Drug Utilization Review (DUR) Board Meeting Summary October 20, 2011

Agenda and Introduction

The Drug Utilization Review Board met on Thursday, October 20, 2011 from 9:00 A.M. to 4:00 P.M., in Meeting Room 6, Concourse, Empire State Plaza, Albany, New York.

A. Background Materials Provided

The DUR Board members were provided copies of materials submitted by interested parties in advance of the meeting.

B. Public Comment Period

The following speakers provided comments to the DUR Board:

1. Sachdeva, Parshotam, Pharm.D., Sr. Regional Scientific Manager, Astra Zeneca Pharmaceuticals, Wilmington, DE
2. Moorjani, Harish, MD, Clinical Assistant Professor of Medicine, New York Medical College, Infectious Disease Consultant, NYSDOCS, Briarcliff Manor, NY
3. Spellman, James, NP, Weill Cornell Medical College, NY, NY
4. Patel, Vik, Pharm.D., Managed Care Liaison, Vertex Pharmaceuticals, Trumbull CT
5. Baran, Daniel, MD, Region Medical Director, Merck, Upper Gwynedd, PA
6. Boukabache, Hassan, MD, Associate Director, Medical Affairs, EMD Serono, Rockland, MA

C. Key Issues Presented by Interested Parties and Discussed by the DUR Board during the Public Comment Period:

Quetiapine:
A general overview of quetiapine was presented including dosages, side effects, and indications, particularly the fact that quetiapine has indications for both major depressive disorder and bipolar disorder.

A Board member clarified that this drug is an adjunct to major depressive disorder therapy rather than a monotherapy. The member also stressed that they would like to see the manufacturer take a greater role in communicating this fact to prescribers.

Hepatitis C Virus Protease Inhibitors:
Testimony addressed personal experience with clinical trials for these agents and the potential implications these agents may have in treating hepatitis C virus more effectively.

Testimony addressed the addition of these agents to the American Association for the Study of Liver Disease Guidelines as an optimal agent for the treatment of genotype 1 hepatitis C.

Testimony addressed hepatitis C as the leading cause of liver cancer, liver failure and liver transplants and the potential for boceprevir to help produce a sustained biological response.

Testimony provided a general overview of telaprevir and its place in therapy regarding the treatment of hepatitis C.

A Board member had questions regarding the percent of patients with HIV co-infection and drug interactions in this patient population. A Board member also asked if there is data available that identifies patients that do not receive a SVR prior to receiving treatment.

Tesamorelin
Testimony provided a general overview of tesamorelin (Egrifta™) and its indication in the medical condition lipodystrophy.

D. Presentations and Discussions:

The following speakers presented to the DUR Board:

1. Catanzaro, Linda, Pharm.D., Clinical Assistant Professor Director, Pharmacotherapy Information Center Chair, HIV Continuing Education Programs, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
2. Coe, Holly, Pharm.D., Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
3. Finnerty, Molly, MD, Director of the Bureau of Evidence Based Services & Implementation Science, NYS Psychiatric Institute, Office of Mental Health

4. Hong, Irene, Pharm.D., Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
5. Lehmann, David, MD, Pharm.D., Professor of Medicine and Pharmacology, State University of New York Upstate Medical University
6. Manley, Harold, Pharm.D., Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
7. McNamara, Daniel, RPh, Medicaid Pharmacy Program, Office of Health Insurance Programs, New York State Department of Health
8. Toohey, Monica, RPh, Medicaid Pharmacy Program, Office of Health Insurance Programs, New York State Department of Health
9. Zachary-Elkind, Janet, Assistant Division Director, DOH/OHIP/DFPP

Methadone

Dr. Hong presented the methadone utilization review. The DUR Board was provided with a general overview of the drug including the indications, accepted uses and clinical considerations. The DUR Board was also provided with NYS Medicaid claims utilization information including utilization of specific methadone products, number of claims, cumulative daily dosages, duration of therapy, utilization per diagnosis and the association with additional factors including potential over-utilization and misuse.

Morphine and Congeners

Dr. Hong presented the morphine and congeners utilization review. The DUR Board was provided with a general overview of the drug class including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claims utilization information including diagnosis, dosages exceeding quantity limits based on FDA-approved labeling, dosages exceeding quantity limits based on 200mg/day of morphine or equivalent, and the association with additional factors including potential over-utilization and misuse.

