

**New York State Medicaid  
Drug Utilization Review (DUR) Board  
Meeting Summary for July 23, 2020**

The Medicaid DUR Board met on Thursday, July 23, 2020 from 9:00 AM to 4:00 PM. In consideration of COVID–19 guidelines, the meeting was held virtually and available for public viewing by way of a live audio-video webcast.

An archived audio cast of the meeting proceedings is available on the Department of Health website: <http://www.health.ny.gov/events/webcasts/>

**A. Welcome and Introductions**

Audio cast start time 00:55:00

Department of Health

Douglas Fish, MD – DUR Board Chairperson

Amir Bassiri

Robert Correia, PharmD

Anthony Merola, RPh, MBA

Robert Sheehan, RPh

Monica Toohey, RPh

Janet Zachary-Elkind

DUR Board Members

Lisa Anzisi, PharmD

Donna Chiefari, PharmD

Marla Eglowstein, MD

James Hopsicker, RPh, MBA

Renante Ignacio, MD

Jacqueline Jacobi, RPh

Jill Lavigne, PhD

Peter Lopatka, FSA

Jadwiga Najib, PharmD

John Powell

Casey Quinn, PhD

Asa Radix, MD

Tara Thomas, RPh, MBA, MPA

Jamie Wooldridge, MD

Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

SUNY – University at Buffalo

Barbara Rogler, PharmD, MS

Institute for Clinical and Economic Review (ICER)

Sarah Emond, MPP

Steven D. Pearson, MD, MSc

## B. Public Comment Period

Audio cast start time 0:10:36

The following speakers provided public comment to the DUR Board:

1.	Sarah R. Hnath, PT, DPT	Abbvie	Hepatitis C Agents
2.	Jeffery S. Olson, PharmD	Gilead Sciences Inc	Hepatitis C Agents
3.	Ryan Gregg, PhD	Ironshore Pharmaceuticals	CNS Stimulants
4.	Mark Owens, DO	League Education and Treatment Center	CNS Stimulants
5.	Elizabeth Lubelczyk, PharmD	Eli Lilly	GLP-1 Agonists
6.	Chirayu Parikh, PharmD	Novo Nordisk	GLP-1 Agonists
7.	Stephen Greco, MBA	Boehringer Ingelheim Pharmaceuticals	SGLT-2 Inhibitors
8.	Norbert Moskovits, MD	Maimonides Medical Ctr	SGLT-2 Inhibitors
9.	Carmelina Tyler PharmD	Veloxis Pharmaceuticals	Immunosuppressives, Oral
10.	Chris Leibman	Biogen	Drug Cap
11.	Michelle Rivera	Advocate	Drug Cap
12.	Mary Schroth, MD	CURE SMA	Drug Cap
13.	Leslie Delfiner, MD	Montefiore	Drug Cap

## C. Preferred Drug Program (PDP) Clinical Review

Audio cast start time 1:02:38 to 2:11:41

Eileen Zimmer, PharmD, MBA  
Robert Correia, PharmD  
Barbara Rogler, PharmD, MS

1. Non-Steroidal Anti-inflammatory Agents
  - Financial review only.
2. Hepatitis C Agents – Direct Acting
  - New indications: Epclusa (sofosbuvir/velpatasvir), Mavyret (glecaprevir/pibrentasvir).
  - New formulations, strengths: Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Epclusa (sofosbuvir/velpatasvir).
  - Key label revisions.
  - Considerations: 1) removal of prior authorization criteria for members initiating Hepatitis C direct acting antiviral (DAA) therapy (i.e. no DAA claims within the past 12 months) and 2) require prior authorization for members requiring retreatment within 1 year.
  - Appropriate choice of therapy within this class is also affected by specific patient co-morbidities and the presence or degree of cirrhosis.
3. CNS Stimulants
  - Financial review only.
4. Acne Agents - Topical
  - New drug entity: Aklief (trifarotene).

- New product: Amzeeq (minocycline).
- New indication: Aczone (dapsonsone).
- All products in this class are indicated for the treatment of acne, but different drugs or combinations may be more relevant to different severity of disease, patient population, or susceptibility of patients to adverse events.

#### 5. Topical Steroids – High Potency

- Financial review only.

#### 6. Glucagon-Like Peptide (GLP-1) Agonists

- New indications: Trulicity (delaglutide), Ozempic (semaglutide).
- New formulation: Rybelsus (semaglutide).
- New practice guidelines.
- Key label revisions.
- Evidence referenced from clinical, randomized trials from the Oregon Health and Science University (OHSU) Drug Effectiveness Review Project (DERP) compared cardiovascular impact.
- In terms of clinical relevance and applicability, comparative evidence between products appears to be clinically marginal.

