Preferred Drug List Committee Meeting
Meeting Minutes, Open Session
September 9, 2020 11:30 a.m. to 1:00 p.m.
DXC Technologies-Capital Room, 6511 SE Forbes Ave., Bldg. 283 J, Topeka, Kansas 66619
*Due to COVID-19, this meeting was held virtually.

Board Members:
Jessica Bates PharmD, BCPS (Chair)
Emily Blew, Pharm.D.
Taylor Gill Pharm.D., BCPS
Katherine Grimsley, M.D
Robert Haneke Pharm.D.
Megan Hedden Pharm.D.
William Pankey, M.D
James Rider, D.O.
Donna Sweet, M.D.
Wayne Wallace, M.D.

KDHE-DHCF Staff:
Annette Grant, RPh
Victor Nguyen Pharm.D.
Carol Arace

DXC Staff:
Karen Kluczykowski, RPh
Harry Vu, PharmD
Kathy Kaesewurm, RN, BSN
Debbie Bruchko, LPN

MCO Attendees:
Alan Carter, Pharm.D. – Aetna Better Health
Angie Yoo Pharm.D. – Sunflower Health Plan
Janette Mueller, RPh – United Healthcare

Public Attendees:
Andrea Tarnish, Audrey Rattan, Kellie Vazzana, Shelley Thompson, Alkermes; Brett McCabe, Aimmune; Camille Kerr, Regeneron; Chelsea Leroue, Karen Floeder, Biohaven Pharma; Dave Miley, Deron Grothe, Teva; Donna Osterlund, Sanofi; Garth Wright, Genentech; Gilbert Rodriguez, Rhonda Clark, Indivior; Mary Shefchyk, Gina Heinen, Ryan Flugge, Novo Nordisk; Jane Stephen, Kelvin Stover, Amgen; Janie Huff, Tricida; Jean Ritter, Zealand Pharma; Jim Baumann, Phil King, Rob Hansen, Pfizer; Melissa Basil, Josh Bishop, AbbVie; Kate Kulesher, Sandoz; Ricki Roberson, Merck; Sean Jones, Takeda Pharma; Sheryl Donahue, Mckenzie Stratton, Sarepta; Susan Kimball, Tony Salicos, Greenwich BioScience; Susan Zalenski, Kim Walter, J&J; Todd Dickerson, Jazz Pharma; Kristi Kemp, Allergan; Lynn Cu, KU; Marc Parker, Sunovion

Item	Notes
I. Call to Order	Dr. Bates called the meeting to order at 11:40AM.
II. Review and Approval of March 11, 2020 Meeting Minutes.	The draft minutes from the March 11, 2020 meeting were reviewed. Dr. Sweet moved to approve the minutes. Dr. Blew seconded the motion. The motion carried unanimously, and the minutes were approved.
III. Old Business **A. Consent Agenda Items** **i. PDL New Drug Placements** 1. Licart™ Patch 2. Lyumjev™ Injection 3. Ortikos™ Capsules 4. Rybelsus® Tablets	**Background:** At the September 13, 2017 PDL meeting, the Committee agreed to the "Consent Agenda Items" pre-management process and to place the associated drug list under the Old Business section. **Public Comment:** None. **Board Discussion:** Dr. Sweet moved to approve. Dr. Haneke seconded the motion. The motion carried unanimously.

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IV. New Business **A. New Drug Classes** i. COPD Agents- Triple Therapy: (Breztri Aerosphere™, Trelegy Ellipta)	**Background:** In 2017, the first COPD triple therapy agent, Trelegy Ellipta was approved by the FDA. This year a second COPD triple therapy agent, Breztri Aerosphere, was approved. Both agents contain a long-acting cholinergic, long-acting beta2- adrenergic agonist, and a corticosteroid. Both agents are for oral inhalation. Single and dual combinations for COPD are currently on the PDL, but have other indications, as well. These triple therapy products are currently only approved for COPD. A comparison chart is included for your review. **Public Comment:** None. **Committee Discussion:** None. Dr. Sweet moved to approve. Dr. Gill seconded. The motion carried unanimously.
ii. Colony Stimulating Factors – Filgrastim Products: (Granix®, Neupogen®, Nivestym™, Zarxio®)	**Background:** Filgrastim is a granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology. G-CSFs stimulate the production, maturation, and activation of neutrophils to increase both their migration and cytotoxicity. Nivestym and Zarxio are biosimilars to Neupogen. Granix went through the full Public Health Service (PHS) Act approval process, therefore is not technically considered biosimilar to Neupogen. The Biologics Price Competition and Innovation (BPCI) Act did not exist at the time of the application submission. A comparison chart is included for your review. **Public Comment:** Dave Miley from Teva spoke about Granix. Committee Discussion: Dr. Gill asked for a reminder on what has been discussed in the past PDL meetings regarding biosimilars. The State said that biosimilars can be part of the Consent