Fentanyl

Dr. Hong presented the fentanyl utilization review. The DUR Board was provided with a general overview of the drug class including the indications, accepted uses and clinical considerations. The Board was also provided with the NYS Medicaid claims utilization information including strength dispensed, quantity dispensed, utilization by age and the association with additional factors including potential over-utilization and misuse.

Tesamorelin

Dr. Manley presented the tesamorelin review. The DUR Board was provided with a general overview of the drug including the single FDA approved indication and clinical considerations. Dr. Manley also presented the lack of labeled health outcomes benefits as well as risk of serious side effects.

Quetiapine
Dr. Coe presented the quetiapine utilization review. The DUR Board was provided with a general overview of the drug class including the indications, accepted uses and clinical considerations. The Board was also provide with the NYS Medicaid claims utilization information including strength dispensed, supratherapeutic dosages, subtherapeutic dosages, utilization by diagnosis, and the association with additional factors including potential over-utilization and misuse.

HCV Protease Inhibitors
Dr. Catanzaro presented the Hepatitis C Virus (HCV) Protease Inhibitors utilization review. The DUR Board was also provided with a general overview of the drug class including indication and clinical considerations. Dr. Catanzaro presented how these medications fall in line with the previous recommendations made pertaining to pegylated interferons. The Board was also provided with NYS Medicaid information including cost of therapy and the association with additional factors including potential for public safety risks that may result from inappropriate utilization.

Medicaid Redesign Team (MRT) Update
Ms. Elkind presented to the DUR Board updates on MRT 2011-12 budget initiatives, "Bundle Pharmacy into Managed Care (MRT#11)" and "Comprehensive Fee-for-Service Reform (MRT#15). Presentation and discussion focused on an update of implemented initiatives and progress of those initiatives to be implemented which included:

- Enhance NY State Leverage for supplemental rebates(Implemented 04/01/2011)
- Tighten the early refill process (Implemented 04/01/2011)
- Rebuild the NY Preferred Drug List (PDL) (Implemented 05/01/2011)
- Reduce pharmacy reimbursement and dispensing fees (Effective 04/01/2011, Implemented 08/25/2011)
- Implement Preferred Drug Program PA based on effective date (Implemented 08/25/2011)
- Allow Prior Authorization for anti-depressants, atypical antipsychotics, anti-retrovirals and immunosuppresants (PA for Anti-depressants implemented 08/25/2011, PA for anti-psychotics to be implemented 01/2012)
- Eliminate the Medicare Part D Drug Wrap (Implemented 10/01/2011)
- Limit opioids to four prescriptions every thirty days (Implementation Date:1/2012)
- Implement a voluntary mail order program (Implementation Date:3/2012)
- Implement Acquisition Cost Based Reimbursement (Implementation Date:Q1, 2012)
- Waste reduction through short cycle dispensing and re-dispensing of returned medications (Implementation Date:1/2013)

- Transitioning the pharmacy benefit from Medicaid Fee-for-service to the managed care plans of 3 million beneficiaries already receiving managed care benefits. (Effective 10/01/2011)

Prescriber Education Program (PEP)
Dr. Lehmann presented the Prescriber Education Program (PEP) update. Dr. Lehmann provided a computer-based presentation, demonstrating an interactive algorithm providing evidence based, non-commercial approach to treating patients presenting with diabetes mellitus and hypertension. This and many other tools are available at the NYS Prescriber Education Program website.

Psychiatric Services and Clinical Knowledge Enhancement Systems (PSYCKES)
Dr. Finnerty presented the PSYCKES overview and discussed the program's impact on improving the safety and quality of psychotropic medication management. She discussed the PSYCKES Continuous Quality Improvement Quarterly Report for the second quarter of calendar year 2011. Dr. Finnerty also provided the Board with information comparing the effectiveness of quality improvement initiatives between PSYCKES participating entities versus PSYCKES nonparticipating entities.

E. DUR Board Discussion:

The DUR Board discussed the utilization of methadone in a clinic setting with the understanding that their recommendations would not apply to this population. The Board also discussed the need to establish quantity limits and a maximum dose for methadone.

