Select HCPF Medication Use Policy Updates

Hepatitis C Virus Treatments → Effective January 1st, 2018
- Mavyret and Epclusa will be preferred products
- There will be no disease severity limitations (no F2 fibrosis score minimum)
- Treatment-experienced members will be considered for therapy on a case-by-case basis

Narcan Nasal Spray → Effective December 1st, 2017
- Narcan nasal spray no longer requires prior authorization

Opioid Morphine Milligram Equivalent (MME) Policy → Effective October 1st, 2017
- The maximum allowable opioid dose is 250 MME
- The prescription that pushes the member’s opioid dose count over this amount will require prior authorization and potentially a provider-provider telephone consult
- The MME will decrease slowly and incrementally with the goal of ultimately being at the standard of care (currently 120 MME)
- All MME calculations use the conversion factors found at http://www.agencymeddirectories.wa.gov/calculator/dosecalculator.htm

What is DUR and what does it do?

The University of Colorado Evidence-Based Drug Utilization Review (CO-DUR) Program is contracted by the Department of Health Care Policy and Financing (HCPF) to meet, but not be limited to, the Federal and State requirements related to DUR. The following are a few of the activities of CO-DUR:
- Facilitate and support a DUR Board that meets publicly to discuss medication use criteria/policy recommendations made to HCPF, who makes a final decision on policy development and implementation
- Retrospective DUR → the DUR Board decides criteria to conduct provider outreach in the form of letters sent to providers
- In collaboration with HCPF, conduct policy-relevant analyses using Medicaid claims data, and use the findings to make policy recommendations
- Conduct analyses of policy impact before and after implementation
- The CO-DUR Team members of University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) faculty.
  - Brandon Utter, PharmD, BCPP, BCPS
  - Robert Lee Page II, PharmD, MSPH, BCPS, CGP
  - Gina Moore, PharmD, MBA
  - Garth Wright, MPH
  - Jon Campbell, PhD
General CO-DUR Update

- The DUR Board has open positions for physicians and pharmacists, please email SSPPS.CO-DUR@ucdenver.edu or visit our DUR Webpage.
- Our August and November DUR Board Meetings were very successful at providing high quality and evidence-based medication use recommendations to HCPF!
- In addition to the preferred drug list (PDL) classes discussed (left sidebar page 1), the following medications/topics were also reviewed:
  - Short-acting beta agonist quantity limits
  - Strensiq (asfotase alpha)
  - Myalept (metreleptin)
  - Egrifta (tesamorelin acetate)
  - Northera (droxidopa)
  - Daraprim (pyrimethamine)
  - Austedo (deutetrabenazine)
- Criteria has been approved through HCPF and is posted on their website within the PDL and Appendix P documents:
  - https://www.colorado.gov/hcpf/pharmacy-resources
  - The latest criteria will be effective on January 1st, 2018
- The next DUR Board meeting will be held at University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences on February 13th, 2018 and will cover the topics listed in the right sidebar on page 1.

Short-Acting Beta Agonist Utilization in the Colorado Medicaid Population

The CO-DUR team recently conducted an analysis investigating short-acting beta agonist (SABA) use by Medicaid recipients in Colorado. There were three aims of this analysis:

1) Describe the number and percentage of members aged 0-64 that have persistent asthma over each year within the five year period of 2011-2015
2) Of those with persistent asthma, estimate use and overuse of SABAs using asthma medication use measures. Further, describe the annual rate of asthma exacerbations within the persistent asthma population.
3) Test for associations of asthma medication use measures with asthma exacerbations

Aim 1: Persistent Asthma (Table 1)

- Methods:
  - Beneficiary is of age ≤ 64 by January 1st of each measurement year
  - HEDIS definition 2016 of persistent Asthmatics used
  - Member must have continuous Medicaid enrollment for 2 years (measurement year and year prior)

