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DMHDS

DRUG FORMULARY

Version 1.0

REFERENCE GUIDELINES

Prepared by:

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And
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Under the direction of:
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Published: January, 2003

Message from Dr. Brandenburg, Administrator DMHDS

The healthcare industry is facing more challenges for survival than we have seen in several decades. Truly, one can venture to state that every provider in this industry is in a binary mode, survival or extinction. Our resources are being tasked to the maximum. It is only through a collective survival awareness tempered with a sense of fiscal responsibility, can we insure our continued business existence.

We are in the dynamic and challenging business of providing services in the Mental Health Industry. I am proud of all your efforts. For my part, I have worked very hard to insure that you have the necessary tools to perform your clinical duties. The medications in our formulary support this approach. For example, we have on our formulary all the established Selective Serotonin Reuptake Inhibitors (SSRIs) available in the market. We also have on our formulary all the established atypical antipsychotics in the market. We have procedures that address the addition of any newly released psychiatric drugs to this formulary. We have placed the novel psychiatric agents in the forefront of our medication usage, without the requirement of a prior trial or failure with the traditional agents. Patient safety and drug efficacy have been paramount in our formulary decisions. In short, we have positioned our practice at the forefront of evidence based and community standard paradigm.

We are in the process of establishing a consolidated statewide DMHDS Drug Formulary. Currently SNAMHS and NNAMHS have different formularies. The SNAMHS, NNAMHS and the MHDS Rural Clinics medical staffs and the Pharmacy and Therapeutic Committees will participate in establishing this uniform formulary. In preparation for this, all new additions to the formulary will be reviewed at the Division level under the responsibility of the Pharmacy Oversight Leadership Committee. Any state formulary drug additions can only be done at this Division level. Our plan is to have this consolidated formulary system available by the end of 2003.

As you are all aware, not too long ago we had to revert 3% of our budget to the State to offset the general budget shortfall. This reversion also affected our pharmacy budget. It is now imperative that we live not only within our current constrained medication budget, but institute ongoing cost savings measures to insure our continued operation in the future. I have given some instructions to assist in achieving this aim.

I have directed Dr. Rosin and Dr. Ebo to liaise with the Medical Directors and the medical staffs at SNAMHS and NNAMHS with regards to developing and implementing physician prescribing patterns that maximize the use of best practice methods, whilst embracing an awareness and sensitivity to the cost of the pharmaceuticals. I have asked them to target the use of SSRIs and the

atypical antipsychotics as the first phase of this project. I have chosen those two classes of medications because of their high drug budget impact.

With these two classes of medications and in the future, other identified classes, what we will see is the establishment of a decision matrix for their uses. The medications within a class shall be tiered into levels at which they shall be considered for prescribing. Documentation in the client's medical records will be required to bypass any tier level. Such documentation must be thorough as to stand review. Dr. Pauly and Dr. Montgomery will work with the medical staffs to determine peer review formats in order to establish surveillance and oversight for the adherence to this program. These decision matrices will be incorporated as part of our modified Texas Medication Algorithm Program (TMAP). I will require a continued update on the progress of this endeavor from the Medical Directors and the medical staff.

I have also instructed that a drug list be made available to the medical staffs of SNAMHS, NNAMHS and the MHDS Rural Clinics. The list will show the unit costs of all medications on the formulary including those on restricted status. The list will assist doctors in making fiscally sound decisions regarding drug therapy for all classes of medications. This list will be updated at least quarterly. The list will be included in the orientation packet of each physician. Dr. Ebo is to insure that each updated list is made available to all DMHDS physicians.

I consider all the above voluntary avenues to solicit your assistance in dealing with this medication budget issue. I am hopeful that you will give it your full attention and commitment so that our efforts will result in a positive fiscal outcome. But, I must make it quite clear that I intend for our system to survive and will institute any additional measures necessary to insure that.

I fully support the need for good, strong clinical judgment directing the choice and use of psychotropic medications for our clients. It is certainly not my intent to interfere with that process. However, be aware that in today's reality, consideration must be given to a major fiscal impact in the prescribing process. This must clearly be kept in mind when agents have been demonstrated to be equally efficacious.

I am attaching a copy of the "Preauthorization Plan" for high cost medications that was instituted in Massachusetts. I do not want to have to down this road

If the above voluntary efforts do not work, I will have no other recourse but to direct the institution of more restrictive actions that will include prior authorization of all high cost medications and quite possibly the implementation of a closed-formulary system. Some of you have worked with the managed care systems

and have experienced first hand the effects of highly restrictive formulary models. I hope it does not come to that, and I know you will do your best. Thank you for your support.

Best Regards,

Carlos Brandenburg, Ph.D.
Administrator, DMHDS

GLOSSARY OF TERMS:

FORMULARY MEDICATIONS:

These are medications that are on the formulary. These medications are routinely available in the Pharmacy, except during out of stock situations caused by wholesaler or manufacturer back order. The only restriction associated with the prescribing of these medications is in allocations to class tier systems. For tiered classes, medications must be considered for use in a systematic order of their levels of assignment within the class. Deviations or exceptions must be documented on the client's medical records.

RESTRICTED FORMULARY MEDICATIONS:

These are medications that are on the formulary, but may not be routinely available for dispensing due to lack of usage. They can be procured by Pharmacy when ordered. Prior authorization is required for this class of medications. Such prior authorization must be reviewed and approved by the P&T Committee Chairman and the Medical Director prior to dispensing by the Pharmacy. It is the responsibility of the prescribing physician to insure that complete justification is included in the prior authorization request. When appropriate, Pharmacy will include the cost of the requested medication to aid in the approval decision process.

