The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – February 17, 2021

DATE: February 11, 2021

NOTE: In response to COVID-19, the February 2021 DUR Board meeting will be held via OHCA webinar at 4:00pm. Please register for the meeting using the following website address: https://zoom.us/j/96869909152?pwd=Q0JOeXZ2VndaQ0RDVzJOemo4UjEwdz09 After registering, you will receive a confirmation email containing information about joining the webinar.

Enclosed are the following items related to the February meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – Appendix A

Narrow Therapeutic Index (NTI) Drug List – Appendix B

Update on Medication Coverage Authorization Unit/Montelukast in Allergic Rhinitis Safety Mailing Update – Appendix C

Action Item – Approval of November 2020 DUR Recommendations – Appendix D

Action Item – Approval of December 2020 DUR Recommendations – Appendix E

Action Item – Vote to Prior Authorize Nexletol® (Bempedoic Acid) and Nexlizet™ (Bempedoic Acid/Ezetimibe) – Appendix F

Action Item – Vote to Prior Authorize Imcivree™ (Setmelanotide) – Appendix G

Action Item – Vote to Prior Authorize Fensolvi® (Leuprolide Acetate) and Oriahnn™ (Elagolix/Estradiol/Norethindrone and Elagolix) – Appendix H

Action Item – Vote to Prior Authorize Durysta™ (Bimatoprost Implant) – Appendix I

Action Item – Annual Review of Crysvita® (Burosumab) – Appendix J

Annual Review of Leukemia Medications and 30-Day Notice to Prior Authorize Inqovi® (Decitabine/Cedzuridine), Onureg® (Azacitidine), and Riabni™ (Rituximab-arrx) – Appendix K

Annual Review of Azedra® (Iobenguane) – Appendix L

Annual Review of Anticonvulsants and 30-Day Notice to Prior Authorize Fintepla® (Fenfluramine) – Appendix M

Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Nurtec™ ODT (Rimegepant) and Vyepti® (Eptinezumab-jjmr) – Appendix N

Annual Review of Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and 30-Day Notice to Prior Authorize Anjeso® (Meloxicam Injection) and Licart™ (Diclofenac Epolamine Topical System) – Appendix O

30-Day Notice to Prior Authorize Oxlumo® (Lumasiran) – Appendix P

Annual Review of Osteoporosis Medications and 30-Day Notice to Prior Authorize Teriparatide – Appendix Q

30-Day Notice to Prior Authorize Zokinvy® (Lonafarnib) – Appendix R

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – Appendix S

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – February 17, 2021 @ 4:00pm

Oklahoma Health Care Authority (OHCA) Webinar
Please register for the meeting at:
https://zoom.us/j/96869909152?pwd=Q0JOeXZ2VndaQ0RDVzJOemo4UjEwdz09
After registering, you will receive a confirmation email containing information about joining the webinar.

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

1. Call to Order

A. Roll Call – Dr. Wilcox

DUR Board Members:	**Telephone Conference Participants**
Dr. Stephen Anderson –	participating via Zoom teleconference
Dr. Jennifer de los Angeles –	participating via Zoom teleconference
Ms. Jennifer Boyett –	participating via Zoom teleconference
Dr. Markita Broyles –	participating via Zoom teleconference
Dr. Theresa Garton –	participating via Zoom teleconference
Dr. Megan Hanner –	participating via Zoom teleconference
Dr. Lynn Mitchell –	participating via Zoom teleconference
Dr. John Muchmore –	participating via Zoom teleconference
Dr. Lee Muñoz –	participating via Zoom teleconference
Dr. James Osborne –	participating via Zoom teleconference

Public Access to Meeting via Zoom:

Please register for the meeting at:
https://zoom.us/j/96869909152?pwd=Q0JOeXZ2VndaQ0RDVzJOemo4UjEwdz09

Or join by phone:
Dial: +1-213-338-8477 or +1-253-215-8782
Webinar ID: 968 6990 9152
Passcode: 64434335

Public Comment for Meeting:

- Speakers who wish to sign up for public comment at the OHCA DUR Board meeting may do so in writing by visiting www.okhca.org/DUR and completing the Speaker Registration Form. Completed Speaker Registration forms should be submitted to *DURPublicComment@okhca.org*. Forms must be received after the DUR Board agenda has been posted and no later than 24 hours before the meeting.
- The DUR Board meeting will allow public comment and time will be limited to 40 minutes total for all speakers during the meeting. Each speaker will be given 5 minutes to speak at the public hearing. If more than 8 speakers properly request to speak, time will be divided evenly.
- Only 1 speaker per manufacturer will be allowed.