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	Agenda Item process for their referenced products. Additionally, the biosimilars for Remicade were added to the Master PDL, as approved at a previous meeting. Dr. Hedden asked if it was necessary to have both a filgrastim and peg-filgrastim PDL class. The State responded that the historical perspective of the State and the PDL Committee was that if there is enough of a subset of a PDL class, then those drugs would then be made into a separate PDL class, to increase rebate potential and cost-effective drug use. Dr. Gill moved to approve. Dr. Sweet seconded. Motion carried unanimously.
iii. Colony Stimulating Factors – Pegfilgrastim Products: (Fulphila®, Neulasta®, Neulasta® Onpro®, Udenyca®, Ziextenzo®)	**Background:** Pegfilgrastim stimulates the production, maturation, and activation of neutrophils and activates neutrophils to increase both their migration and cytotoxicity. Pegfilgrastim has a prolonged duration of effect relative to filgrastim and a reduced renal clearance. Fulphila, Udenyca, and Ziextenzo, are biosimilars to Neulasta. All are available as a subcutaneous injection. A comparison chart is included for your review. **Public Comment:** None. **Committee Discussion:** None. Dr. Sweet moved to approve. Dr. Gill seconded. The motion was carried unanimously.
iv. Migraine – Acute Treatment Agents: (Nurtec™ ODT, Reyvow™, Ubrelvy™)	**Background:** In late 2019 and early 2020, three new drugs were FDA approved for acute treatment of migraines. Nurtec and Ubrelvy are both CGRP receptor antagonists. Reyvow is a serotonin 5-HT1F receptor agonist. Pivotal studies for all three drugs have the same primary outcome measures (pain freedom at 2h post-dose; freedom from most bothersome symptoms at 2h). Ubrelvy, Nurtec ODT, and Reyvow all appear very similar in terms of primary outcomes. A comparison chart is included for your review.

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	Public Comment: Chelsea Leroue spoke about Nurtec ODT. Josh Bishop spoke about Ubrelvy. **Committee Discussion:** Dr. Pankey asked about whether Nurtec ODT or Ubrelvy had any adolescent age indications. The State said that they did not add that to the chart, but that all three products are for adult patients. Dr. Gill asked about Triptan drug management. The State said that in the State clinical prior authorization for the medications, the patient is required to step through Triptans first. We do have a Triptan PDL class, as well. Dr. Gill asked about the name of the class, when both classes are for migraine treatment. Several class name suggestions were made. The final decision was to make this PDL class be called Migraine - Acute Treatment- Non Triptans. There was a request to rename the current Triptan PDL class: Migraine- Acute Treatment- Triptans. According to meeting rules, the renaming of the other PDL class would need to be an agenda item for a future meeting. Dr. Sweet moved to approve the PDL class with the amended class name. Dr. Pankey seconded the motion. The motion carried unanimously.
v. Opioid Dependence Agents: (Bunavail, Naltrexone Tablets, Probuphine®, Sublocade™, Suboxone®, Subutex, Vivitrol®, Zubsolv®)	**Background:** In 2002, the FDA approved Subutex and Suboxone as the first medications to treat opioid dependency, that could be prescribed or administered in physicians' offices. This approval provided for increased access to Opioid Use Disorder treatment. Probuphine, Sublocade, and Subutex are single agent buprenorphine products. Buprenorphine exerts its effect via partial mu-opioid receptor agonist, whereby its analgesic effects plateau at higher doses and it then behaves like an antagonist. Probuphine and Sublocade are long-acting products and require induction with transmucosal buprenorphine prior to use. Bunavail, Suboxone, and Zubsolv are combination agents with Naloxone. The opioid antagonist, naloxone, is included as a safeguard against abusing the drug by injection. Naltrexone (a pure opioid antagonist) is a cyclopropyl derivative of oxymorphone similar in structure to naloxone and nalorphine (a morphine derivative); it acts as a competitive antagonist at opioid receptor sites, showing the highest affinity for mu receptors. Naltrexone tablets have a

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	low adherence rate and are not recommended, due to decreased treatment success. Naltrexone injection (Vivitrol) is a once monthly intramuscular injection, which improves adherence potential. A class comparison chart is provided for the committee's review. **Public Comment:** Shelly Thompson spoke on behalf of Vivitrol. Gilbert Rodriguez spoke on behalf of Sublocade. **Committee Discussion:** None. Dr. Sweet moved to approve. Dr. Blew seconded the motion. The motion carried unanimously.
B. New Drugs to Existing Classes i) Acne Agents- Topical- Antibiotics: (Amzeeq™) **i.**	**Background:** A general Acne Agents PDL class was first introduced to the PDL Committee in May 2015. In June 2019, the Acne Agents PDL class was divided into subclasses (Antibiotics, Combination Agents, Retinoids, and "Other" Acne Agents). Two additional acne agent classes were added at the March 2020 PDL meeting. Today, a new agent, Amzeeq, is being proposed for addition to the Acne- Antibiotic Agents PDL class. A class comparison chart is included for the committee's review. **Public Comment:** None. **Committee Discussion:** None. Dr. Pankey moved to approve. Dr. Gill seconded the motion. The motion carried unanimously.