<table>
<thead>
<tr>
<th>MEMBER AGE RANGES</th>
<th>% PERSISTENT ASTHMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 4</td>
<td>0.00%</td>
</tr>
<tr>
<td>5 - 11</td>
<td>0.50%</td>
</tr>
<tr>
<td>12 - 18</td>
<td>1.00%</td>
</tr>
<tr>
<td>19 - 50</td>
<td>1.50%</td>
</tr>
<tr>
<td>51 - 64</td>
<td>2.00%</td>
</tr>
<tr>
<td>Total</td>
<td>2.50%</td>
</tr>
</tbody>
</table>

TABLE 1: % PERSISTENT ASTHMA
AIM 2: SABA use/Overuse and Exacerbations (Tables 2 and 3)

Measures of SABA use were investigated to further characterize use/overuse, including:

- Members with ≥ 6 canisters dispensed during calendar year
- Members with ≥ 12 canisters dispensed during calendar year
- Members with ≥ 18 canisters dispensed during calendar year
- Members with > 2 canisters dispensed during a 30 day period (current HCPF policy)

Table 2 depicts the averaged values resulting from years 2011-2015 of SABA use/overuse in the persistent asthma cohort

Table 3 displays the percentage of the persistent asthma cohort that experienced an episode of asthma exacerbation over the years measured

AIM 3: Associations between SABA Overuse and Asthma Exacerbation (Tables 4-7)

A negative binomial regression was conducted for each of the measures of use/overuse to determine if meeting the measure criteria correlated with an increase in asthma exacerbations. Available in Tables 4-8 (Pages 3-5).

Table 4: (Page 4) Filling > 6 SABA Canisters Per Year and Correlation with Asthma Exacerbation Incidents

- Members who filled more than six SABA canisters in a year were investigated for a correlational relationship to asthma exacerbation incidents using a negative binomial regression
- All years studied showed a significant relationship between filling > 6 SABA canisters and annualized asthma exacerbations

Table 5: Filling > 12 SABA Canisters Per Year and Correlation with Asthma Exacerbation Incidents

- All years studied show a statistically significant association between filling >12 canisters and annualized asthma exacerbations

Table 6: Filling > 18 SABA Canisters Per Year and Correlation with Asthma Exacerbation Incidents

- All years except 2013 show a statistically significant association between filling >18 canisters and annualized asthma exacerbations
**Table 7: (page 5): Filling > 2 SABA Canisters in a 30 day period and Correlation with Asthma Exacerbations**

- This is currently the maximum quantity limit set by HCPF per the PDL
- All years studied demonstrate a statistically significant association between filling > 2 SABA canisters in a 30 day period and annualized asthma exacerbations

**Discussion/Conclusion:**
We observed that during the period of 2011 through 2015, the number of members continuously enrolled in Medicaid increased. Within this group of continuously enrolled members, the rate of persistent asthma also increased, but at a lesser rate than the whole enrolled population. This observation is consistent with the expansion population including more male adults who have a lower than average prevalence of asthma. A similar proportion of persistent asthma members using SABA across all years (~25%) had filled six or more prescriptions for SABA canisters suggesting potential overuse of SABA. Asthma exacerbations are arguably the most useful measure of a deleterious outcome within a claims database for this chronic disease. The two most compelling associations we were able to detect with the measures of overuse that we explored were SABA overuse, defined as six or more, 12 or more, and 18 or more canisters during the year, and the Colorado Medicaid PDL policy of >2 canisters of inhalers during any 30 day period. SABA overuse no matter the canister cutoff value (6, 12, or 18 or more canisters in one year) was associated with an increase of approximately 28-94% in the rate of annualized exacerbation events while not adhering to the Colorado Medicaid PDL policy (that occurred in only 2.55% of persistent asthma members) was associated with an increase of approximately 50-60% in the rate of annualized exacerbation events.
New Drug in Focus: Mavyret®

Mavyret® is a new (August 3, 2017) combination (glecaprevir / pibrentasvir) anti-retroviral therapy used to treat genotypes (GT) 1-6 of chronic Hepatitis C without cirrhosis or with compensated cirrhosis. Effective January 1st, 2018 it will become one of the preferred agents requiring prior authorization.

