FAQ on Mental Health Drugs and Preferred Drug List (PDL)/Prior Authorization (PA)

Pharmaceutical & Therapeutics (P&T) Committee

1. **Q:** What is the summary of all the recommendations made by the P&T committee in the mental health drug area, both preferred and nonpreferred?
   A: Of the 38 drugs recommended to be moved from the RDL to the PDL:
   - 28 drugs recommended to move to Preferred status
   - 3 drugs recommended to move to Non-Preferred status: Pexeva, Metadate CD, and Ritalin LA. However, different brands of the same chemical entity are preferred drugs.
   - 7 drugs recommended to move to Non-Preferred with Conditions: Seroquel XR, Luvox CR, Risperdal M-Tab, Zyprexa Zydis, Abilify Discmelt, Pristiq, and Invega. Seroquel XR claims currently require PA and Luvox CR is being added to the Extended Release Formulation PA Criteria with Seroquel XR. The DUR Commission will develop the PA criteria for the other 5 drugs. The pharmacist may use up to a 72-hour override one time if PA cannot be immediately received.

2. **Q:** What were the 10 drugs that were recommended to become non-preferred or non-preferred with conditions*?
   A: The ten drugs are: Luvox CR*, Seroquel XR*, Risperdal M-Tab*, Zyprexa Zydis*, Abilify Discmelt*, Pristiq*, Invega*, Pexeva, Metadate CD, and Ritalin LA.

3. **Q:** Of the 10 drugs recommended to become non-preferred, which ones currently require PA?
   A: Of these ten drugs, the ones that currently require PA are Luvox CR and Seroquel XR (Extended Release Formulations criteria). Metadate CD and Ritalin LA currently require PA for members over the age of 21 (ADD/ADHD/Narcolepsy criteria). PA criteria are defined on the PA Criteria chart located at www.iowamedicaidpdl.com.

4. **Q:** What does "With Conditions" mean? That it has to have a PA?
   A: Preferred or non-preferred drug with conditions means before getting the drug a member must meet medical criteria and guidelines that coincide with current PA requirements, regardless of the drugs status on the PDL. A drug with conditions has a number in the comments column to indicate a PA is required, as defined on the first page of the Preferred Drug List (PDL). The requirements are defined in the prior authorization (PA) criteria chart at www.iowamedicaidpdl.com.

5. **Q:** What is the difference between accept PA, add PA and keep PA on some of the Non-Preferred drugs with Conditions?
   A: Accept PA - for example under Luvox CR, means PA criteria has already been recommended by the DUR but is not currently in place. Accept means along with the recommendation to make Luvox CR non-preferred, the member must meet the medical criteria and guidelines to get the drug, which will be added to and defined in the PA Criteria chart at the link above.

Add PA- for example Pristiq and Invega, means PA criteria needs to be developed by the DUR. Along with the recommendation to make Pristiq and Invega nonpreferred, the member must meet the medical criteria and guidelines to get the drug, which will be developed by the DUR and then added to and defined in the PA Criteria chart at the link above.

Keep PA- for example Seroquel XR, means PA criteria is already in place. Keep means along with the recommendation to make Seroquel XR nonpreferred, the member must meet the medical criteria and guidelines to get the drug which is defined in the PA Criteria chart at the link above.

To summarize, anywhere it says PA, whether it says accept, add, or keep, the PA Criteria Chart will provide the medical criteria and guidelines that must be met.

6. **Q:** What happens if a psychiatrist wants to prescribe a nonpreferred medication?
   A: Ten drugs will become nonpreferred, or require a prior authorization (PA). Existing users will be grandfathered. New users will require the prescriber to fill out a prior authorization form located at www.iowamedicaidpdl.com or change to a preferred drug.

Grandfathering

7. **Q:** We were told all established users on these ten medications recommended to go non-preferred would be grandfathered. Is that correct?
   A: Yes all established users will be grandfathered.

8. **Q:** What is the programming process of a "POS look back" used to allow grandfathering, and what limits are put on those prescriptions if the result is negative?
   A: Grandfathering allows members currently on a drug to remain on the drug. The pharmacy claims processing system identifies members on a particular drug by looking back in the claims system 180 days to see which members have had paid claims for the specific drug and allows the members to continue to get the same drug without restrictions. This grandfathering process remains in place for the duration of the member's eligibility.

   The change in drug status to non-preferred would only stop pharmacy claims from paying for "new users" or those members that have not had the drug previously paid by Medicaid. If the member does not have a history of the requested drug in the Medicaid paid claims system, a prior authorization would be required.

