**Preferred Drug List Committee Meeting**
Meeting Minutes, Open Session
January 18, 2022 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 (Absent)
Emily Blew, Pharm.D.
Taylor Gill Pharm.D., BCPS (Chair)
Katherine Grimsley, M.D
Robert Haneke Pharm.D.
Megan Hedden Pharm.D.
Lucy Lot, M.D
James Rider, D.O. (Absent)
Donna Sweet, M.D. (Absent)
Wayne Wallace, M.D.

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

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

**MCO Attendees:**
Mark DeMary, Pharm.D. – Aetna Better Health
Angie Yoo Pharm.D. – Sunflower Health Plan
Sunny Bounyalath, PharmD – United Healthcare

**Public Attendees:**
Melissa Basil; Jim Baumann; Kenneth Berry; Jennifer Davis; Chris Dobberpuhl; Kelly Flannigan; Rob Hansen; Kurt Hendrickson; Heather Higgins; Erin Hohman; Sean Jones; Marc Parker; Ricki Roberson; David Large; Ed Davis; Jenny Carrell; JJRoth; John Bullard; Kevin Hinthorne; Kimberlinh Kim; Lisa Tracz; Mariola Vazquez; Matt Grewe; Porscha Showers; Robert Firnberg; Sally Falahat; Sam Khader; Sara Voisard; Sarah Sanders; Sharon Cahoon-Metzger; Stephen Le; Stormy Cameron

| Item | Notes |
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| **I. Call to Order**<br>A. Introductions<br>B. Announcements | Dr. Gill called the meeting to order at 11:33AM.<br><br>**Introductions**:<br>Dr. Lucy Lot was introduced as taking over Dr. William Pankey's position on the Committee.<br>Dr. Ximena Garcia was introduced as the acting Medical Director for Kansas Medicaid.<br><br>**Announcements:**<br>None |
| **II. Review and Approval of September 8, 2021 Meeting Minutes.** | The draft minutes from the September 8, 2021 meeting were reviewed.<br><br>Dr. Haneke moved to approve the minutes.<br>Dr. Blew seconded the motion.<br>The motion carried unanimously, and the minutes were approved. |
| **III. Old Business**<br>**A. Consent Agenda Items**<br>**i. PDL New Drug Placements**<br>1. Epclusa® pellets<br>2. Mavyret® pellets<br>3. Semglee® (yfgn) and insulin glargine (yfgn) | **Background:**<br>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.<br><br>**Public Comment:**<br>None.<br><br>**Committee Discussion:**<br>The Committee asked for a reminder on past discussions on biosimilar products. The State noted that the PDL Committee accepted biosimilars as part of the Consent Agenda Items at the March 11, 2020 meeting and was subsequently approved by the DUR Board on July 8, 2020.<br><br>Dr. Wallace moved to approve.<br>Dr. Haneke seconded the motion. |

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| **IV. New Business**<br>**A. New PDL Classes**<br>i. Dry Eye Disease: Cequa™, Restasis®, Tyrvaya™, Xiidra™ | **Background:**<br>Keratoconjunctivitis sicca (dry eye disease) is a condition where the quality or quantity of natural tears are insufficient to provide a thin tear film over the cornea and conjunctiva. Over-the-counter products such as artificial tears are available for the temporary relief of burning and irritation due to dry eye. Restasis and Cequa are opthalmic cyclosporine products that were approved in 2003 and 2018 and are indicated to increase tear production. Xiidra contains a lymphocyte function-associated antigen-1 (LFA-1) antagonist that may inhibit secretion of inflammatory cytokines in human peripheral blood mononuclear cells. Tyrvaya contains varenicline, a cholinergic agonist originally approved as an aid to smoking cessation. As a nasal spray, it may bind to nicotinic acetylcholine receptors, activating trigeminal parasympathetic pathways resulting in increased production of basal tear film. A class comparison chart is included for the committee's review.<br><br>**Public Comment:**<br>Sarah Sanders (Novartis, Xiidra™) spoke on Xiidra™.<br>Erin Hohman (Abbvie, Restasis) yielded her time back to the Committee.<br><br>**Committee Discussion:**<br>The Committee discussed whether or not having drugs with different mechanisms of action would be appropriate in this class. The State noted that there are times where there aren't enough products with the same mechanism of action to make a class. When classes get too big (Diabetes), the State has divided the PDL class into smaller parts. After reflecting on other PDL classes that contained products with different mechanisms of action (i.e. biologics, acne), the Committee agreed to move forward with the Dry Eye Disease as originally proposed.<br><br>Dr. Wallace moved to approve.<br>Dr. Blew seconded the motion.<br>The motion carried unanimously. |
| **ii.** Immunomodulation Agents- Atopic Dermatitis: Adbry™, Dupixent® | **Background:**<br>This is a new class presented for inclusion to the PDL today. The related PDL Class, Atopic Dermatitis Agents – Topical, was first approved in June 2018. Today's new class for Atopic Dermatitis includes two injectable biologics. Both Dupixent and Adbry are monoclonal antibodies that inhibit the IL-4 and IL-13 interaction, although in different ways. A class comparison chart is included for the committee's review.<br><br>**Public Comment:**<br>Mariola Vazquez (Leo Pharma, Adbry™) spoke on Adbry™.<br><br>**Committee Discussion:** |

