MEETING SUMMARY OF APPROVED RECOMMENDATIONS

Recommendations made and approved at the March 2, 2018 DCF PMAC meeting.
Your comments, suggestions, etc. are WELCOME.

DRUG CLASS REVIEW: Stimulants

- A change in the format of the protocol was recommended and approved to detail out each drug formulation along with max dose for that formulation.
- A new branded preparation was added to the protocol: Cotempla XR-ODT.
- A recommendation was made to revisit the literature for guidance on total maximum dosage for stimulants in combination preparations (for example, Adderall XR + IR) as these requests are received commonly.

Consideration for addition to the approved drug list: **Modafinil**

- Efficacy was noted for ADHD in children (*cite study?)*. However, there are no FDA approvals for children/adolescents due to an adverse drug reaction – skin rash – that may be very severe.
- It was noted that CMCU has seen no requests for this medication.
- A recommendation not to add modafinil to the approved drug list was made and approved.

OTHER

- Sublocade Injection review (informational only): Noted that registered providers order, receive, and administer this medication; it is available through specialty pharmacies only.
  Cost is about $1,600/month.
  Patients must be over 18yrs of age.
  No action recommended.

- Molindone: Still not currently available. There is an older study (*cite study, TEOSS??)* that showed comparable efficacy in children to olanzapine and risperidone, with less weight gain but more akathisia.
  There is a company (Supernus Pharmaceuticals) that has a phase III study and an extension study currently in process for an XR molindone formulation (SPN810). This will continue to be monitored and new information reported to PMAC as it becomes available.

DCF Psychotropic Medication Advisory Committee
Meeting Minutes
March 2, 2018, 1:00 PM

Present: Amy Veivia, Pharm. D.; M.D.; David S. Aresco, Pharmacist; Paul Rao, M.D.; Carlos Gonzalez, M.D.; Carissa Patsky, M.D., Beth Muller, APRN; Allan Alton, M.D.; Angela Ojide, APRN.

1. Dr. Rao called the meeting to order at 1:09PM.

2. The date/time of the next meeting is scheduled for April 6, 2018 from 1pm – 2:30pm at Albert J. Solnit Children's Center 915 River Rd Middletown CT, A Building, Conference Rm A.

3. The minutes of the February 2017 meeting were reviewed and approved.

4. Announcements: A recommendation was made and approved to search 2014-2015 records for a PMAC survey as well as information relating to a mini-conference for pediatricians.

5. Medication Therapeutic Class Review: Stimulants
   - A change in the format of the protocol was recommended and approved to detail out each drug formulation along with max dose for that formulation.
   - A new branded preparation was added to the protocol: Cotempla XR-ODT.
   - A recommendation was made to place %CR and %IR for combination products and ingredient ratios for the mixed salts.
   - The format of maximum dosing was discussed including shifting to weight and/or age based dosing when appropriate. It was recommended to add to the Adderall dosing 3yrs old to <6yrs old 0.5mg/kg/day and >=6yrs old 30mg for Adderall XR.
   - The bioavailability of various generics for time released products was discussed extensively, as there is concern that there is a difference between brand-name and generic. A recommendation was made to put under special considerations "Switching between generic manufacturers may effect outcomes". It was recommended and approved that more research is needed regarding A-B rating especially as it relates to bi-phasic vs continuous release mechanisms. This information can then help determine the language of the special consideration.
   - A report will be presented at the next PMAC meeting detailing what medications in this class are no longer branded only.

- The issue of defining a maximum daily dosage when mixed ER and IR forms of the same compound are prescribed was discussed. There was a discussion of current practice.
- It was approved that all recommendations except the format change are to be held until the next PMAC meeting.
- The A, B rating system for generics was briefly discussed. A report including excerpts from the regulations will be presented at the next PMAC meeting.

Consideration for addition to the Approved Drug List: Modafinil.

- A medication formulary monograph was distributed, reviewed and discussed.
- Five studies/trials were discussed and it was noted that two were the most rigorous.
- Efficacy for ADHD symptoms was noted in children.
- There are no FDA approvals for children/adolescents due to an adverse drug reaction- skin rash – that may be very severe.
- It was noted that CMCU has seen no requests for this medication.
- A recommendation not to add modafinil to the approved drug list was made and approved.

6. Old Business:
   - Treating substance use disorders in children/adolescents.
     An attempt was made to cull out the names of the pediatricians from the list of prescribers approved to prescribe suboxone. The process was started but proved to be very labor intensive.
     The URL for this list was provided to the CMCU.
     Noted that CMCU is seeing no requests for Suboxone.
     A suggestion was made to contact Craig Allen at Rushford as an information source for this issue.
   - Sublocade Injection review (informational only): A fact sheet was distributed, reviewed and discussed.
     Noted that registered providers order, receive, and administer this medication; it is available through specialty pharmacies only.
     Cost is about $1,600/month.
     Patients must be over 18yrs of age.
     No action recommended.
   - Continuing education outreach to providers: New AAP guidelines for the management of depression by primary care providers were distributed, reviewed, and discussed.
     It was noted that CMCU is not getting requests from pediatricians for antidepressants.
     Noted that when requests from non-psychiatric practitioners are made, vital information is often lacking for committed children.
     The continuity of follow-up, transition of care, and availability of necessary psychosocial supports is often not clear.

It was noted that the depression rates for adolescents may have increased over the years due to more routine screening by PCPs.

7. New Business: Molindone: Still not currently available. There is an older study that showed comparable efficacy in children to olanzapine and risperidone, with less weight gain but more akathisia.
    - There is a company (Supernus Pharmaceuticals) that has a phase III study and an extension study currently in process for an XR molindone formulation (SPN810). The study involves depression in children. This will continue to be monitored and new information reported to PMAC as it becomes available.

8. Other as time allows.
   Ketamine: Protocols from ketamine “clinics” will be obtained (if possible) and presented at the next PMAC meeting.

9. Dr. Rao adjourned the meeting at 2:25PM.

Respectfully submitted by: David S. Aresco, Pharmacist