 30-day trials of both armodafinil and modafinil.
modafinil ^{CL}	PROVIGIL (modafinil)	
	SUNOSI (solriamfetol)	
	WAKIX (pitolisant)	

Recommendation was made to add a subclass for Narcoleptic Agents moving brand and generic versions of Nuvigil and Provigil to the sub class with current statuses. Recommendation was made to add Sunosi and Wakix to the category as Non-Preferred. Chris Terpening made a motion to approve the changes to the Stimulants and Related Agents category as recommended; the motion was seconded by Kelli Jennings. All members were in favor and the motion was approved.

xviii. Tosymra Spray (sumatriptan)

ANTIMIGRAINE AGENTS, TRIPTANS^{AP}		
CLASS PA CRITERIA: Non-preferred agents require three (3) day trials of each preferred unique chemical entity before they will be approved, unless one (1) of the exceptions on the PA form is present.		
TRIPTANS		
naratriptan rizatriptan ODT rizatriptan tablet sumatriptan injection ^{CL} sumatriptan nasal spray sumatriptan tablets	almotriptan AMERGE (naratriptan) AXERT (almotriptan) eletriptan FROVA (frovatriptan) frovatriptan IMITREX INJECTION (sumatriptan) ^{CL} IMITREX NASAL SPRAY (sumatriptan) IMITREX tablets (sumatriptan) MAXALT MLT (rizatriptan) MAXALT (rizatriptan) ONZETRA XSAIL (sumatriptan)* RELPAX (eletriptan) SUMAVEL (sumatriptan) TOSYMRA NASAL SPRAY (sumatriptan) ZECUITY PATCH (sumatriptan) ZEMBRACE SYMTOUCH (sumatriptan) zolmitriptan zolmitriptan ODT ZOMIG (zolmitriptan) ZOMIG ZMT (zolmitriptan)	*In addition to the Class Criteria: Onzetra Xsail requires three (3) day trials of each preferred oral, nasal and injectable forms of sumatriptan.

Steve Neal made a motion to approve the changes to the Antimigraine Agents, Triptans category as recommended; the motion was seconded by Kelli Jennings. All members were in favor and the motion was approved.

xix. Tovet Foam (clobetasol)

STEROIDS, TOPICAL		
CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of one (1) form of EACH preferred unique active ingredient in the corresponding potency group before they will be approved, unless one (1) of the exceptions on the PA form is present.		
VERY HIGH & HIGH POTENCY		
betamethasone dipropionate cream betamethasone valerate cream betamethasone valerate lotion betamethasone valerate oint clobetasol propionate cream/gel/ointment/solution clobetasol emollient clobetasol propionate shampoo fluocinonide gel triamcinolone acetonide cream, ointment triamcinolone acetonide lotion	amcinonide APEXICON (diflorasone diacetate) APEXICON E (diflorasone diacetate) betamethasone dipropionate gel, lotion, ointment BRYHALI LOTION (halobetasol) clobetasol lotion clobetasol propionate foam CLOBEX (clobetasol propionate) CLODAN KIT (clobetasol propionate) CLODAN SHAMPOO (clobetasol propionate) CORMAX (clobetasol propionate) desoximetasone cream/gel/ointment diflorasone diacetate DIPROLENE (betamethasone dipropionate/propylene glycol)	

STEROIDS, TOPICAL

CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of one (1) form of **EACH** preferred unique active ingredient in the corresponding potency group before they will be approved, unless one (1) of the exceptions on the PA form is present.

