Medicaid Pharmacy
Expanded Mental Health Drug (SSRI) Review Committee
January 6, 2004
Meeting Summary

I. Follow-up from December Meeting

The Medicaid Pharmacy Prior Authorization (PA) Advisory Committee met on January 6, 2004, to discuss and make recommendations about Selective Serotonin Re-uptake Inhibitor (SSRI) Drugs.

Mark Moody, Administrator of the Division of Health Care Financing (DHCF), opened the meeting by reviewing the agenda. Molly Cisco asked to have a report of the drug symposium several committee members attended last week added to the agenda. Minutes from the two earlier meetings about SSRIs were approved with no comments.

Russell Pederson, Section Chief, DHCF, presented the Department's fiscal estimate including a review of the budget and current costs for each SSRI. Handouts detailing the presentation were distributed to the committee.

Ms. Greenley asked about cost of implementing PA. Given our current system, staff recommended that addition of another drug has only negligible cost. Dr. Blackwell was concerned that there might be switching to other more expensive drugs in other therapeutic classes. Ms. Cisco asked whether we had looked at the cost to the entire Medicaid program, including increases in hospitalization, not just drugs. No such costs were included in the fiscal estimate.

Mike Mergener, Pharmacy Consultant at APS Healthcare presented the results of SSRI switching analyses. One study published in the Journal of Clinical Psychiatry in September 1999 found that there were no statistical differences in switching rates for SSRIs. That is, regardless of which product is used first, approximately 25 percent of patients switch to another agent. Wisconsin Medicaid claims over a two-year time period were reviewed to see what the switch rate in the Medicaid population was. Like the earlier study, there was no statistical difference in switching rates regardless of which agent was used first. Dr. Blackwell challenged whether the proper statistical tests had been applied.

II. Summary of Written Correspondence on SSRIs

Pris Boroniec, Associate Administrator of DHCF, presented a summary of the SSRI correspondence received by the Division. This included 25 letters and represented 65 doctors. One letter supported the proposal and the other 25 opposed. Fifteen or 16 of the letters made specific points using the same standardized language. There were also nonstandardized comments, but none cited any studies to support their positions.

III. Report on Mental Health Symposium

Molly Cisco presented a brief overview of the National Association of Mental Health and Milwaukee Drug Symposium attended by several committee members last week. Major points included savings in mental health drugs could come through looking at prescribing practices broadly as well as prescriber profiling and retrospective Drugs and Utilization Review (DUR).

Mr. Moody stated that this approach could be complementary to PA and that the focus of the symposium was on atypicals, not SSRI's. Ms. Cisco stated that since utilization review does no harm, it should be done first. Dr. Hirsch stated utilization review has been used for quite some time without much success.

IV. Discussion of PA Criteria and Additional SSRI Studies

Mike Boushon, Pharmacy Consultant, DHCF, presented draft forms (attached) relating to the PA process and criteria for SSRIs. In general, the Committee found the forms to be very helpful to provide a clear process for prescribers, pharmacists and recipients to use to receive PA.

The Committee made comments relating to the proposed policy:

Summarized Committee Comments and Final Recommendations

Steve Maike, RPh, Director of Pharmacy, APS Healthcare [Standing]

- Fluoxetine has been a remarkably successful drug.
- Proposal is remarkably simple – much more so than anticipated.
- The PA form is an educational opportunity.
- More passive utilization review programs have not been effective in commercial settings; tide is turning back to PA as a management strategy.
- Impact of PA will be reduced as more drugs in the class go off patent.
- There is a need now for this kind of proposal.

Allen Liegel, RPh, (retired), NAMI Member [Expanded]

- Financial considerations are indeed relevant.
- Reasonable to start with fluoxetine since there is no clear, best first choice in a naïve patient.
- Policy is flexible, and acceptable to him.
- He practices in nursing home and uses all SSRIs including fluoxetine for that population.
- Need to incorporate a way to measure adverse effects of the policy and confirm that we did not incur higher hospital costs.

