Janet T. Mills
Governor

Sara Gagne- Holmes
Commissioner

Maine Department of Health and Human Services
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TO: Maine Drug Utilization Review Board
DATE: 11/06/24
RE: Maine DUR Board Meeting minutes from November 5, 2024

ATTENDANCE	UNEXCUSED	EXCUSED	IN-PERSON	REMOTELY
Linda Glass, MD				X
Kathleen Polonchek, MD				X
Erin Ackley, PharmD.				X
John Deason, PharmD.				X
Caitlin Morrow, PharmD.				X
Non –Voting				
Mike Ouellette, R.Ph., Optum			X	
Roberta Capp, MD, Optum			X	
Anne-Marie Toderico, PharmD MaineCare			X	

Guests of the Board: Gavin Gillespie PharmD, Optum

CALL TO ORDER: 6:00PM

Erin Ackley called the meeting to order at 6:00 PM.

PUBLIC COMMENTS

Dennis Sholler from Intra Cellular Therapies: Highlighted the attributes of Caplyta.
Ray Kong from Neurocrine BioSciences: Highlighted the attributes of Ingrezza.
Nicole Trask from J& J: Highlighted the attributes of Tremfya.
Anna Basoff from Otsuka: Highlighted the attributes of Abilify Asimtufi.
Tyson Thompson from Pfizer: Highlighted the attributes of Nurtec & Zavzpret.
Shirley Quach from Novartis: Highlighted the attributes of Cosentyx.
Timothy Birner from Alkermes: Highlighted the attributes of Lybalvi.
James Monckton from SK LifeScience Inc: Highlighted the attributes of Xcopri.
Corey O'Brien from Novo Nordisk: Highlighted the attributes of Wegovy.
Ronnie DePue from Axsome Therapeutics: Highlighted the attributes of Auvelity & Sunosi.
Heidi Kay from Genetech: Highlighted the attributes of Xolair.
Jalal Nait Hammoud from Viking: Highlighted the attributes of Siklos.
Omer Aziz from Teva: Highlighted the attributes of Uzedy, Simlandi, and Ajovy.

MAINECARE UPDATE- ANNE-MARIE TODERICO

- With the end of the American Rescue Plan Act, copayments returned for some MaineCare services, including prescriptions. More information can be found on our website.

OLD BUSINESS

DUR MINUTES

Approval of September DUR meeting minutes

Board Decision: The Board unanimously approved the above recommendation.

REVISED CLINICAL CRITERIA

VASMOTOR SYMPTOMS AGENTS

VASOMOTOR SYMPTOMS AGENTS * will be updated in November

- Updated VEOZAH criteria
    - Veozah: Approval requires at least one preferred Hormone Replacement Therapy (HRT) and two preferred non-hormonal therapies (i.e., SSRIs, SNRIs, gabapentin, pregabalin, clonidine).

Board Decision: The Board unanimously approved all the above recommendations.

NEW BUSINESS

PRESENT 2025 MEETING SCHEDULE

The DUR Committee will meet from 5:30pm to 8:30pm on:
March 11, 2025
June 10, 2025
September 9, 2025
November 4, 2025(1:00pm to 2:30pm Closed Session, 2:30pm to 5:30pm Public Session)
December 9, 2025

Board Decision: The Board unanimously approved all the above recommendations.

PRESENT 2025 RETRODUR POTENTIAL INITIATIVES

Treatment of C. Diff

Purpose: IDSA guidelines have changed.

- Can evaluate use of metronidazole (no longer recommended), vancomycin, Difficid(fidaxomicin, and Zinplava (bezlotoxumab) injection in members with diagnosis of C. Diff in medical claims.
- Attempt to evaluate recurrences by looking at repeat prescriptions or change in therapy after first fill.

Co-Administration of PPIs and Bisphosphonates

Purpose: Long term use of PPIs may be associated with an increased fracture risk. Patients also taking bisphosphonates may be at further risk.

- Identify members with overlapping claims of PPi and bisphosphonates.

- Look at duration and dose of PPI where possible.

Hepatitis C Adherence and Cure Rates

Purpose: Utilize information gathered form the Pharmacy Care Management (PCM) program.

- Evaluate frequency of use for 8-week, 12-week, and 16-week regimens based on genotype of other clinical parameters.
- Report cure rates for members (will only be reported for those whose MD's have sent follow up information to PCM)
- Evaluate adherence rates

Hemlibra

Purpose: Cost benefit of Hemlibra

- Analyze medical claims, looking at number and cost of hospitalizations, ER visits, factor use and provider visits for the year prior to starting Hemlibra and 1 year after starting the medication in those who had been on traditional factor prophylaxis prior to starting Hemlibra, to see if the increased cost of Hemlibra is offset by decreased utilization of medical care, including factor use.
- Compare kids who start Hemlibra with those who initially started factor
- Look at those who started Hemlibra after developing an inhibitor to look at pre and post costs.