- Glecaprevir is an inhibitor of hepatitis C virus (HCV) NS3/4A protease, necessary for the proteolytic cleavage of the HCV-encoded polyprotein and is essential for viral replication.
- Pibrentasvir is an inhibitor of HCV NS5A, essential component for viral replication and virion assembly.
- Comes in tablet form containing glecaprevir 100mg/pibrentasvir 40mg → Dosing is 3 tablets taken once daily with food
- Duration of therapy depends on presence of cirrhosis:
  - If member non-cirrhotic and treatment naive → 8 weeks
  - If compensated cirrhosis is present and member is treatment naive → 12 weeks
  - Mavyret® is not recommended for use in patients with decompensated cirrhosis
- Please see PDL effective January 1, 2018, for updated Medicaid use criteria
- Preferred treatments with FDA-approved durations of therapy (from PDL):

<table>
<thead>
<tr>
<th>Preferred HCV Agent Treatment Regimens For Adults ≥18 years</th>
<th>GT 1-6 NC</th>
<th>GT 1-6 CC</th>
<th>GT 1-6 DC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mavyret</td>
<td>8 weeks</td>
<td>12 weeks</td>
<td>Not Approved</td>
</tr>
<tr>
<td>Epclusa</td>
<td>12 weeks</td>
<td>12 weeks</td>
<td>12 weeks + ribavirin</td>
</tr>
</tbody>
</table>

(GT-Genotype, NC-Non-Cirrhotic, CC-Compensated Cirrhosis, DC-Decompensated Cirrhosis)

*Jeffrey Taylor, Pharm.D. 2017

We are pleased to welcome Jeff Taylor as the new DUR pharmacist for Health First Colorado. Jeff worked previously for Safeway in the retail pharmacy arena where he had been proudly providing pharmacy care services to Denver area communities for the past 4 years. Jeff completed his Bachelor of Science in Biology at the University of Alabama at Birmingham (2007) and his Doctor of Pharmacy degree at Auburn University (2011). He has also enjoyed working with pharmacy students as a preceptor for the University of Colorado Skaggs School of Pharmacy Experiential Program over the past year. He is enthusiastic about being part in the DUR process and hopes to provide a unique perspective from his experience in the retail pharmacy setting.

Outside of work, Jeff, like many Coloradans, enjoys taking in the outdoor beauty of this great state, whether that means skiing, hiking, or spending a relaxing afternoon at the Denver Botanic Gardens. Being a true Southerner, he also looks forward to Saturdays during football season when he can join local Auburn fans at the alumni bar in Denver to cheer on his favorite team. War Eagle!
Expert Opinion: Nucynta® (tapentadol)

In response to the new Medicaid policy on opioids in the naive:
Position article on tapentadol, an underutilized and misunderstood opioid
Alex Reish, DO

In general opioids should be avoided if possible, but if there is clinical indication for an opioid in the acute (or chronic) pain setting, it is important to understand differing mechanisms of actions and why some opioids are not advantageous and have higher associated risks than others. I would argue that tapentadol (Nucynta®) offers perhaps a better choice than other full agonist mu opioids in the current environment of opioid minimization and avoiding adverse risk and reactions. With the new Medicaid policy of prescribing opioids in the naive, please strongly consider tapentadol as a superior and first line option compared to all other Schedule II opioids.

Tapentadol is unique having a dual action mu agonist opioid and norepinephrine receptor uptake inhibitor (NRI). This dual action combines synergistic actions in the ascending and descending pain pathways. It comes in short IR and long acting ER forms and is the only opioid with a neuropathic indication in the long acting form. Mechanisms of action are critical to understand, not all opioids are alike. In general, opioids that have strong binding to the mu opioid receptor are more potent and often have higher risk and adverse reactions than those that are weak binders. Our own endogenous opioids are thought of as weak binders. We now better understand that locking up the mu opioid receptor with a strong binding opioid can have multiple negative consequences. Tapentadol is a weak binder and is 18 times less potent than morphine in binding to the mu opioid receptor. Tramadol, which was a good idea utilizing a weak binding mu opioid and SNRI is often thought of as pretty weak clinically and not effective compared to other opioids, but could be offered first line as well for some. In contrast, tapentadol based on the initial studies, demonstrated non-inferiority to oxycodone, which is thought of as a potent opioid and familiar to providers.

