IMPLEMENTATION OF SERVICE DELIVERY AND PAYMENT

Dr. Christopher Jones, Assistant Secretary for Planning and Evaluation
Ms. Catherine Underwood, American Pain Society
Examining Insurance Coverage for Acute and Chronic Back Pain Treatment – A Pilot Study

Christopher M. Jones, PharmD, MPH
Acting Associate Deputy Assistant Secretary (Science and Data Policy)
Office of the Assistant Secretary for Planning and Evaluation
Impetus for Study

- CDC opioid prescribing guidelines, other national and state guidelines, and the National Pain Strategy call for clinicians to use the full complement of pain treatments.
- If treatments are not covered or if the extent of coverage is less generous or more burdensome to obtain, they will be under-utilized.
- Little is known about current coverage parameters for many types of pain treatments.
- Having this information can be used to frame and target policy interventions among public and private payers that are necessary to promote the use of non-opioid alternatives to treat acute and chronic pain.
Study Team

• Johns Hopkins University Bloomberg School of Public Health
  – Caleb Alexander, Irene Murimi, Dora Lin, Jonothan Tierce
• ASPE (Chris Jones)
• CDC (Grant Baldwin – Injury Center)
• NIH (Wilson Compton, Dave Thomas – NIDA and Linda Porter – NINDS)
• CMS (John Coster – CMCS)
• ~12 week project in summer of 2016
Pilot Study Design and Goals

- Focus on treatments for acute and chronic back pain
- Develop a methodology to examine benefit coverage documents (benefit plan summaries, pharmacy formularies, conversations with plan administrators)
  - Large state Medicaid plan (Medi-Cal)
  - Large private insurer (Anthem)
  - Large pharmacy benefit manager (CVS Caremark)
- Determine how coverage differs for non-opioid pharmacological and non-pharmacological treatments compared to opioids
- Determine feasibility of conducting a national-level assessment based on pilot study
# Pharmacological Interventions

## Opioids
- Buprenorphine (for pain)
- Codeine (single entity & combo)
- Dihydrocodeine (combo)
- Fentanyl, transdermal
- Hydrocodone (single entity ER, combo IR)
- Hydromorphone (IR & ER)
- Meperidine
- Methadone (for pain)
- Morphine (IR & ER)
- Oxycodone (single entity IR, ER, combo IR)
- Oxymorphone (IR & ER)
- Pentazocine
- Tramadol (single entity IR, ER, combo IR)
- Tapentadol (IR & ER)

## Other Medications used for Back Pain

### NSAIDS
- Diclofenac, ibuprofen, naproxen, meloxicam, piroxicam, celecoxib

### Skeletal muscle relaxants
- Carisoprodol, metaxalone, cyclobenzaprine, methocarbamol

### Topical analgesics
- Capsaicin, diclofenac, lidocaine

### Anticonvulsants
- Gabapentin, pregabalin

### Antidepressants
- SNRIs & TCAs
## Medication Coverage

**n=64**

<table>
<thead>
<tr>
<th></th>
<th>Covered by all organizations (n=18 molecules)</th>
<th>Not covered by any organizations (n=8 molecules)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Opioids</strong></td>
<td>Codeine-acetaminophen</td>
<td>Hydrocodone (ER)</td>
</tr>
<tr>
<td></td>
<td>Fentanyl patches</td>
<td>Hydrocodone-aspirin</td>
</tr>
<tr>
<td></td>
<td>Hydrocodone-APAP</td>
<td>Meperidine</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oxycodone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oxycodone-APAP</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tramadol</td>
<td></td>
</tr>
<tr>
<td><strong>NSAIDs</strong></td>
<td>Diclofenac sodium DR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ibuprofen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Naproxen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Meloxicam</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Piroxicam</td>
<td></td>
</tr>
<tr>
<td><strong>Antidepressants</strong></td>
<td>Duloxetine DR</td>
<td>Levomilnacipran ER</td>
</tr>
<tr>
<td></td>
<td>Venlafaxine ER</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Amitriptyline</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Desipramine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Imipramine</td>
<td></td>
</tr>
<tr>
<td><strong>Anticonvulsants</strong></td>
<td>Gabapentin</td>
<td>Gabapentin enacarbil</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pregabalin</td>
</tr>
<tr>
<td><strong>Topical Analgesics</strong></td>
<td></td>
<td>Capsaicin</td>
</tr>
<tr>
<td><strong>Skeletal Muscle Relaxants</strong></td>
<td></td>
<td>Cyclobenzaprine ER</td>
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</table>
# Medication Coverage