#### 7. Sodium Glucose Co-Transporter 2 Inhibitors (SGLT-2)

- New indications: canagliflozin-containing products (Invokana, Invokamet, Invokamet XR); dapagliflozin-containing products (Farxiga, Xigduo XR)
- New formulation/strengths: Synjardy XR (empagliflozin/metformin, extended release).
- New practice guidelines.
- Key label revisions.
- Evidence referenced from clinical, randomized trials from the Oregon Health and Science University (OHSU) Drug Effectiveness Review Project (DERP) compared cardiovascular impact.

#### 8. Sulfasalazine Derivatives

- Financial review only.

#### 9. Immunosuppressives - Oral

- Financial review only.

#### 10. Phosphate Binders/Regulators

- Financial review only.

### **D. Recess/Lunch**

The Board recessed for lunch at 11:30 AM. The Board reconvened to the public session at 12:15pm.

## E. Drug Cap – Spinraza (nusinersen)

Barbara Rogler, PharmD, MS

A background summary of the Drug Cap legislation followed by a utilization review of Spinraza:

- Patients with severe forms of spinal muscular atrophy (SMA) have a life expectancy of <2 years. Patients with less severe disease can survive until adulthood. Severe SMA is more common with Type 1 accounting for > 50%.
- Two nusinersen phase 3 trials were terminated as results showed favorable outcomes. Post marketing studies showed benefits in adults with spinal muscular atrophy (SMA).
- The incidence of spinal muscular atrophy (SMA) in New York State approximates 20-30 cases per 253,000 births. New York includes SMA testing in newborn screening.
- Between April 2017 and September 2019 there were 336 claims for nusinersen for NY Medicaid members (Fee-For-Service and Managed Care).
- Total WAC for initial year of nusinersen therapy totals \$765,000; total WAC for maintenance year therapy totals \$382,500.
- Coverage policies (Medicaid programs, commercial insurance) in other states and countries specify criteria and/or restrictions for nusinersen coverage.

The information presented is viewable at the end of the meeting summary.

Steven Pearson, MD, MSc

Audio cast start time 2:52:15

A value assessment of Spinraza was presented and including the following:

- Elements in determining a reasonable price for pharmaceuticals.
- Elements of a cost-effectiveness threshold.
- Cost effectiveness thresholds.
- Spinraza improves patient health outcomes compared to best supportive care alone for all subpopulations of SMA. Its greatest impact appears to be when used for pre-symptomatic infants.
- In proportion to the clinical benefits, the added cost of Spinraza therapy exceeds commonly used thresholds for cost-effectiveness for all patient subpopulations.
- The modified societal perspective scenario analysis did not notably improve the cost-effectiveness of Spinraza.

The information presented is viewable at the end of the meeting summary.

## F. Executive Session

Recess to Excessive Session

The DUR Board recessed to executive session at 1:45 PM to review financial information relating to each of the ten PDP therapeutic classes under review and Drug Cap - Spinraza (nusinersen). No official action was taken in the executive session. The DUR Board reconvened to the public session at 2:30 PM.

**G. DUR Board PDP Recommendations**

Audio cast start time 3:30:09 to 3:57:27

Based on clinical and financial information, the DUR Board recommended the following to the Commissioner of Health for final determination:

Recommendations of the DUR Board	Commissioner's Final Determination
<p><b>1. Non-Steroidal Anti-inflammatory Agents - NSAIDS</b>  <span style="float: right;">Audio cast start time 3:33:04</span></p> <p><b>Preferred:</b> diclofenac topical gel, ibuprofen (tab, OTC susp), indomethacin, ketorolac, meloxicam(tab), naproxen(tab), naproxen EC, piroxicam, sulindac</p> <p><b>Non- Preferred:</b> Arthrotec, Cambia, Celebrex, celecoxib, Daypro, diclofenac epolamine(generic for Flector), diclofenac/misoprostol, diclofenac potassium, diclofenac sodium, diclofenac topical solu, diclofenac sodium ER, diflunisal, Duexis, etodolac, etodolac ER, Feldene, fenoprofen, Flector patch, flurbiprofen, ibuprofen RX susp, Indocin, indomethacin ER, ketoprofen, ketoprofen ER, meclofenamate, mefenamic acid, Mobic, nabumetone, Nalfon, Naprelan, naproxen CR, naproxen-esomeprazole, naproxen sodium, naproxen susp, oxaprozin, Pennsaid, Qmiiz ODT, Relafen DS, Sprix Nasal, Timvorbex, tolmetin sodium, Vimovo, Vivlodex, Voltaren gel, Zipsor, Zorvolex.</p> <p>Vote: 14 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>
<p><b>2. Hepatitis C Agents – Direct Acting*</b>  <span style="float: right;">Audio cast start time 3:37:51</span></p> <p><b>Preferred:</b> Mavyret, ribavirin, sofosbuvir/velpatasvir (generic Epclusa), Vosevi</p> <p><b>Non-Preferred:</b> Epclusa, Harvoni, ledipasvir/sofosbuvir (generic Harvoni), Ribasphere, Sovaldi, Viekira Pak, Zepatier</p> <p>* In addition to the standard clinical criteria for non-preferred products, all products require prior authorization if there is no evidence of an FDA approved or compendia supported diagnosis in history or if the patient is being retreated.</p> <p>Vote: 14 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>

<p><b>3. Central Nervous System Stimulants</b> <span style="float: right;">Audio cast start time 3:42:22</span></p> <p><b>Preferred:</b> amphetamine salt combo IR (generic Adderall), amphetamine salt combo ER (generic Adderall XR), Aptensio XR, Concerta, Daytrana, dexamethylphenidate (generic Focalin), dextroamphetamine tab, Focalin XR, methylphenidate tab (generic Ritalin) methylphenidate solution (generic Methylin), Vyvanse (cap, chew)</p> <p><b>Non-Preferred:</b> Adderall XR, Adhansia XR, Adzenys (ER susp, XR-ODT), amphetamine (generic Adzenys ER, Evekeo), armodafinil (generic Nuvigil), Cotempla XR-ODT, Desoxyn, Dexedrine, dexamethylphenidate ER(generic Focalin XR), dextroamphetamine ER (generic Dexedrine), dextroamphetamine soln (generic ProCentra), Dyanavel XR, Evekeo, Evekeo ODT, Focalin, Jornay PM, methamphetamine (generic Desoxyn), Methylin solu, methylphenidate chew tab (generic Methylin), methylphenidate ER(generic Concerta, Metadate, Ritalin LA, Aptensio XR), methylphenidate CD, methylphenidate ER 72mg, modafinil (generic Provigil), Mydayis, Nuvigil, ProCentra, Provigil, Quillichew ER, Quillivant XR, Ritalin, Ritalin LA, Sunosi, Wakix, Zenedi</p> <p>Vote: 14 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>
<p><b>4. Acne Agents - Topical</b> <span style="float: right;">Audio cast start time 3:47:17</span></p> <p><b>Preferred:</b> adapalene (crm, pump), adapalene/benzoyl peroxide, Differin Gel OTC, Retin-A Cream, tazarotene, tretinoin gel (generic Avita and Retin-A)</p> <p><b>Non-Preferred:</b> Aczone, adapalene gel, Aklief, Altreno, Amzeeq, Atralin, Avita, Azelex, clindamycin/tretinoin, dapsone, Differin (crm, pump, lotion), Epiduo, Epiduo Forte, Fabior, Retin-A gel, Retin-A Micro, Tazorac, tretinoin crm, tretinoin gel (generic Atralin), tretinoin micro, Ziana</p> <p>Vote: 14 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>
<p><b>5. Topical Steroids – High Potency</b> <span style="float: right;">Audio cast start time 3:43:55</span></p> <p><b>Preferred:</b> betamethasone dipropionate (lotion), betamethasone valerate (crm, oint), triamcinolone acetonide (crm, oint, lotion)</p> <p><b>Non-Preferred:</b> amcinonide, Apexicon-E, betamethasone dipropionate (crm, gel, oint), betamethasone dipropionate augmented, betamethasone valerate lotion, desoximetasone, diflorasone, Diprolene, fluocinonide 0.1% crm (generic for Vanos), fluocinonide (oint, crm, gel, sol, emol), halcinonide crm (generic for Halog), Halog, Kenalog, Sernivo, Topicort, triamcinolone spray, Trianex, Vanos</p> <p>Vote: 14 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>