Serious adverse reactions are clinically less in tapentadol compared to other more potent opioids. It has reduced GI side effects of nausea/vomiting and constipation, which is important especially in seniors or post-operative patients. There is less than 1% euphoria reported in clinical studies, which likely represents its low street value and abuse compared to other Schedule II opioids. There is a maximum dose in both the short acting and long acting forms, limiting unnecessary escalation. On abrupt discontinuation there is little to no withdrawal, in the majority of patients. Furthermore, weak binding opioids and mixed agonist/antagonist opioids tend to have less respiratory depression than strong full agonist opioids.

In clinical application, tapentadol IR, 50mg, 75mg, 100mg was equal or non-inferior to 5mg, 10mg, 15mg of oxycodone respectively. Standard conversions show 100mg = 40mg of morphine, although it is likely less of an opioid load when remembering the weak binding affinity. There is currently no prior authorization** required for Medicaid. Only a quantity of 4 per day is allowed and should be started at 50mg BID - QID in the opioid naive and titrated if necessary. Always remember to consider risk factors before prescribing and follow up in less than 1 week for tolerability and side effects. Please read the full prescribing information before initiating. I do not have any disclosures nor speak for tapentadol, but have strong clinical experience utilizing it in my practice. Again, avoid opioids if possible, but if indicated, I hope you will become more familiar with tapentadol and think of it before choosing other Schedule II opioids when prescribing to the opioid naive in the future.

Respectfully,
Alex Reish DO, AOBNMM, AOBFP

**PDL Notes on Nucynta:

- **Nucynta ER (tapentadol)** requires a prior authorization and is listed on the PDL, one preferred long-acting opioid trial is required prior
- **Nucynta IR (tapentadol)** does not currently require a prior authorization for use, this status is subject to change in the future as medication use and use criteria are continually evaluated by HCPF

The views and opinions expressed in this position article are those of the author only. Any references to specific products are not endorsements, recommendations, or promotions by the Colorado Department of Health Care Policy & Financing.
DUR Telephone Consult Service

- DUR provides as needed telephone consults with physicians in two different specialties:
  - Child and Adolescent Psychiatry
  - Pain Management
- If you have patients in these fields who are Medicaid members and for whom you would like a consult, if you are an enrolled Medicaid provider, you are qualified to use this service. You may request a consult when speaking with Magellan (Phone (800)-424-5725) or by emailing SSPPS.co-dur@ucdenver.edu
- A consult can also be triggered if a member meets criteria established by HCPF. In this situation, a medication that is being prescribed for the member will require prior authorization and Magellan will gather information that our consultants need to contact the provider to conduct the consult.

New Letters Coming Soon

- The CO-DUR team is currently developing letters that will compare prescribing metrics of a provider to that of their peers in the state of Colorado
- The goal for initial beta-test of these letters in the first quarter of 2018
- The letters will be heavy on graphics and contain provider-specific data
- Please feel free to provide feedback regarding the content and layout, contact information will be distributed with the letters
- Minnesota and Washington have also utilized this method

Questions/Comments/Feedback

- Please email SSPPS.co-dur@ucdenver.edu
  - If you would like more information about the DUR team or board activities
  - If you have comments on this newsletter or its content

References

1) National Quality Measures, C. Medication management for people with asthma: percentage of members 5 to 85 years of age during the measurement year who were identified as having persistent asthma and who were dispensed an asthma controller medication that they remained on for at least 75% of their treatment period. (2015).
2) Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago, IL: AbbVie Inc; August 2017.