Dianne Greenley, JD, Supervising Attorney, Wisconsin Coalition for Advocacy [Expanded]

- Remains concerned that the committee has not received information on effects of PA in other state Medicaid programs.
- Not sure that Wisconsin should be the experimental state.
- May be more effective alternative approaches.
- May not be worth the headache for relatively small savings, especially given that there appears to be well organized, unified opposition to the proposal.
- Impressed that approximately 60 psychiatrists are in agreement opposing the proposed policy.
- Policy is flexible but will still clearly steer physicians to prescribe fluoxetine.
- Agrees with Mr. Liegel – should evaluate for unintended consequences and "real savings."

Barry Blackwell, MD, Psychiatrist [Expanded]

- Political and fiscal realities are driving the process.
- Doing something no other state has done.
- Pleased that policy as proposed is flexible, making it easy for the physician to prescribe something other than fluoxetine.
- But remains concerned that it does not protect patients because it will steer patients to fluoxetine.
- There are only three studies that address effectiveness vs. efficacy, and all favor sertraline (Zoloft).
- Agree that there is no good evidence that Prozac produces more manic episodes, but studies do show greater agitation.
- A type 2 Bi-polar patient (unrecognized florid episode) could be pushed into manic episode with devastating consequences if prescribed fluoxetine.
- Should list drug-drug interactions; majority of practitioners cannot predict adverse drug interactions.
- Limitations of family practitioners' experience with nuances of drugs in class.
- Believes that sertraline (Zoloft) is clearly superior and that patients will be deprived of the best drug as a result of the policy.
- Not in favor of proposal because it will force too many patients to take a drug that may be harmful to them, and could be very expensive for the state.

Molly Cisco, Executive Director, Grassroots Empowerment Project, Inc. [Expanded]

- The Department's summary of Dr. Ron Diamond's statement to the committee omitted Dr. Diamond's comment that he objects to PA and favors utilization review.
- Concerned about hidden costs are not adequately considered in the estimated fiscal effect of the policy and the they will equal or exceed the cost savings.
- Cost of doctor and Rx education, EDS implementation and consumer education may eat up most of savings attributable to PA, as estimated by the Department.
- Believes policy will have other, unanticipated cost consequences such as greater hospitalizations.

- Do not do a good job in this state of looking at the big picture; problem of "silos."
- Drug symposium provided good alternatives.
- Favors DUR approach and believes it should have been considered first.
- Not adopting/reviewing the best solution; do not have all the facts.

Virginia Bryan, Consumer [Expanded]

- Does not support PA.
- Not fair to PA mental health drugs because mental health patients are often passive and poor.
- Feels the decision to use PA was made before committee was ever formed.
- More effective alternatives have not been sufficiently considered by the group.

Tom Hirsch, MD, Medical Director, Dean Health Plan [Standing]

- Strongly favors this proposal.
- PA is being done for other drug classes and should do for SSRIs as well.
- Obligation to make decision based on data.
- State is experiencing significant fiscal problems. In the absence of evidence that one agent is clearly superior to another, then we should require the low cost option.
- Would not downplay state savings: given that Medicaid funding is a zero sum game, any dollar not spent on pharmacy care of marginal value can be spent on other health care for Medicaid recipients.
- Likely face decreases in Medicaid eligibility if not address increasing health care costs.
- Feels there is no evidence in the medical literature that a primary care physician can rely on to make a rational decision about the best SSRI for initial treatment in a naïve patient.
- Must stay literature-based; cannot rely on professional opinions solely vs. clinical evidence.
- Professional opinion is the lowest level of evidence.
- DeanCare psychiatric department and Dr. Diamond do not agree with Dr. Blackwell that sertraline (Zoloft) is the best SSRI in class.
- The commercial world has used PA for many years and there is no evidence of substantial harm to patients or of an increase in lawsuits.

Peg Smelser, WEA Trust [Standing]

- At WEA, they have seen tremendous increases in costs due to direct-to-consumer and MD marketing by drug companies with no evidence basis.
- Retrospective review of prescriber practices is too late.
- Intervening at pharmacy is the only way to control costs.
- All of the SSRIs have serious side effects.
- Sees PA policy as a positive opportunity to educate doctors and consumers.
- Department should closely monitor policy through a quarterly audit of adverse effects, switching, and costs and should report back to this committee.

- Policy should be discontinued if it does not work; if it does work, other states and commercial markets may be able to use it as a model.
- Humane approach.