<p><b>6. Glucagon-like Peptide-1 (GLP-1) Agents*</b> <span style="float: right;">Audio cast start time 3:50:36</span></p> <p><b>Preferred:</b> Bydureon, Byetta, Trulicity, Victoza</p> <p><b>Non-Preferred:</b> Adlyxin, Bydureon Bcise, Ozempic, Rybelsus, Soliqua, Xultophy</p> <p>*Requires trial with metformin with or without insulin prior to GLP-1 agonist. PA required with lack of covered diagnosis.</p> <p>Vote: 15 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>
<p><b>7. Sodium Glucose Co-Transporter 2 (SGLT-2) Inhibitors*</b> <span style="float: right;">Audio cast start time 3:52:17</span></p> <p><b>Preferred:</b> Farxiga, Invokana, Jardiance</p> <p><b>Non-Preferred:</b> Invokamet, Invokamet XR, Segluromet, Steglatro, Synjardy, Synjardy XR, Xigduo XR</p> <p>*Requires a trial with metformin with or without insulin prior to initiating SGLT-2 inhibitor therapy, unless there is a documented contraindication.</p> <p>Vote: 15 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>
<p><b>8. Sulfasalazine Derivatives</b> <span style="float: right;">Audio cast start time 3:55:48</span></p> <p><b>Preferred:</b> Apriso, Lialda, Pentasa, sulfasalazine DR/EC, sulfasalazine IR</p> <p><b>Non-Preferred:</b> Asacol HD, Azulfidine, Azulfidine Entabs, Balsalazide, Colazal, Delzicol, Dipentum, mesalamine DR (generic for Delzicol), mesalamine DR (generic for Lialda), mesalamine ER (generic for Apriso), mesalamine DR</p> <p>Vote: 15 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>
<p><b>9. Immunosuppressives, Oral</b> <span style="float: right;">Audio cast start time 3:55:26</span></p> <p><b>Preferred:</b> azathioprine, Cellcept (susp), cyclosporine (softgel, cap), cyclosporine modified (cap,solu), mycophenolate mofetil (caps, tab), Rapamune solu, sirolimus (tab), tacrolimus</p> <p><b>Non-Preferred:</b> Astagraf XL, Azasan, Cellcept (cap, tab), Envarsus XR, Imuran, mycophenolic acid*, mycophenolate mofetil (susp), Myfortic, Neoral, Prograf, Rapamune (tab), Sandimmune (solu, cap*), sirolimus (solu), Zortress</p> <p>*Prior authorization will not be required for patients stabilized on a non-preferred drug</p> <p>Vote: 15 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>

<p><b>10. Phosphate Binders/Regulators</b> <span style="float: right;">Audio cast start time 3:57:27</span></p> <p><b>Preferred:</b> calcium acetate, sevelamer carbonate (tab)</p> <p><b>Non-Preferred:</b> Auryxia, lanthanum carbonate, Fosrenol (chew tab, pwd), Phoslyra, Renagel, Renvela, sevelamer carbonate pwd (generic for Renvela), sevelamer HCL (generic for Renagel), Velphoro</p> <p>Vote: 15 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>
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## H. DUR Board Drug Cap Recommendations

Based on the clinical and financial information, the DUR Board recommended the following to the Commissioner of Health for final determination:

Recommendations of the DUR Board	Commissioner's Final Determination
<p><b>Drug Cap Review of Spinraza (nusinersen)</b> <span style="float: right;">Audio cast start time 3:59:35</span></p> <p>The supplemental rebate target amount is the value resulting in a unit price equal to \$25,667 (net of all rebates).</p> <p>Vote: 15 yes, 0 no, 0 abstentions <span style="float: right;">Passed</span></p>	<p>Approved as Recommended</p>

## I. Final Comments and Adjournment

Audio cast start time 4:12:00

Douglas Fish, MD  
Janet Zachary-Elkind, BA  
Anthony Merola, RPh, MBA

Contact for post meeting questions: [DUR@health.ny.gov](mailto:DUR@health.ny.gov) or 518-486-3209

**Meeting adjourned at 3:50 PM**

## J. Commissioner Final Determinations

The impact of the final determinations on the PDP is as follows:

State Public Health Population:

- Minimal effect on Medicaid beneficiaries, as a large majority of beneficiaries currently utilize preferred products. Non-preferred products remain available with prior authorization.

Program Providers:

- No impact on prescribers when utilizing preferred products. Prescribers, or their agents, will need to initiate the prior authorization process when ordering non-preferred products.

State Health Program:

- Annual gross savings associated with the PDP therapeutic class reviewed (and preferred or non-preferred status modifications) are estimated at \$4.4M. The savings would be achieved through utilization changes and the receipt of supplemental rebates from pharmaceutical manufacturers.