**n=64**

<table>
<thead>
<tr>
<th>Number (%)</th>
<th>Medi-Cal</th>
<th>Anthem</th>
<th>CVS Caremark</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Opioids</strong></td>
<td>10/33 (30%)</td>
<td>28/33 (85%)</td>
<td>10/33 (30%)</td>
</tr>
<tr>
<td><strong>Non-opioids</strong></td>
<td>13/30 (43%)</td>
<td>24/30 (80%)</td>
<td>20/30 (67%)</td>
</tr>
<tr>
<td><strong>NSAIDs</strong></td>
<td>6/10 (60%)</td>
<td>10/10 (100%)</td>
<td>8/10 (80%)</td>
</tr>
<tr>
<td><strong>Antidepressants</strong></td>
<td>6/9 (66%)</td>
<td>7/9 (78%)</td>
<td>7/9 (78%)</td>
</tr>
<tr>
<td><strong>Anticonvulsants</strong></td>
<td>1/3 (33%)</td>
<td>1/3 (33%)</td>
<td>1/3 (33%)</td>
</tr>
<tr>
<td><strong>Topical Analgesics</strong></td>
<td>0/3 (0%)</td>
<td>2/3 (67%)</td>
<td>2/3 (67%)</td>
</tr>
<tr>
<td><strong>Skeletal Muscle Relaxants</strong></td>
<td>0/5 (0%)</td>
<td>4/5 (80%)</td>
<td>2/5 (40%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>23/63 (37%)</td>
<td>52/63 (83%)</td>
<td>30/63 (48%)</td>
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</table>
## Medication Coverage

n=64

<table>
<thead>
<tr>
<th></th>
<th>Medi-Cal</th>
<th></th>
<th></th>
<th>CVS Caremark</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Opioids</td>
<td>Non-opioids</td>
<td>Opioids</td>
<td>Opioids</td>
</tr>
<tr>
<td><strong>Covered products, N</strong></td>
<td>10</td>
<td>13</td>
<td>28</td>
<td>10</td>
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<tr>
<td><strong>Drug utilization management, %</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior Authorization</td>
<td>0</td>
<td>31%</td>
<td>4%</td>
<td>4%</td>
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<tr>
<td>Step Therapy</td>
<td>0</td>
<td>8%</td>
<td>4%</td>
<td>9%</td>
</tr>
<tr>
<td>Quantity Limits</td>
<td>100%</td>
<td>0</td>
<td>64%</td>
<td>25%</td>
</tr>
<tr>
<td>Duration Limits</td>
<td>10%</td>
<td>0</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dose Optimization</td>
<td>---</td>
<td>---</td>
<td>0</td>
<td>9%</td>
</tr>
</tbody>
</table>
Non-Pharmacological Interventions

- Physical therapy
- Occupational therapy
- Acupuncture
- Chiropractic care
- Biofeedback
- Cognitive behavioral therapy
- Yoga
- Transcranial magnetic stimulation
- Transcutaneous electrical nerve stimulation (TENS)
- Electrical Stimulation with other surface and percutaneous devices
- Steroid injections
- Nerve block injections
- Trigger point injections
- Facet injections
- Spinal neurostimulation
- Lumbar Fusion / Lumbar Total Disc Arthroplasty (TDA)
## Non-pharmacological Interventions

**Medi-Cal**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Therapy</td>
<td>Yes</td>
<td>Physician Dentist</td>
<td>Approved Physical Therapist</td>
<td>No</td>
<td>Duration, Quantity</td>
<td>Prescriptions limited to 6 months; PA granted for max. 30 treatments</td>
</tr>
<tr>
<td>Occupational therapy</td>
<td>No**</td>
<td>Physician Dentist</td>
<td>Medi-Cal Provider</td>
<td>No</td>
<td>Quantity</td>
<td>2 visits per month</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>No</td>
<td>N/A</td>
<td>Physician Dentist</td>
<td>No</td>
<td>Quantity</td>
<td>2 visits per month</td>
</tr>
<tr>
<td>Chiropractic care</td>
<td>Not available</td>
<td>Not available</td>
<td>No</td>
<td>No</td>
<td>Quantity</td>
<td>2 visits per month</td>
</tr>
<tr>
<td>Spinal Neurostimulation</td>
<td>Yes</td>
<td>Yes</td>
<td>Multidisciplinary team evaluation</td>
<td>Must have failed all others</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
</tbody>
</table>