NON-FORMULARY MEDICATIONS:

These are medications not on the formulary. They are not routinely available in the Pharmacy. Procurement of non-formulary medications may extend from 72 hours to 120 hours. These medications also require the prior authorization process as stated above. Newly released medications do not belong in this category as their inclusion creates a back door entry into usage of medications not yet reviewed and/or admitted to the formulary.

DMHDS DRUG LIST UNIT COST:

This is a list of formulary and restricted formulary medications indicating the unit actual acquisition costs of a majority of the medication doses available on the formulary. The list is updated at least quarterly. The list will be provided to every physician in the DMHDS system. The listed costs do not coincide with the Average Wholesale Prices (AWPs). They are the actual special acquisition costs obtained through the state contract buying group arrangement. These costs are privileged information. Please treat costs as private, if not confidential. See Attachment A for a copy of the list.

REQUESTS FOR MEDICATION ADDITION TO FORMULARY:

Any staff physician can request a medication to be added to the state formulary. Such a physician must provide supporting documentation for the need for the request. Requests for formulary additions will be presented to the appropriate medical staff and P&T Committees. The physician submitting the request must be prepared to appear before the medical staff and the P&T Committee to present evidence to support his/her request. If the P&T Committee is in agreement with the request for addition to the formulary, then the request will be forwarded to the Pharmacy Oversight Leadership Committee. It is the responsibility of the Oversight Committee to make a final decision on whether or not to add the medication to the state formulary system. As part of the process in the consideration of formulary additions, the P&T Committee will also review possibility of replacing the new medication with a formulary agent. Fiscal analysis and impact must be factored into any formulary addition recommendations made to the Oversight Committee.

MANUFACTURERS' DRUG SAMPLES:

Use of manufacturers drug samples is highly encouraged. Pharmacy is utilized for the primary storage of drug samples. Procedures governing the use of drug samples are specific and localized to the areas of SNAMHS, NNAMHS and the MHDS Rural Clinics. Physicians are encouraged to familiarize themselves with the particular procedures governing their area of operation. As much as possible, drug samples will be utilized for commencement of new drug treatments and for returning clients who are to be tried on new drug regimens. Some form of documentation, either via copies of prescriptions or notations in the client's medical records must be present to document the use of the drug samples. All such documentation must include the name of the drug sample, the dose and the quantity dispensed.

PHARMACY OVERSIGHT LEADERSHIP COMMITTEE:

Membership comprises:

Carlos Brandenburg, Ph.D.	Administrator, DMHDS
David Rosin, M.D.	Statewide Medical Director, DMHDS
Jonna Triggs, Ed.D.	Agency Director, SNAMHS
Harold Cook, Ph.D.	Agency Director, NNAMHS
Larry Buel, Ph.D.	Agency Director, Rural Clinics
Larry Montgomery, M.D.	Medical Director, SNAMHS
Ira Pauly, M.D.	Medical Director, NNAMHS
Mark Depew, R.Ph.	Acting Pharmacy Director, NNAMHS
Debbie Hosselkus	DMHDS
Bob Harnish	Business Manager, NNAMHS
Emmanuel Ebo, Pharm.D.	Statewide Pharmacy Director, DMHDS

DECISION MATRIX IN THE USE OF ATYPICAL ANTIPSYCHOTICS

We are still in the process of completely adopting the TMAP in Schizophrenia. The TMAP guidelines (algorithm) reflect the state of current knowledge on effective and appropriate care, as well as clinical consensus judgments. The TMAP authors further caution that the guidelines may not apply to all patients, but must be adapted and tailored to each individual patient. Proper use, adaptation modifications or decisions to disregard, in whole or in part, are entirely the responsibility of the clinician. The decision matrix denoted below follows the TMAP model, but with the incorporation of fiscal responsibility requirement. Fiscal responsibility is not a new concept in the optimal treatment of patients. It has always been implicit in the overall clinical responsibility of the clinician. Unfortunately it has not received as much attention as it merits. Because of the inevitable changes in scientific information and technology including the future availability of single source drugs in generic forms, it is imperative that periodic review resulting in the updating and revisions of the decision matrix be needed from time to time. Thus, the decision matrix will become a very dynamic concept that seeks to maximize and stabilize the clinical and fiscal positions of our patients and our organization. The medical staff will be involved in developing new decision matrices as they apply to different classes of drugs.

In the attached TMAP Antipsychotic Algorithm, the atypical antipsychotics referenced in Stages 1 to 3 are Olanzapine, Quetiapine and Risperidone. This was developed prior to the release of Ziprasidone. The modification in the MHDS system is as follows:

Stage 1: Risperidone or Ziprasidone (Use in any order)

Stage 2: Use the other in above

Stage 3: Use Quetiapine or Olanzapine (Use in any order)

Stage 4: Use the other in above

Stage 5: Typical Antipsychotic

Stage 6: Clozapine

Stage 7: Augmentation per TMAP (denoted as Stage 5a and Stage 6)

DECISION MATRIX IN THE USE OF SSRIs

Tx medical algorithm program

We have not yet started orientation for the implementation of the TMAP Depression Algorithm. We are on schedule to adopt the principles of the guidelines. And, like in the use of atypical antipsychotics, we shall make modifications in the interest of our clinical and fiscal goals. Review the clinician's responsibility as denoted above in the decision matrix for the use of atypical antipsychotics.

However, our establishment of a decision matrix in the class of SSRIs prepares us for such an implementation. In the attached TMAP SSRIs feature in Stages 1,2, and 3 of the algorithm. Monotherapy is recommended in those first 3 stages.

The modification in the MHDS system is as follows:

In considering the use of SSRIs, regardless of the Stage, the decision matrix is:

a. Fluoxetine

b. Lexapro

c. Celexa, Paxil, Zoloft