Janet T. Mills
Governor

Sara Gagné-Holmes
Commissioner

Maine Department of Health and Human Services
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DUR COMMITTEE AGENDA

Date: Tuesday, September 9, 2025

Time: 5:30 – 8:30 PM

Location: **Virtual:**

To Dial in: 1-207-209-4724
Phone Conference ID: 250298062#
Teams link: **Join the meeting now**

In-Person:

109 Capitol Street
11 State House Station Rooms A and B
Augusta, Maine 04333

CLOSED SESSION (5:30 – 6:00 PM)

Board members only (Invitations for Closed and Open Sessions Will Be Sent Separately)

1) Introduction: Dan Mickool, R.Ph, M.S., Ed D, Associate Director of Pharmacy
2) MaineCare Updates
3) Public Comments
4) Old Business
5) Consent Agenda
   - Approve June 10, 2025, Meeting Minutes
   - New Cancer Medications: General CA category/class criteria is published on the MaineCare PDL
     - Avmapki Fakzynja
     - Emrelis
     - Lynozyfic
   - Biosimilars
     - Bomyntra (Xgeva)
     - Conexxence (Prolia)
     - Imuldosa (Stelara)
     - Jubbonti (Prolia)
     - Merilog (Novolog)
     - Osenvelt (Xgeva)
     - Selarsdi (Stelara)
     - Stoboclo (Prolia)
     - Wyost (Xgeva)
6) Revised clinical criteria
   - None at this time

OPEN SESSION (6:00 – 8:30 PM)

7) New Business
   - Retro DUR
     - Data Presentation: Biosimilar PDL Cost Saving Evaluation
     - Introduction: Long-Acting Antipsychotic Injection Purpose
   - New/Revised Criteria
     - None at this time

- New Drug Review
  - Andembry
  - Ctexli
  - Harliku
  - Hemiclor
  - Imaavy
  - Khindivi
  - Leqselvi
  - Ryzneuta
  - Sofdra
  - Symbravo
  - Tryptyr
  - Vykat XR
  - Xifyrm
  - Yeztugo
  - Zelsuvmi

8) FDA Safety Alerts
   - Transdermal Scopolamine Drug Safety Communication – FDA adds warning about serious risk of heat-related complications with antinausea patch – click here for the link (June 18, 2025)
   - FDA warning in labeling of mRNA COVID-19 vaccines regarding myocarditis and pericarditis following vaccination – click here for the link (June 25, 2025)
   - Expanded Safety Labeling on Extended-Release Stimulants for ADHD – click here for the link (June 30, 2025)
   - FDA is requiring opioid pain medicine manufacturers to update prescribing information regarding long-term use – click here for the link (July 31, 2025)
   - Elevidys Concerns:
     - FDA investigating deaths due to acute liver failure in non-ambulatory Duchenne Muscular Dystrophy patients following Elevidys – click here for the link (June 24, 2025)
     - FDA requests Sarepta Therapeutics suspend distribution of Elevidys and places clinical trials on hold for multiple gene therapy products following 3 deaths – click here for the link (July 18, 2025)

9) Next Meeting: **Annual Meeting will be held on Tuesday, November 4, 2025**
   - Closed Session 1:00 – 2:30 PM
   - Open Session 2:30 – 5:30 PM

10) Adjournment: 8:30 PM