9. **Q:** If an established user was grandfathered on one of the ten medications going to non-preferred or non-preferred with conditions (Luvox CR, Seroquel XR, Risperdal M-Tab, Zyprexa Zydis, Abilify Discmelt, Pristiq, Invega, Pexeva, Metadate CD and Ritalin LA)

and the presriber switches the dose after June 15, 2009, will the drug still pay without a prior authorization?
A: Yes, a switch in dosage strength on a previously grandfathered drug will pay without a prior authorization.

Drug Utilization/Savings/Expenditures

10. **Q:** Is there data regarding the utilization of the 10 drugs recommended to become non-preferred?
    A: On www.iowamedicaidpdl.com there is a Reports tab on the left that provides Marketshare/Medicaid drug utilization information where utilization of any drug within Medicaid can be found.

11. **Q:** What would be the anticipated cost savings of the P&T recommendation?
    A: The projected State savings based on the mental health drug recommendations from the November 2008 P&T Committee meeting, applying only to new starters of newly nonpreferred mental health drugs, would be as follows:
    SFY 09 $0.043 million
    SFY 10 $0.754 million
    SFY 11 $1.237 million

12. **Q:** What percentage of the Medicaid drug budget expenditures is on mental health drugs?
    A: For SFY 08, behavioral health drugs represented 44.9% of the drug budget, or approximately $105 million out of $234 million (total dollars-state and federal).

13. **Q:** Do the costs savings in the proposed budget this year reflect the savings if all mental health drugs were included on the PDL, or just this current list of ten?
    A: The amount of savings proposed in the budget this year (SFY 10) was savings if all mental health drugs were on the PDL and were not subject to grandfathering.

Drug Utilization Review (DUR) Committee Recommendations

14. **Q:** Following review of the P&T Committee recommendations regarding 3 drugs recommended to move to Non-Preferred status: Pexeva, Metadate CD, and Ritalin LA, and 7 drugs recommended to move to Non-Preferred with Conditions: Seroquel XR, Luvox CR, Risperdal M-Tab, Zyprexa Zydis, Abilify Discmelt, Pristiq, and Invega, what changes were recommended by the DUR?
    A: The DUR made the following recommendations:
    - 1 drug is recommended to move to Non-Preferred status: Pexeva. However, different brands of the same chemical entity are preferred drugs. The pharmacist may use up to a 30-day override one time if PA can not be immediately received.
    - 9 drugs are recommended to move to Non-Preferred with Conditions: Seroquel XR, Luvox CR, Risperdal M-Tab, Zyprexa Zydis, Abilify Discmelt, Pristiq,

Invega, Metadate CD, and Ritalin LA. With conditions means before getting the drug a member must meet medical criteria and guidelines that coincide with current PA requirements. The move of Metadate CD and Ritalin LA to non-preferred with conditions is because all non-preferred ADD/ADHD/Narcolepsy drugs require a member to meet PA requirements. Seroquel XR and Luvox CR currently require PA pursuant to the Extended Release Formulation PA Criteria. Risperdal M-Tab, Zyprexa Zydis, Abilify Discmelt, Pristiq, and Invega must meet Modified Formulations PA criteria. The pharmacist may use up to a 72-hour override one time if PA can not be immediately received.

Prior Authorization (PA)

15. **Q:** Who develops the PA criteria?
    A: The Drug Utilization Review (DUR) Commission develops PA criteria and makes recommendations to the Department of Human Services (DHS), which makes the final decision. Public comments are sought as the criteria is developed and finalized.

16. **Q:** How long does it take for the PA approval or denial to be made?
    A: The pharmacist reviewer will make a decision and respond within 24 hours of the request. Federal law requires Medicaid programs that utilize prior authorization programs to respond within 24 hours of a request for prior authorization. The average determination time for a PA request is currently two to three hours.

17. **Q:** How is the PA approval or denial sent – by fax or phone?
    A: If a prior authorization request is *denied*, a letter of denial will be faxed to both the prescriber and pharmacy. A letter of denial will be mailed to the member.

    Upon *approval* of a prior authorization request, a letter of approval will be faxed to the prescriber and the pharmacy indicating the prior authorization number and dates of authorization.

18. **Q:** If the PA for the medication is denied, is a reason given other than it doesn't meet the requirement?
    A: Yes. For instance, for a non-preferred drug request, preferred alternatives or reference to the Preferred Drug List would be given. Evaluation of prior authorization requests consider published prior authorization criteria posted at www.iowamedicaidpdl.com.