| Item | Notes |
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| | The Committee asked Mariola about why the dosage reduction was only for patients under 100kg and if there were any head-to-head trials. Mariola explained that this was required by the FDA due to the altered pharmacokinetics and lower drug concentrations in patients weighing over 100kg. She also noted that there were not any head-to-head trials.<br><br>Dr. Wallace moved to approve.<br>Dr. Haneke seconded the motion.<br>The motion carried unanimously. |
| **B. New Drugs to Existing PDL Classes**<br>i. Acne Agents- Other Topical- New agent: Winlevi® | **Background:**<br>This class was last reviewed in June 2019 when it was divided from one topical class to more specific subclasses. It currently includes Aczone 5% gel, Aczone 7.5% gel, and Azelex cream. Winlevi contains clascoterone 1% cream, which is an androgen receptor inhibitor. It is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. A class comparison chart is included for the committee's review.<br><br>**Public Comment:**<br>None<br><br>**Committee Discussion:**<br>None<br><br>Dr. Wallace moved to approve.<br>Dr. Haneke seconded the motion.<br>The motion carried unanimously. |
| ii. Atopic Dermatitis Agents- Topical: New agent Opzelura™ | **Background:**<br>This class was last reviewed in September 2019 when it was requested to have its name changed from "Topic Immunomodulators" to "Atopic Dermatitis Agents – Topical". Opzelura™ cream contains ruxolitinib which was originally approved in oral form (Jakafi®) for the treatment of myelofibrosis. Janus kinase (JAK) inhibitors, such as ruxolotinib, have recently received boxed warnings for the increase in risk of major adverse cardiovascular events (MACE) and thrombosis when used for inflammatory conditions. As with the topical calcineurin inhibitors, short-term use of Opzelura should be limited to when signs and symptoms of atopic dermatitis resolve. Patients should be re-evaluated within 8 weeks. A class comparison chart is included for the Committee's review.<br><br>**Public Comment:**<br>None |

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| | **Committee Discussion:**<br>Dr. Haneke moved to approve.<br>Dr. Hedden seconded the motion.<br>The motion carried unanimously. |
| iii. Growth Hormones- New agent: Skytrofa™ | **Background:**<br>This class was last reviewed in September 2015 for the inclusion of Zomacton and currently also includes Genotropin & Genotropin MiniQuick, Norditropin, Humatrope, Nutropin AQ NuSpin, Omnitrope, saizen, Saizenprep, and Saizen Click Easy. Skytrofa's active ingredients is lonapegsomatroopin-tcgd, which is a long-acting prodrug of somatotropin. It has been approved for patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormones. A class comparison chart is included for the committee's review.<br><br>**Public Comment:**<br>Sharon Cahoon-Metzger (Ascendis, Skytrofa™) spoke on and compared Skytrofa™ to short-acting somatropins. She commented that there are two other long-acting products coming to market and predicted that the landscape will be similar to hemophilia, where there will be a short-acting category of products, and a long-acting category.<br><br>**Committee Discussion:**<br>The Committee acknowledged that this was another example of a class that might need to be separated out in the future. The Committee agreed to move forward as proposed at this time.<br><br>Dr. Haneke moved to approve.<br>Dr. Wallace seconded the motion.<br>The motion carried unanimously. |
| iv. Migraine- Acute Treatment- Non-Triptan: Elyxyb® | **Background:**<br>This class was last reviewed in September 2020. It currently includes Nurtec ODT®, Reyvow®, and Ubrelvy®. Elyxyb™ is an oral solution that contains the non-steroidal anti-inflammatory drug celecoxib. It has been FDA-approved since May 2020 but has not been available on the market until now. A class comparison chart is included for the committee's review.<br><br>**Public Comment:**<br>None. |

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| | **Committee Discussion:**<br>None.<br><br>Dr. Wallace moved to approve.<br>Dr. Lot seconded.<br>The motion was carried unanimously. |
| **V. Adjourn** | Dr. Blew moved to adjourn.<br>Dr. Grimsley seconded the motion.<br>The motion was carried unanimously.<br><br>The meeting adjourned at 12:27 p.m. |

**APPENDIX A**

| **January 2022 Consent Agenda Item List** | | | | |
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| **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 includes 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** |
| Epclusa pellets | Epclusa | | 1/18/2022 | Yes |
| Mavyret pellets | Mavyret | | 1/18/2022 | Yes |
| Semglee (yfgn) | Lantus | | 1/18/2022 | Yes |
| Insulin Glargine (yfgn) | Lantus | | 1/18/2022 | Yes |