

Preferred Drug List Committee Meeting

Meeting Minutes, Open Session

July 17, 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 Pharm.D, BCPS (Chair)

Emily Blew, Pharm.D. (*Absent*)

Taylor Gill Pharm.D., BCPS

Katherine Grimsley, M.D

Robert Haneke Pharm.D.

Megan Hedden Pharm.D. (*Absent*)

Lucy Lot, M.D

Donna Sweet, M.D.

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:

Annie Wagar, Camille Kerr, Craig Bloom, Christopher Stanfield,

Erin Hohman, Gary Parenteau, Gina Heinen, Howard Thomas,

John Bullard, John Ring, Kurt Hendrickson, Kyle Webster, Lee

Ward, Lisa Tracz, Melissa Basil, Ricki Roberson, Rob Hansen,

Sara Hovland, Sarah Sanders, Tom Seignious

[Non-identified participants are not listed.]

Item	Notes
<p>I. Call to Order A. Introductions B. Announcements</p>	<p>Dr. Bates called the meeting to order at 11:35AM.</p> <p>Introductions: None</p> <p>Announcements: None</p>
<p>II. Review and Approval of September 8, 2021 Meeting Minutes.</p>	<p>The draft minutes from the January 18, 2022 meeting were reviewed.</p> <p>Dr. Wallace moved to approve the minutes. Dr. Sweet seconded the motion. The motion carried unanimously, and the minutes were approved.</p>
<p>III. Old Business A. Consent Agenda Items i. PDL New Drug Placements</p> <ol style="list-style-type: none"> 1. Citalopram capsules 2. Conjupri® 3. Fleqsuvy™ 4. Infliximab 5. Insulin Glargine 6. Lyvispah™ 7. Norliqva® 8. Releuko™ 9. Semglee® 10. Sertraline capsules 11. Tlando® 	<p>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.</p> <p>Public Comment: None.</p> <p>Committee Discussion: None.</p> <p>Dr. Sweet moved to approve. Dr. Gill seconded the motion.</p>

Item	Notes
<p>IV. New Business</p> <p>1. New PDL Classes</p> <p>i. Imiquimod: Aldara®, Zyclara®</p>	<p>Background: Imiquimod modifies the immune response by inducing cytokines and enhancing cell-mediated cytolytic antiviral activity. The imiquimod products are indicated for actinic keratosis and external genital warts. In addition, Aldara® is indicated for superficial basal cell carcinoma. Aldara® was FDA-approved in 1997, while the two Zyclara® formulations were approved in 2010 and 2011. The Zyclara® formulations contain lower concentrations of imiquimod in an effort to improve tolerability while maintaining efficacy. Depending upon the indication, Zyclara® is approved for up to a shorter 6- or 8-week dosing cycle, compared with the up to 16-week regimen of Aldara®. The Imiquimod Products is a new class presented for inclusion to the PDL today. A class comparison chart is included for the committee’s review.</p> <p>Public Comment: None</p> <p>Committee Discussion: The Committee discussed briefly about the difference in duration of treatment between the two products. The State acknowledged that Aldara® is at a higher strength and longer duration, but at a lower frequency of two times per week. The lower strength Zyclara® allows for daily administration and shorter duration of therapy.</p> <p>Dr. Sweet moved to approve. Dr. Gill seconded the motion. The motion carried unanimously.</p>
<p>ii. Prenatal Vitamins: Various Products</p>	<p>Background: Prenatal vitamins can be helpful bridges to nutritional gaps when diet alone is not enough. Nutritional content varies between products, but most contain the key nutrients recommended by the American College of Obstetricians and Gynecologists (ACOG). Where indicated, the ACOG recommends supplementation, especially with folic acid, iron, calcium, and vitamin D. The Prenatal Vitamins is a new class presented for inclusion to the PDL today. A class comparison chart is included for the committee’s review.</p> <p>Public Comment: None</p> <p>Committee Discussion: The Committee asked whether or not these products were over-the-counter (OTC). The State explained that although some OTC products exist, most are legend drugs that require a prescription.</p>

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	<p>Dr. Wallace moved to approve. Dr. Haneke seconded the motion. The motion carried unanimously.</p>
<p>iii. Thyroid Hormones: Levoxyl®, Synthroid®, Tirosint®, Unithroid®, Thyquidity™</p>	<p>Background: Current guidelines recommend against switching between FDA-approved levothyroxine products from different manufacturers due to concerns related to stability and pharmacokinetics. The FDA has recently (May 5, 2022) issued an announcement of the results of a large, retrospective, comparative effectiveness study that they sponsored and published in JAMA Internal Medicine (February 2, 2022). The study found no difference in the proportion of patients with normal TSH between those who switched among different generic levothyroxine products and those that used the same generic levothyroxine product.</p> <p>Levothyroxine tablets have been available since 2000. The capsule formulation, Tirosint®, was approved several years later. Recently, oral solution formulations, including Tirosint-Sol and Thyquidity, were also approved. The Thyroid Hormones is a new class presented for inclusion to the PDL today and a class comparison chart is included for the Committee’s review.</p> <p>Public Comment: None</p> <p>Committee Discussion: None</p> <p>Dr. Sweet moved to approve. Dr. Haneke seconded the motion. The motion carried unanimously.</p>

