

Janet T. Mills
Governor

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Commissioner



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DUR COMMITTEE AGENDA

Date: Tuesday, September 14, 2021
Time: 6:00PM to 8:30PM
Location: **Virtual: [Join Teams Meeting](#)** (please see live Teams link in the Agenda that is posted at mainecarepd.org/durfiles)
To Dial in: 1-877-455-0244 Access Code: 2076246948

- 1) **Closed Session: 5:30PM- 6:00PM- Board members only (a separate invitation to be sent)**
- 2) MaineCare Updates- Anne-Marie Toderico
- 3) Public Comments
- 4) Old Business
 - Approve June Meeting Minutes
- 5) Revised clinical criteria
 - None at this time.
- 6) New Business (open session)
 - Retro DUR
 - Introduce: Herpes Zoster vaccination rates
 - Data Presentation: Long-acting Injectable Antipsychotics
 - New Drug Review (<http://www.mainecarepd.org/>)

Exservan (riluzole oral film)- ALS Drugs
Aduhelm (aducanumab-avwa)- Alzheimer- Cholinomimetics/Other
Elespia XR (levetiracetam extended-release tablets)- Anticonvulsants
Jemperli (dostarlimab-gxly)- Cancer
Lumakras (sotorasib)- Cancer
Rybrevant (amivantamab-vmjw)- Cancer
Rylaze (asparaginase erwinia chrysanthemi(recombinant)-rywn)- Cancer
Truseltiq (infigratinib)- Cancer
Zynlonta (loncastuximab tesirine)- Cancer
Kerendia (finerenone)- Diuretics
Zegalogue (dasiglycagon)- Glucose Elevating Agents
Empaveli (pegcetacoplan)- Monoclonal Antibody
Ozobax (baclofen oral solution)- Muscle Relaxants
Kloxxado (naloxone hydrochloride)- Narcotic- Antagonists
Myfembree (relugolix, estradiol, and norethindrone acetate)- Pituitary Suppressive Agents, LHRH
Brexafemme (ibrexafungerp)- Antifungals- Assorted

7) FDA Safety Alerts

FDA Approves a Nasal Antihistamine for Nonprescription Use

https://www.fda.gov/news-events/press-announcements/fda-approves-nasal-antihistamine-nonprescription-use?utm_medium=email&utm_source=govdelivery

FDA notifies Amgen of misbranding of its biological product, Neulasta, due to false or misleading promotional communications about the product's benefit

https://www.fda.gov/drugs/drug-safety-and-availability/fda-notifies-amgen-misbranding-its-biological-product-neulasta-due-false-or-misleading-promotional?utm_medium=email&utm_source=govdelivery

FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes

https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes?utm_medium=email&utm_source=govdelivery

Clozapine Risk Evaluation and Mitigation Strategy (REMS) requirements will change on November 15, 2021

https://www.fda.gov/drugs/drug-safety-and-availability/clozapine-risk-evaluation-and-mitigation-strategy-rems-requirements-will-change-november-15-2021?utm_medium=email&utm_source=govdelivery

- 8) Next Meeting (Tuesday, October 12, 2021)
- 9) Adjournment: 8:30PM