VERY HIGH & HIGH POTENCY

DIPROLENE AF (betamethasone dipropionate/propylene glycol)	
DIPROSONE (betamethasone dipropionate)	
fluocinonide cream	
fluocinonide ointment	
fluocinonide solution	
fluocinonide/emollient	
halcinonide	
HALAC (halobetasol propionate)	
halobetasol propionate	
HALOG (halcinonide)	
HALONATE (halobetasol propionate)	
KENALOG (triamcinolone acetonide)	
LEXETTE FOAM (halobetasol)	
LIDEX (fluocinonide)	
LIDEX-E (fluocinonide)	
OLUX (clobetasol propionate)	
OLUX-E (clobetasol propionate/emollient)	
PSORCON (diflorasone diacetate)	
SERNIVO SPRAY (betamethasone dipropionate)	
TEMOVATE (clobetasol propionate)	
TEMOVATE-E (clobetasol propionate/emollient)	
TOPICORT CREAM, GEL, OINTMENT (desoximetasone)	
TOPICORT SPRAY (desoximetasone)	
TOVET FOAM (clobetasol)	
ULTRAVATE (halobetasol propionate)	
ULTRAVATE PAC cream	
ULTRAVATE X (halobetasol propionate / lactic acid)	
VANOS (fluocinonide)	

Philip Galapon made a motion to approve the changes to the Steroids, Topical category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

xx. Valtoco (diazepam)

ANTICONVULSANTS

CLASS PA CRITERIA: For a diagnosis of seizure disorder, non-preferred agents require a fourteen (14) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present; patients currently on established therapies shall be grandfathered.

For all other diagnoses, non-preferred agents require a thirty (30) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

In situations where AB-rated generic equivalent products are available, "Brand Medically Necessary" must be handwritten by the prescriber on the prescription for the brand name product to be reimbursed.

BENZODIAZEPINES^{AP}

clonazepam diazepam rectal gel diazepam tablets NAYZILAM NASAL SPRAY (midazolam) VALTOCO NASAL SPRAY (diazepam)	clobazam* clonazepam ODT DIASTAT (diazepam rectal) KLONOPIN (clonazepam) ONFI (clobazam)* ONFI SUSPENSION (clobazam)* SYMPAZAN (clobazam film)*	*Onfi shall be authorized as adjunctive therapy for treatment of Lennox-Gastaut Syndrome without further restrictions. Off-label use requires an appeal to the Medical Director. NOTE: generic clobazam is preferred over brand ONFI.
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Valtoco review and recommendation was made and discussed in combination with the Nayzilam review. Philip Galapon made a motion to approve the changes to the Anticonvulsants category as recommended; the motion was seconded by Steve Neal. All members were in favor and the motion was approved.

xxi. Wakix (pitolisant)

STIMULANTS AND RELATED AGENTS

CLASS PA CRITERIA: A PA is required for adults eighteen (18) years of age or older.

Non-preferred agents require a thirty (30) day trial of at least one preferred agent in the same subclass and with a similar duration of effect and mechanism of action, unless one (1) of the exceptions on the PA form is present. **NOTE:** Non-preferred agents will NOT be "grandfathered" for adults. Children under the age of 18 may continue their current therapy until the end of the school year after which they will be required to switch to a preferred agent.

NARCOLEPTIC AGENTS

armodafinil ^{CL} modafinil ^{CL}	NUVIGIL (armodafinil) PROVIGIL (modafinil) SUNOSI (solriamfetol)* WAKIX (pitolisant)	* Sunosi is approvable only with documentation of treatment failure after 30-day trials of both armodafinil and modafinil.
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Wakix presentation and recommendation was reviewed in combination with the Sunosi review. Recommendation was made to add a subclass for Narcoleptic Agents moving brand and generic versions of Nuvigil and Provigil to the sub class with current statuses. Recommendation was made to add Sunosi and Wakix to the category as Non-Preferred. Chris Terpening made a motion to approve the changes to the Stimulants and Related Agents category as recommended; the motion was seconded by Kelli Jennings. All members were in favor and the motion was approved.

VII. Old Business

There was no old business discussed at this time.

VIII. Other Business

There was no other business discussed at this time.

IX. Next Meeting

The next P&T Committee Meeting is scheduled for August 26, 2020, 2PM – 5PM, Diamond, Rooms B10 and B11

X. Adjournment

The Committee adjourned the meeting at 4:32 PM.

DRAFT