Item	Notes
<p>2. New Drugs to Existing PDL Classes</p> <p>i. Acne Agents – Combination Agent (Topical) – New Agents: Twyneo®</p>	<p>Background: The Acne Agents class was divided into different groups in June 2019 and was last reviewed in January 2022 for the inclusion of Winlevi®. Twyneo® is a new combination product that contains benzoyl peroxide and tretinoin. It was FDA-approved in July 2021. A class comparison chart is included for the committee’s review.</p> <p>Public Comment: None</p> <p>Committee Discussion: None</p> <p>Dr. Haneke moved to approve. Dr. Gill seconded the motion. The motion carried unanimously.</p>
<p>ii. ADHD Agents – Miscellaneous Type – New Agent: Qelbree®</p>	<p>Background: This class was last reviewed in March 2018 for the inclusion of the immediate release forms of clonidine and guanfacine. Qelbree® was FDA-approved in April 2021 and has a similar mechanism of action to Strattera®. Qelbree® recently received an expanded indication indicated for the treatment of ADHD in adults. A class comparison chart is included for the committee’s review.</p> <p>Public Comment: None</p> <p>Committee Discussion: The Committee asked for clarification on the name of the class (on display was “ADHD Stimulants – Miscellaneous”). The State adjusted the naming on the class comparison chart to match the actual name of the PDL class, which is “ADHD – Miscellaneous”.</p> <p>Dr. Sweet moved to approve. Dr. Gill seconded the motion. The motion carried unanimously.</p>

Item	Notes
iii. Bladder Relaxant Agents – New Agent: Gemtesa®	<p>Background: This class was previously named “Urologic Agents” and did not contain Beta-3 Adrenergic Agonists before March 2017. Myrbetriq® oral granules was approved in March 2021, but has an indication limited to neurogenic detrusor overactivity (NDO) in pediatric patients age 3 years and older. Gemtesa® (approved December 2020) is another beta-3 adrenergic agonist indicated to treat overactive bladder in adults. A class comparison chart is included for the committee’s review.</p> <p>Public Comment: None</p> <p>Committee Discussion: None</p> <p>Dr. Gill moved to approve. Dr. Haneke seconded the motion. The motion carried unanimously.</p>
iv. Immunomodulation Agents – Asthma – New Agent: Tezspire®	<p>Background: This class was first introduced in June 2019. Tezspire® was FDA-approved in December 2021 as an add-on maintenance treatment in patients age 12 years and older with severe asthma. Tezspire® binds to human thymic stromal lymphopoietin, blocking its interaction with its receptor and reducing biomarkers and cytokines associated with inflammation. A class comparison chart is included for the committee’s review.</p> <p>Public Comment: None.</p> <p>Committee Discussion: None.</p> <p>Dr. Haneke moved to approve. Dr. Wallace seconded. The motion was carried unanimously.</p>

Item	Notes
v. Opioids-Short - Acting – New class Agent: Seglentis®	<p>Background: This class was last reviewed in September 2018 for the inclusion of Roxybond™. Seglentis® is a new combination product of tramadol and celecoxib that was FDA-approved in October 2021. It's indicated for the management of moderate to severe acute pain in adults where alternative treatments were inadequate to provide relief. A class comparison chart is included for the committee's review.</p> <p>Public Comment: None.</p> <p>Committee Discussion: None.</p> <p>Dr. Wallace moved to approve. Dr. Sweet seconded. The motion was carried unanimously.</p>
vi. PCSK-9 Inhibitors – Requesting class name change to PCSK-9 Modulators – New Agent: Leqvio®	<p>Background: The Committee originally approved this class in September 2015, which includes Praluent® and Repatha®. The prices of these products were cut by 60% between 2018-2019. They have also received expanded indications for reducing major adverse cardiovascular events in patients with established CVD. Recently, a new related agent, Leqvio®, was approved as an adjunct to diet and statin therapy for adults with heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease who require additional lowering of LDL. Because Leqvio® indirectly affects PCSK9 activity, a new name is proposed for the class. A class comparison chart is included for the committee's review.</p> <p>Public Comment: Sarah Sanders (Novartis) spoke on Leqvio™ and said that she appreciated the renaming of this class.</p> <p>Committee Discussion: None.</p> <p>Dr. Wallace moved to approve. Dr. Sweet seconded. The motion was carried unanimously.</p>

Item	Notes
<p>vii. Rosacea Agents – Topical – New Agent: Epsolay®</p>	<p>Background: This class was last reviewed in September 2020, where Zilxi® was added. Epsolay was recently FDA-approved as a 5% benzoyl peroxide cream for the treatment of rosacea. Most single-agent benzoyl peroxide are unapproved legend drugs, or, are marketed as over-the-counter products for the treatment of acne. A class comparison chart is included for the committee’s review.</p> <p>Public Comment: None.</p> <p>Committee Discussion: None.</p> <p>Dr. Haneke moved to approve. Dr. Wallace seconded. The motion was carried unanimously.</p>
<p>V. Adjourn</p>	<p>Dr. Wallace/Sweet moved to adjourn. Dr. Haneke seconded the motion. The motion was carried unanimously.</p> <p>The meeting adjourned at 12:07 p.m.</p>

APPENDIX A**July 2022 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 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
Citalopram Capsules	Citalopram tablets		7/19/2022	
Conjupri (Levamlodipine)	Norvasc tablets		7/19/2022	
Fleqsuvy (Baclofen) Oral suspension	Lioresal tablets		7/19/2022	
Infliximab	Remicade		7/19/2022	
Insulin Glargine	Lantus		7/19/2022	
Lyvispah (Baclofen) Oral granules	Lioresal tablets		7/19/2022	
Norliqva (Amlodipine) Oral solution	Norvasc tablets		7/19/2022	
Releuko (Filgrastim) Solution	Granix		7/19/2022	
Semglee (Insulin glargine)	Lantus		7/19/2022	
Sertraline Capsules	Zoloft tablets		7/19/2022	
Tlando (Testosterone Oral) Capsules	Androgel		7/19/2022	