Items to be presented by Dr. Muchmore, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers for Public Comment

Items to be presented by Dr. Muchmore, Chairman:

3. Action Items – Approval of DUR Board Meeting Minutes – See Appendix A

A. **Action Item –** November 4, 2020 DUR Minutes – Vote
B. November 4, 2020 DUR Recommendations Memorandum
C. **Action Item –** December 9, 2020 DUR Minutes – Vote
D. December 9, 2020 DUR Recommendations Memorandum
E. January 13, 2021 DUR Recommendations Memorandum

Items to be presented by Dr. Wilson, Dr. Muchmore, Chairman:

4. Narrow Therapeutic Index (NTI) Drug List – See Appendix B

A. Introduction
B. SoonerCare NTI Drug List

Items to be presented by Dr. Nawaz, Dr. Ha, Dr. Muchmore, Chairman:

5. Update on Medication Coverage Authorization Unit/Montelukast in Allergic Rhinitis Safety Mailing Update – See Appendix C

A. Pharmacy Helpdesk Activity for January 2021
B. Medication Coverage Activity for January 2021
C. Montelukast in Allergic Rhinitis Safety Mailing Update

Items to be presented by Dr. Nawaz, Dr. Muchmore, Chairman:

6. Action Items – Approval of November 2020 DUR Recommendations – See Appendix D

A. **Action Item –** Vote to Prior Authorize AirDuo® Digihaler® (Fluticasone Propionate/Salmeterol), ArmonAir® Digihaler® (Fluticasone Propionate), Breztri Aerosphere™ (Budesonide/Glycopyrrolate/Formoterol Fumarate), Asmanex® HFA (Mometasone Furoate) 50mcg, and Dulera® (Mometasone/Formoterol) 50mcg/5mcg and to Update the Approval Criteria for Nucala® (Mepolizumab)
    i. New U.S. Food and Drug Administration (FDA) Approval(s)
    ii. New FDA Expanded Indication(s) and/or Formulation(s)
    iii. College of Pharmacy Recommendations
B. **Action Item –** Vote to Prior Authorize Blenrep (Belantamab Mafodotin-blmf), Darzalex® (Daratumumab), Darzalex Faspro™ (Daratumumab/Hyaluronidase-fihj), Empliciti® (Elotuzumab), Hemady™ (Dexamethasone 20mg Tablet), Ninlaro® (Ixazomib), Sarclisa® (Isatuximab-irfc), and Xpovio® (Selinexor)
    i. U.S. Food and Drug Administration (FDA) Approval(s) and Indication(s)
    ii. Product Summaries
    iii. College of Pharmacy Recommendations
C. **Action Item –** Vote to Prior Authorize Lenvima® (Lenvatinib)
    i. Lenvima® (Lenvatinib) Product Summary
    ii. College of Pharmacy Recommendations

Items to be presented by Dr. Ha, Dr. Muchmore, Chairman:

7. Action Items – Approval of December 2020 DUR Recommendations – See Appendix E

A. **Action Item –** Vote to Prior Authorize Enspryng™ (Satralizumab-mwge) and Uplizna™ (Inebilizumab-cdon) and to Update the Approval Criteria for Soliris® (Eculizumab)
    i. New U.S. Food and Drug Administration (FDA) Approval(s)
    ii. College of Pharmacy Recommendations
B. **Action Item –** Vote to Prior Authorize Abrilada™ (Adalimumab-afzb), Avsola™ (Infliximab-axxq), and Hulio® (Adalimumab-fkjp) and to Update the Targeted Immunomodulator Agents Tier-2 Approval Criteria and the Approval Criteria for Entyvio® (Vedolizumab), Benlysta® (Belimumab), and Ilaris® (Canakinumab)

i. Introduction
ii. College of Pharmacy Recommendations

C. **Action Item –** Vote to Prior Authorize Ortikos™ [Budesonide Extended-Release (ER) Capsule]
   i. New U.S. Food and Drug Administration (FDA) Approval(s)
   ii. College of Pharmacy Recommendations
D. **Action Item –** Vote to Prior Authorize Pizensy™ (Lactitol)
   i. Introduction
   ii. College of Pharmacy Recommendations
E. **Action Item –** Vote to Update the Approval Criteria for Spravato® (Esketamine)
   i. New U.S. Food and Drug Administration (FDA) Approval(s)
   ii. College of Pharmacy Recommendations
F. **Action Item –** Vote to Update the Approval Criteria for Bavencio® (Avelumab), Braftovi® (Encorafenib), Keytruda® (Pembrolizumab), Opdivo® (Nivolumab), and Yervoy® (Ipilimumab)
   i. U.S. Food and Drug Administration (FDA) Approval(s) and Indication(s)
   ii. College of Pharmacy Recommendations

Items to be presented by Dr. Ha, Dr. Muchmore, Chairman:

8. Action Item – Vote to Prior Authorize Nexletol® (Bempedoic Acid) and Nexlizet™ (Bempedoic Acid/Ezetimibe) – See Appendix F

A. New U.S. Food and Drug Administration (FDA) Approval(s) and Indication(s)
B. Product Summaries
C. College of Pharmacy Recommendations

Items to be presented by Dr. Chandler, Dr. Muchmore, Chairman:

9. Action Item – Vote to Prior Authorize Imcivree™ (Setmelanotide) – See Appendix G

A. Introduction
B. College of Pharmacy Recommendations

Items to be presented by Dr. Wilson, Dr. Muchmore, Chairman:

10. Action Item – Vote to Prior Authorize Fensolvi® (Leuprolide Acetate) and Oriahnn™ (Elagolix/Estradiol/Norethindrone and Elagolix) – See Appendix H

A. New U.S. Food and Drug Administration (FDA) Approval(s)
B. College of Pharmacy Recommendations

Items to be presented by Dr. Nawaz, Dr. Muchmore, Chairman:

11. Action Item – Vote to Prior Authorize Durysta™ (Bimatoprost Implant) – See Appendix I

A. New U.S. Food and Drug Administration (FDA) Approval(s)
B. College of Pharmacy Recommendations

Items to be presented by Dr. Nawaz, Dr. Muchmore, Chairman:

12. Action Item – Annual Review of Crysvita® (Burosumab-twza) – See Appendix J

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Crysvita® (Burosumab-twza)
D. Prior Authorization of Crysvita® (Burosumab-twza)
E. Market News and Updates
F. College of Pharmacy Recommendations
G. Utilization Details of Crysvita® (Burosumab-twza)

Items to be presented by Dr. Borders, Dr. Muchmore, Chairman:

13. Annual Review of Leukemia Medications and 30-Day Notice to Prior Authorize Inqovi® (Decitabine/Cedzuridine), Onureg® (Azacitidine), and Riabni™ (Rituximab-arrx) – See Appendix K

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Leukemia Medications
D. Prior Authorization of Leukemia Medications
E. Market News and Updates
F. Product Summaries
G. College of Pharmacy Recommendations
H. Utilization Details of Leukemia Medications

Items to be presented by Dr. Borders, Dr. Muchmore, Chairman:

14. Annual Review of Azedra® (Iobenguane I-131) – See Appendix L

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Azedra® (Iobenguane I-131)
D. Prior Authorization of Azedra® (Iobenguane I-131)
E. Market News and Updates
F. College of Pharmacy Recommendations

Items to be presented by Dr. Ha, Dr. Muchmore, Chairman:

15. Annual Review of Anticonvulsants and 30-Day Notice to Prior Authorize Fintepla® (Fenfluramine) – See Appendix M

A. Current Prior Authorization Criteria
B. Utilization of Anticonvulsants
C. Prior Authorization of Anticonvulsants
D. Market News and Updates
E. Fintepla® (Fenfluramine) Product Summary
F. Cost Comparison: Anticonvulsant Therapies for DS
G. College of Pharmacy Recommendations
H. Utilization Details of Anticonvulsants

Items to be presented by Dr. Chandler, Dr. Muchmore, Chairman:

16. Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Nurtec™ ODT (Rimegepant) and Vyepti® (Eptinezumab-jjmr) – See Appendix N

A. Current Prior Authorization Criteria
B. Utilization of Anti-Migraine Medications
C. Prior Authorization of Anti-Migraine Medications
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Anti-Migraine Medications

Items to be presented by Dr. Wilson, Dr. Muchmore, Chairman:

17. Annual Review of Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and 30-Day Notice to Prior Authorize Anjeso® (Meloxicam Injection) and Licart™ (Diclofenac Epolamine Topical System) – See Appendix O

A. Current Prior Authorization Criteria
B. Utilization of NSAIDs
C. Prior Authorization of NSAIDs
D. Market News and Updates
E. Product Summaries

F. College of Pharmacy Recommendations
G. Utilization Details of NSAIDs

Items to be presented by Dr. Wilson, Dr. Muchmore, Chairman:

18. 30-Day Notice to Prior Authorize Oxlumo™ (Lumasiran) – See Appendix P

A. Introduction
B. Oxlumo™ (Lumasiran) Product Summary
C. College of Pharmacy Recommendations

Items to be presented by Dr. Daniel, Dr. Muchmore, Chairman:

19. Annual Review of Osteoporosis Medications and 30-Day Notice to Prior Authorize Teriparatide – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of Osteoporosis Medications
C. Prior Authorization of Osteoporosis Medications
D. Market News and Updates
E. Teriparatide Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Osteoporosis Medications

Items to be presented by Dr. Nawaz, Dr. Muchmore, Chairman:

20. 30-Day Notice to Prior Authorize Zokinvy™ (Lonafarnib) – See Appendix R

A. Introduction
B. Market News and Updates
C. Zokinvy™ (Lonafarnib) Product Summary
D. College of Pharmacy Recommendations

Items to be presented by Dr. Nawaz, Dr. Muchmore, Chairman:

21. U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – See Appendix S

Items to be presented by Dr. Adams, Dr. Muchmore, Chairman:

22. Future Business* (Upcoming Product and Class Reviews)

A. Multiple Sclerosis Medications
B. Hereditary Angioedema (HAE) Medications
C. Granulocyte Colony-Stimulating Factors (G-CSFs)
D. Hemophilia Medications

**Future product and class reviews subject to change.*

23. Adjournment

NOTE: An analysis of the atypical [Aged, Blind, and Disabled (ABD)] patient subgroup of the Oklahoma Medicaid population has been performed pertaining to all recommendations included in this DUR Board meeting packet to ensure fair and knowledgeable deliberation of the potential impact of the recommendations on this patient population.