Biosimilar PDL

Purpose: Cost benefit

- Analyze inclusion of bio similar PDL into the MaineCare benefit to see if changes effective utilization and cost benefit

Long-Acting Antipsychotic Injection

Purpose: Cost benefit

- Benefit in the weekly, monthly, every two months or six month doses compared to cost of hospitalizations, ER visits and other services.

Board Decision: The board chose the following topics for RetroDURs for 2025: Long-Acting Antipsychotic Injection, Biosimilar PDL, Hemlibra and Co-Administration of PPIs and Bisphosphonates. Optum will create a presentation schedule that will be presented at the December meeting.

2025 PDL CATEGORY REVIEW

ANTIASTHMATIC - ANTICHOLINERGICS – INHALER

- Move FLUTICASONE-SALMETEROL to preferred

ANTIASTHMATIC - ANTIINFLAMMATORY AGENTS:

- Move NUCALA to non-preferred
    - For patients with severe asthma aged 12 years or older and eosinophilia.

ANTIASTHMATIC - BETA – ADRENERGICS

- Add ALBUTEROL HFA Sandos labler 00781 to preferred
- Move LEVALBUTEROL HFA to preferred
- Move STRIVERDI to preferred

ANTICONVULSANTS

- Move BRIVIACT to preferred
- Move LAMOTRIGINE XR to preferred
- Move LAMICTAL XR to non-preferred
- Remove DIASTAT from the PDL

ANTI-EMETOGENICS

- Move DOXYLAMINE SUCC-PYRIDOXINE HCL to preferred
- Move BONJESTA to non-preferred
- Move DICLEGIS to non-preferred

ANTIHEMOPHILIC AGENTS

- Move REBINYN to preferred
- Move ALTUVIIIO to non-preferred
    - Clinical PA required for appropriate diagnosis.
- Move AFSTYLA to non-preferred

ANTIPSYCHOTICS – ATYPICALS

- Move ABILIFY ASIMTUFII to preferred
- Move RYKINDO to preferred

ANTIRETROVIRALS

- Move ATRIPLA to non-preferred
    - Quantity limit of one per day
- Move TRIUMEQ to preferred
    - Quantity limit of one per day

ANTISPASMODICS - LONG ACTING

- Move FESOTERODINE to preferred
- Move TOVIAZ to non-preferred

CARDIAC- SODIUM- GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR

- Rename category CARDIAC RISK REDUCTION- SGLT2/GLP-1
- Add WEGOVY to non-preferred
    - Patient has BMI > 27 kg/m2, and is not being used for weight loss only
    - Patient has history of at least one of the following:
        - o Stroke
        - o Myocardial Infarction
        - o Symptomatic peripheral arterial disease
    - Patient does not have diagnosis of diabetes, end stage renal disease/dialysis, or NYHA class IV heart failure
    - Patient has received counseling on chronic weight management (increased physical activity and a reduce calorie diet) and will continue to follow a treatment plan

DIABETES THERAPIES

DIABETIC – INSULIN

- Move FIASP to preferred
- Move APIDRA to non-preferred
- Move INSULIN DEGLUDEC to non-preferred
- Move NOVOLOG, NOVOLOG MIX, NOVOLOG MIX 70/30 to non-preferred

DIABETIC – PENFILLS

- Move NOVOLOG MIX PENFILL, NOVOLOG PENFILL SOLN, NOVOLOG FLEXPEN to non-preferred

GI - MISC.

- Move ENEMEEZ to non-preferred

DIURETICS

- Move KERENDIA to non-preferred
    - Patient must be on max tolerated preferred ACE-I/ARB and SGLT-2

EAR

- Move FLUOCINOLONE ACETONIDE OIL to preferred
- Move DERMOTIC to non-preferred

GRANULOCYTE CSF

- Move FULPHILA to preferred
- Move ZIEXTENZO to non-preferred

GOUT

- Move MITIGARE to preferred

GROWTH HORMONE

- Remove NUTROPIN AQ from the PDL
- Move SKYTROFA to preferred
    - Clinical PA is required to establish diagnosis and medical necessity.
    - All preferred agents must be used in step therapy must be tried and failed.