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ii. Acne Agents- Topical Retinoids: (Aklief®)	**Background:** A general Acne Agents PDL class was first introduced to the PDL Committee in May 2015. In June 2019, the Acne Agents PDL class was divided into subclasses (Antibiotics, Combination Agents, Retinoids, and Other Acne Agents). Two additional acne agent classes were added at the March 2020 PDL meeting. Today, a new agent, Aklief, is being proposed for addition to the Acne- Retinoid Agents PDL class. A class comparison chart is included for the committee's review. **Public Comment:** None. **Committee Discussion:** None. Dr. Gill moved to approve. Dr. Grimsley seconded the motion. The motion carried unanimously.
iii. Ankylosing Spondylitis Agents: (Taltz®)	**Background:** The Ankylosing Spondylitis PDL class was last reviewed in March 2020 for the inclusion of biosimilars to their corresponding reference products. An IV dose formulation of Simponi, Simponi Aria, approved for the same indications except for ulcerative colitis was also added in March 2020. Today, Taltz is being proposed for addition to this PDL class. A class comparison chart is included for the committee's review. **Public Comment:** None. **Committee Discussion:** None. Dr. Sweet moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.

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iv. CGRP Receptor Antagonists: (Vyepti™)	**Background:** In March 2019, the calcitonin gene-related peptide (CGRP) receptor antagonists were added as a new PDL class. CGRPs are biologics that work as human monoclonal antibodies that bind to the calcitonin gene-related peptide ligand and block its binding to the receptor. Although the exact mechanism of the calcitonin gene-related peptide receptor is unknown, these products are indicated for migraine prophylaxis. Today, a new agent Vyepti, is being proposed for inclusion to this PDL class. A class comparison chart is included for the committee's review. **Public Comment:** None. **Committee Discussion:** None. Dr. Wallace moved to approve. Dr. Sweet seconded the motion. The motion was carried unanimously.
v. Sleep Agents- Scheduled- Non-Benzodiazepine: (Dayvigo™)	**Background:** Initial reviews for this class were in 2005 and included Lunesta, Sonata and Ambien/Ambien CR. Since then, Edluar, and Belsomra were FDA approved and included in this PDL class. Variations of the class title have been used by the state for PDL organizational purposes, but this class has always contained the PDL Committee approved products that are scheduled, non-benzodiazepine, sleep agents. A new agent, Dayvigo, was approved in December 2019 and is now available on the market. This agent is like the other Orexin Receptor Antagonist, Belsomra. A comparison chart is included for the committee's review. **Public Comment:** None. **Committee Discussion:** None. Dr. Sweet moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.

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vi. Rosacea Agents- Topical: (Zilxi™)	**Background:** The medications in this class are indicated for the treatment of rosacea. These agents either exhibit antimicrobial effects or elicit vasoconstriction, which reduces erythema induced discoloration of the skin. The new agent, Zilxi, is a Minocycline topical foam. A class comparison chart is included for the committee's review. **Public Comment:** None. **Committee Discussion:** None. Dr. Wallace moved to approve. Dr. Pankey seconded the motion. The motion carried unanimously.
V. Open Public Comment	Ryan Flugge spoke to Rybelsus®. The State discussed bringing back some migraine classes for renaming at the next meeting.
VI. Adjourn	Dr. Wallace moved to adjourn. Dr. Sweet seconded the motion. The meeting adjourned at 12:53 p.m.

APPENDIX A

September 2020 Consent Agenda Item List				
This PDL option/process was approved 09/13/2017 by the PDL Committee and 10/11/2017 by the DUR Board. The Extended Consent Agenda was approved at the March 2019 PDL Committee meeting and the April 2019 DUR Board meeting. Further expansion of the Consent Agenda Item criteria to include the addition of Biosimilars to their Reference Product was approved at the March 2020 PDL Committee meeting and the July 2020 DUR Board meeting.				
Drug Proposed - Consent Agenda Item	**Compare Drug**	**Supporting information**	**Meeting Date listed on the PDL Agenda**	**PDL Committee Approval Yes/No**
Licart™ Patch	Flector® patch		9/9/2020	Yes
Lyumjev™ Injection	Humalog®		9/9/2020	Yes
Ortikos™	Uceris®		9/9/2020	Yes
Rybelsus® Tablets	Ozempic® Injection		9/9/2020	Yes