James Heersma, MD, (retired), SeniorCare Advisory Committee Member [Standing]

- Considers all the drugs in the SSRI category comparable.
- Very difficult field to evaluate results – subjective.
- Specifically queried Dr. Sabin (Harvard Medical School) regarding a preferred first agent for a naïve patient; he stated there are no valid criteria for starting patient on one SSRI over another.
- Initially thought that psychiatrists should be exempted, but does not now given the proposed form.
- All funds impact of the policy proposal is important, as we are federal taxpayers, too.
- State budget pressures cannot be ignored.
- Strongly favors policy.

John Gates, RPh, Director of Pharmacy Services, Aurora Health Care [Standing]

- Initially concerned about the effect of STAT-PA on patients.
- Concern about wait time of PA process.
- The proposed policy and PA process allows prescriber flexibility and reduces wait time.
- In favor of proposed process due to modifications presented on the draft form.
- Would like to see fax PA for grandfathered patients to speed up process.

Tom Frazier, Executive Director, Council of Wisconsin Aging Groups (CWAG) and Member, SeniorCare Advisory Committee [Standing]

- Drug costs are out of control; all sectors (employers, consumers, advocates) are dealing with this problem.
- Supports the proposed policy.
- Department should add drugs going off patent to the list of agents exempted from PA as quickly as possible once prices fall.
- Department has done a great deal to address consumer concerns.
- Proposed form is a good solution –need to keep the physician/patient experience and concerns central, and the proposed process does this to a large extent.

Bradley Fedderly, MD, Academy of Family Physicians, Covenant Medical Group [Standing]

- In favor of proposal.
- Many who testified have shown great courage to tell us their stories.
- Follow-up is critical in primary care, e.g., in his practice, he does not give 12 months of refills of an SSRI at the first encounter.

- Steering (through interventions like the PA form) is fine, as long as the physician has flexibility to make their own judgment.
- State must audit the PA forms:
  - Wants to ensure that physicians' efforts are worthwhile for the state; not just going through the effort just to make a pile of paper.
- Reconvene committee to present outcomes of PA policy decisions.
- He would like to see a link with some adverse event reporting:
  - Web-based feedback/database
  - Interactive feedback

John Frey III, MD, University of Wisconsin Family Practice Center [Expanded]

- Thinks this is good policy, as it is based on evidence and science and has the potential to positively affect a large patient population.
- This policy is a careful and easy nudge.
- Must start this process.
- We should have evidence-based depression treatment guidelines, along the lines of those produced by commercial health plans.
- We have to have formularies – prescribers need guidance as to which drugs are the clear superstars vs. those that are only versions of each other.
- Have to have oversight – sooner rather than later.
- All about quality improvement – ongoing process evaluation.

Ken Robbins, MD, University of Wisconsin Health [Expanded]

- Supports the idea to save money, but is not clear that PA process is the best way to achieve that outcome.
- Have made a misleading jump that since there is no best first agent that all SSRIs are the same.
- Know that there are different side effects profiles among agents in the class.
- Studies in the area are not adequate: can come to almost any conclusion by looking at industry studies; few independent studies.
- Switching studies are extremely small.
- Anxiety is the most serious co-morbid condition and is concerned that policy may lead to prescribing fluoxetine for patients with anxiety.
- Form is simple, but is concerned that it may not be sufficiently accessible to physicians at time of patient care.
- Concern about agitation in elderly patients.
- Not persuaded that this is a good idea.

Michelle Thoma, RPh, PharmD, Clinical Pharmacist\Clinical Instructor UWHC [Expanded]

- Initial and ongoing concern about MDs being limited to one choice of drug in class.
- Proposed policy and form provide a way for MDs to opt out, such that they do have a choice.

- Add paroxetine (Paxil) to the list of those agents exempt from PA when it becomes competitively priced.
- Supports ongoing review and future assessment of the policy by the committee.

Not Present:

Larry Fleming, MD, Professor, Department of Medicine, University of Wisconsin, Madison Medical School; Medical Director, Unity Health Plan; practicing physician, University of Wisconsin, Madison. [Standing]
Christine Sorkness, PharmD, RPh, Professor of Pharmacy and Medicine (CHS), Pharmacy Practice Division, University of Wisconsin, Madison. [Standing]
Randy Lewis, Consumer. [Expanded]