INCRETIN MIMETIC

- Move RYBELSUS to preferred
- Move OZEMPIC to non-preferred
    - Step 5

MIGRAINE THERAPIES

MIGRAINE – PREVENTATIVE TREATMENT

- AIMOVIG preferred
    - See criteria section
    - Dosing limits apply, please see the dose consolidation list
- AJOVY preferred
    - See criteria section
- AJOVY AUTO INJCT preferred
    - See criteria section
- EMGALITY SYRINGE 200mg/ml preferred
    - See criteria section
- EMGALITY PEN preferred

    - See criteria section
- NURTEC ODT preferred
    - Dosing limits apply, please see the dose consolidation list
- QULIPTA non-preferred
- VYEPTI non- preferred
    - Dosing limits apply, please see the dose consolidation list

MIGRAINE ACUTE TREATMENT

- NURTEC ODT preferred
    - Dosing limits apply, please see the dose consolidation list.
- SPASTRIN TABS preferred
- BELCOMP-PB SUPP non-preferred
- ELYXYB non-preferred
- MIGRAZONE CAPS non-preferred
- MIGERGOT SUP non-preferred
- REYVOW non-preferred
- UBRELVY non-preferred
- ZAVZPRET non-preferred

MULTIPLE SCLEROSIS - NON-INTERFERONS

- Add criteria to KESIMPTA
    - Clinical PA is required to establish diagnosis and medical necessity.
    - Approved after single step through preferred drugs.

MUSCULAR DYSTROPHY AGENTS

- Move EMFLAZA to preferred
    - For the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older and a documented intolerance of oral corticosteroid
- Move DEFLAZACORT to non-preferred

OP. - ANTI-INFLAMMATORY / STEROIDS OPHTH.

- Move LOTEMAX GEL to preferred
- Move FLAREX SUSP to non-preferred

OP. - NSAID'S

- Move ACULAR SOLN to preferred

OP. - OF INTEREST

- Move EYSUVIS to preferred
    - For the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

OPIOID DEPENDENCE TREATMENTS

- Add sub-category Extended-Release Buprenorphine
- Move BRIXADI to preferred
    - Clinical PA required.
- Move SUBLOCADE to preferred
    - Clinical PA required.

PLATELET AGGREGATION INHIBITORS

- Move BRILINTA 60mg to non-preferred
- Keep BRILINTA 90mg preferred

PSORIASIS BIOLOGICALS

- Move ADALIMUMAB-FKJP to preferred
- Move SIMLANDI to preferred
- Move SKYRIZI to preferred
- Add criteria on STELARA
    - Stelara will require using preferred trial of Skyrizi if unable please provide clinical rational as why inappropriate.

PSYCHOTHERPEUTIC COMBINATION

- Move CHLORDIAZEPOXIDE/AMITRIPT to preferred
- Move PERPHENAZINE/AMITRIPTYLIN to preferred

RHEUMATOID ARTHRITIS

- Move ADALIMUMAB-FKJP to preferred
- Move SIMLANDI to preferred
- Move RINVOQ to preferred

SGLT 2 INHIBITORS

- Move INVOKANA to non-preferred
    - Dosing limits apply please refer to Dose Consolidation List

SGLT 2 INHIBITOR COMBINATIONS

- Move SYNJARDY XR to preferred
- Move INVOKAMET to non-preferred

SICKLE CELL DISEASE

- Move LYFGENIA to preferred- ***Tabled until Decembers meeting***
    - For the treatment of patients ≥ 12 years of age.
    - PA required to confirm FDA approved indication.
- Remove OXBRYTA from the PDL

STIMULANT - METHYLPHENIDATE - LONG ACTING

- Move FOCALIN XR to preferred
- Move METHYLPHENIDATE CD CAPS 30-70 to preferred
- Move METHYLPHENIDATE ER2,4 CAPS 50/50 to preferred
- Move METHYLPHENIDATE ER TAB to preferred
- METHYLPHENIDATE ER TAB 24 to preferred

TOPICAL- ATOPIC DERMATITIS

- Move OPZELURA to preferred
    - Clinical PA required.
    - For the treatment of patients ≥ 12 years of age.
    - Preferred after a trial and failure of TCSs and TCIs.

Board Decision: The Board unanimously approved all the above recommendations except for Lyfgenia which has been tabled until December's meeting.

FDA SAFETY ALERTS

FDA adds warning about rare occurrence of serious liver injury with use of Veozah (fezolinetant) for hot flashes due to menopause | FDA

FDA is alerting patients and health care professionals about the voluntary withdrawal of Oxbryta from the market due to safety concerns | FDA

Board Decision: Oxbryta will be removed from the PDL.

ADJOURNMENT: 8:30PM

The next meeting will be held on December 10, 2024, 6pm-8pm EST hybrid.