19. **Q:** Can the physician talk to a staff person on the phone if the PA is denied? Would the prescriber be allowed a second request on the appropriate form to provide additional clarifying medical information that would aid in the decision-making process?
    A: The prescriber requesting the PA may call the PA Provider Help Desk (725-1106 for local or 877-776-1567) and speak with the pharmacist that reviewed the request. If the provider has additional clarifying medical information that would aid in the decision

process based on the denial received, this additional information should be faxed in on the PA form as a second request. There is no limit to the number of additional PA requests the prescriber can submit through a faxed PA form providing additional clarifying medical information.

20. **Q:** If the second request is denied, can the physician making the request speak to a board certified psychiatrist representing IME within 24 hours to discuss the clinical reasoning for the PA request?
A: The current process allows for the prescriber to speak with the pharmacist that reviewed the request. If the prescriber is not satisfied with the response, it can be referred to the IME Medical Director for further review and discussion if needed. If deemed necessary by the IME Medical Director, it will be referred to a consulting board certified psychiatrist. The IME Medical Director is responsible for facilitating a discussion between the prescriber and the consultant. The recommendation from the consultant is considered along with other factors in formulating a final decision by the IME. This is the process utilized for a request for review of coverage of all medically necessary services through the Iowa Medicaid program.

Prior Authorization Forms

21. **Q:** Where can the prior authorization forms be located?
A: The prior authorization forms are located at www.iowamedicaidpdl.com under PA Forms.

22. **Q:** When would a prescriber use the Modified Formulations PA form?
A: When prescribing Abilify Discmelt, Invega, Pristiq, Risperdal M-Tab, and Zyprexa Zydis.

23. **Q:** What drug trial would the member have to try before filling out a prior authorization request for Abilify Discmelt?
A: The member would have to have a failure on Abilify unless evidence is provided that use of the parent product would be medically contraindicated.

24. **Q:** What drug trial would the member have to try before filling out a prior authorization request for Invega?
A: The member would have to have a failure on risperidone unless evidence is provided that use of the parent product would be medically contraindicated.

25. **Q:** What drug trial would the member have to try before filling out a prior authorization request for Pristiq?
A: The member would have to have a failure on Effexor XR unless evidence is provided that use of the parent product would be medically contraindicated.

26. **Q:** What drug trial would the member have to try before filling out a prior authorization request for Risperdal M-Tab?
    A: The member would have to have a failure on risperidone unless evidence is provided that use of the parent product would be medically contraindicated.

27. **Q:** What drug trial would the member have to try before filling out a prior authorization request for Zyprexa Zydis?
    A: The member would have to have a failure on Zyprexa unless evidence is provided that use of the parent product would be medically contraindicated.

28. **Q:** When would a prescriber use the Extended Release Formulations PA form?
    A: When prescribing Luvox CR or Seroquel XR.

29. **Q.** What prior authorization form would a prescriber use for Metadate CD?
    A: The ADD/ADHD/Narcolepsy Agent PA form.

30. **Q:** What prior authorization form would a prescriber use for Ritalin LA?
    A: The ADD/ADHD/Narcolepsy Agent PA form.

31. **Q:** Which prior authorization form would a prescriber use for Pexeva?
    A: The Non-Preferred PA form.

Appeal Process

32. **Q:** If a denial is appealed, how long after receiving the letter at DHS does it take to have a hearing scheduled?
    A: This varies dependent upon the availability of an administrative law judge. Appeals, from appeal file date to decision date, typically take less than 90 days.

33. **Q:** How long after the hearing, if approved, does it take to get a response?
    A: The administrative law judge submits the decision in writing typically within 30 days.

34. **Q:** If the decision is appealed in writing, can there be a hearing by an administrative law judge providing a final decision within 60 days? In addition, can the data provided on prior authorizations requested, denied, and appealed for these medications be available after a three-month period?
    A: Appeals must be made in writing within 30 calendar days of the written notice of decision. There is an online version of the Appeal form that can be used. If you are eligible for a hearing, the DHS Appeals Section will send your appeal file to the Department of Inspections and Appeals-Division of Administrative Hearings. They will schedule a telephone hearing and send you a written notice of the date and time. Appeals, from appeal file date to decision date, typically take less than 90 days. The administrative

law judge submits the decision in writing typically within 30 days of the appeal hearing. The Department does not have control over the timeframes for hearing completion and receipt of a decision. Data contained in the prior authorizations requested, denied, and appealed are provided to all appeal participants as part of the Department's appeal summary.