**Not covered:** Biofeedback, transcranial magnetic stimulation, trigger point injections, cognitive behavioral therapy, yoga, and transcutaneous electrical nerve stimulation (TENS)
# Non-Pharmacological Interventions

## Anthem

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Medical Necessity Requirement</th>
<th>Conservative Therapy Fail First</th>
<th>Authorization Required?</th>
<th>Coverage Limits (Per Year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Therapy</td>
<td>Yes</td>
<td>None</td>
<td>Yes</td>
<td>30 visits combined in home, office or outpatient facility**</td>
</tr>
<tr>
<td>Occupational therapy</td>
<td>Yes</td>
<td>None</td>
<td>Yes</td>
<td>30 visits combined in home, office or outpatient facility**</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>Yes</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Chiropractic care</td>
<td>Yes</td>
<td>---</td>
<td>Yes, after 5th visit</td>
<td>None</td>
</tr>
<tr>
<td>Transcutaneous electrical nerve stimulation (TENS)</td>
<td>Yes</td>
<td>None</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Steroid Injections</td>
<td>Yes</td>
<td>6 weeks</td>
<td>---</td>
<td>4 per spinal region (cervical or lumbar), &gt;1 week between injections</td>
</tr>
<tr>
<td>Trigger Point Injections</td>
<td>Yes</td>
<td>Yes</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Facet Injections</td>
<td>Yes</td>
<td>3 months</td>
<td>---</td>
<td>4 per spinal region, 2 months between injections</td>
</tr>
<tr>
<td>Spinal Neurostimulation</td>
<td>Yes</td>
<td>6 months</td>
<td>---</td>
<td>None</td>
</tr>
<tr>
<td>Lumbar Fusion, Lumbar Total Disc Arthroplasty (TDA)</td>
<td>Yes</td>
<td>6 months</td>
<td>---</td>
<td>None</td>
</tr>
<tr>
<td>Peripheral Nerve Block Injections</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Electrical Stimulation Devices***</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Not covered:** Biofeedback, Transcranial magnetic stimulation, Cognitive behavioral therapy, and yoga
Limitations/Conclusions

- Small sample size
- Generalizability
- Publically available benefit design documents don’t provide as much detail as we would like, particularly around co-pays and co-insurance
- Limited in our ability to conduct key informant interviews during our short pilot study period

- Variation in coverage parameters across the programs evaluated
- Some non-pharm interventions with potential utility for back pain such as CBT & biofeedback were not covered
- Certain policies for non-pharmacological therapies such as determinations of medical necessity could be barriers to using these treatments
Next Steps
HHS Opioid Strategy

Strengthening public health surveillance

Supporting cutting-edge research

Targeting availability and distribution of overdose-reversing drugs

Advancing the practice of pain management

Improving access to treatment and recovery services

Supporting cutting-edge research
Next Steps

- National-level study kicking off this week
  - Johns Hopkins, ASPE, NIH, CDC
- Projected final report fall 2017
- Coupled with the AHRQ systematic review on nonpharmacological treatments for pain and other activities within the department, we will be well positioned to drive policy change
THANK YOU

QUESTIONS?

CHRISTOPHER.JONES@HHS.GOV
APS – Pfizer
Independent Grants for Learning & Change
Implementing the National Pain Strategy
Catherine Underwood – Chief Executive Director
### Implementing the National Pain Strategy

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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</thead>
<tbody>
<tr>
<td>5/15</td>
<td>Pfizer approached APS leadership about research partnership opportunity</td>
</tr>
<tr>
<td>9/15</td>
<td>APS appointed a panel to author an RFP and to serve as a grant review group</td>
</tr>
<tr>
<td>12/15</td>
<td>APS and Pfizer signed LOA</td>
</tr>
<tr>
<td>1/16</td>
<td>Work began</td>
</tr>
<tr>
<td>3/16</td>
<td>National Pain Strategy Officially Released</td>
</tr>
</tbody>
</table>

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**American Pain Society**

**Research**

**Education**

**Treatment**

**Advocacy**
APS - Pfizer Grant Steering Committee Roster

- David Williams PhD - Chair
  University of Michigan

- Robert Gereau PhD
  Washington University School of Medicine

- Keela Herr FAAN PhD RN
  University of Iowa

- Robert Kerns PhD
  VA Connecticut Healthcare System

- Mark Sullivan MD PhD
  University of Washington
Implementing the National Pain Strategy in an Era of Accountable Care: Improving Chronic Pain Care in America

Release Date: April 13, 2016
Plan of Work

- Request for Letters of Intent
- RFP to Eligible Projects
- Recommendation for Funding
Three Proposals Selected

• All Non-pharmacological projects
• Span youth to geriatric persons with chronic pain
• Each 2 years in length
Web-based Self-management of Adolescent Chronic Pain: National Implementation Project

PI: Tonya Palermo, PhD
Seattle Children’s Hospital

Expected Outcome:
A strategy to successfully disseminate a mobile pain self-management intervention to adolescents with chronic pain that can be sustained in real-world clinic settings.
National Pain Strategy
Recommendations Addressed

Objective 2: Prevention and Care
- To develop nationwide pain self-management programs

Objective 4: Disparities
- To improve access to high-quality pain services for vulnerable populations
How it will be Accomplished

• Create an app of WebMAP™ (to be publicly available for iPhone and Android)
• Test the strategy
  – clinical trial in 8 specialty care pediatric clinic sites (GI, Neurology or Pain)
• Learn how to sustain the intervention in clinic settings
The Vision

“Ultimately we hope to improve access to evidence-based pain self-management for all youth with chronic pain”
Development of an Electronic Prescription Bundle of non-Pharmacological Strategies for Chronic Musculoskeletal Pain

PI: Kathleen Sluka, PT, PhD, FAPTA
   Barbara Rakel RN, PhD, FAAN

University of Iowa – Colleges of Medicine & Nursing

Expected Outcome:
– Improved use of non-pharmacological treatment for adults with chronic musculoskeletal pain
– Leverage strengths of the EHR to assist primary care providers in use of non-pharmacological treatment
– Facilitate multimodal, interdisciplinary care in an integrated health system
Objective 1: Service Delivery & Payment

- To…develop strategies to address the existence of more effective models, and the steps that can be taken toward achieving high quality care and outcomes.

**Overall goal:** develop, implement, evaluate and disseminate the integration of two non-pharmacological pain treatments in primary care
How it will be Accomplished

• Develop and refine an electronic prescription bundle for Exercise and TENS
  – To be used by primary care providers
  – Care for adults with chronic musculoskeletal pain
  – First time application for EPIC

• Trial in three outpatient clinics UIHC
  – family medicine and general internal medicine
  – 48 prescribers

• Evaluate the effect on prescription frequency of non-pharmacological and pharmacological treatments
A Personalized Self-Management Program for Older Adults with Chronic Pain & Negative Emotions

**PI:** M. Cary Reid MD, PhD
Dimitris Kiosses PhD
Weill Cornell Medicine (WCM) at the NY Presbyterian Hospital
Wright Center on Aging

**Expected Outcomes:**
- Test efficacy of *Problem Adaptation Therapy for Pain* (PATH-Pain) vs Usual Care & Evaluation (UCE)
- Focus on older adults (60+) with chronic pain, negative emotions, and wide range of cognitive functioning (including mild to moderate cognitive impairment)
- Reduce pain intensity and pain related disability
Objective 2: Prevention and Care
- Providing patients and their caregivers with an approach to gain the requisite skills, education & resources to play an active role in managing their pain

Objective 1: Service Delivery & Payment
- Conduct rigorous evaluations of models through independent evaluators, ...especially those using... the biopsychosocial model, team-based care, pain self-management approaches
How it will be Accomplished

• Implement manualized 8-week emotion-regulation self-management for primary care patients
• Teach patients and caregivers strategies to reduce negative emotions and increase positive emotions
• Include group educational and individual sessions
• Manualized treatment delivered in primary care
• Control condition: Usual Care and Evaluation, including “Take Charge of Your Pain” educational manual
• “Train the trainer (therapist)” manual
• Goal: reduce pain intensity and pain-related disability
Next Steps

5-17
• Convene a meeting of successful grantees to coordinate efforts

Ongoing
• Oversee progress reports

2019
• Present outcomes at the 2019 APS Annual Scientific Meeting

NOW
• Begin conversation about future grant partnership