The DUR Board discussed the utilization of morphine and congeners in relation to quantity and dosing frequency limits based on Food and Drug Administration (FDA) labeling and use supported by the Compendia for non-cancer and non-sickle cell pain. The Board also discussed immediate release, extended release products, combination products, and concurrent therapies.

The DUR Board discussed the utilization of transmucosal and transdermal fentanyl in relation to specific patient populations, daily dosages and frequency. The Board also discussed those patients that have obtained a prior approval and have established therapy going forward.

The DUR Board discussed tesamorelin in relation to the indication in the treatment of lipodystrophy associated with Human immunodeficiency virus (HIV) infection. The Board also discussed potential long term side effects of the medication in relation to its perceived medical benefit.

The DUR Board discussed the utilization of quetiapine in relation to approved indications, dose and dose frequency limits based on Food and Drug Administration (FDA) labeling and use supported by the Compendia. The Board also discussed distributing educational materials to providers outlining appropriate FDA and Compendia dosages and the risks associated with suboptimal off-label prescribing.

The DUR Board discussed the appropriate utilization of HCV protease inhibitors, boceprevir and telaprevir, in relation to quantity, duration limits, and quantitative HCV RNA testing. The Board discussed the importance of appropriate utilization in the prevention of HCV resistance. The Board also discussed appropriate time frames in which HCV RNA tests are to be reported before dispensing the remainder of either medication.

F. DUR Board Action:

Methadone

The DUR Board took the following action(s) regarding methadone for non-cancer and non-sickle cell disease:

- Quantity limit: maximum 12 units per day, 360 units per 30 days

Morphine and Congeners

The DUR Board took the following actions(s) regarding morphine and congeners for non-cancer and non-sickle cell disease:

- Quantity limit for immediate release (IR) combination products: maximum recommended acetaminophen (4 grams), aspirin (4 grams), or ibuprofen (3.2 grams) dose OR the FDA approved maximum opioid dosage as listed in the PI, whichever is less

- Quantity limit form IR non-combination products:

    - Codeine: maximum 6 units per day, 180 units per 30 days
    - Morphine, hydromorphone, oxymorphone IR: maximum 6 units per day, 180 units per 30 days

- Quantity limit extended-release (ER) products:

    - Morphine ER (excluding MS Contin products): maximum 2 units per day, 60 units per 30 days

- Hydromorphone ER, Oxymorphone ER: maximum 4 units per day, 120 units per 30 days
- Morphine ER (MS Contin 15mg, 30mg, 60mg only): maximum 3 units per day, 90 units per 30 days
- Morphine ER (MS Contin 100mg only): maximum 2 units per day, 60 units per 30 days
- Morphine ER (MS Contin 200mg only): maximum 1 units per day, 30 units per 30 days

Fentanyl

The DUR Board took the following action(s) regarding fentanyl for non-cancer and non-sickle cell disease:

- Quantity limit transdermal: maximum 100mcg/hr (over the 72 hour dosing interval), 10 patches per 30 days

- Quantity limit transmucosal: maximum 4 units per day, 120 units per 30 days

Tesamorelin

The DUR Board took the following action(s) regarding tesamorelin:

- Not eligible for coverage by the NYS Medicaid program

Quetiapine

The DUR Board took the following action(s) regarding quetiapine:

- Provider letter: Educational letter to providers outlining appropriate FDA and Compendia dosages and dangers of suboptimal off-label prescribing

- Quantity limit:
  - Minimum 100mg/day
  - Maximum 800mg/day

- Quantity limit IR products: maximum 3 units per day, 90 units per 30 days

- Quantity limit XR products for 150mg and 200mg: maximum 1 unit per day, 30 units per 30 days

- Quantity limit XR products for 50mg, 300mg and 400mg: maximum 2 units per day, 60 units per 30 days

HCV Protease Inhibitors

The DUR Board took the following action(s) regarding HCV Protease Inhibitors:

- Provider letter: Educational letter to providers outlining appropriate baseline testing and follow-up monitoring to determine duration of therapy

The DUR Board took the following action(s) regarding telaprevir:

- Step therapy will be applied to guarantee concomitant peginterferon and ribavirin therapy

- Quantity limit: maximum 6 capsules per day, 180 capsules per 30 days

- Duration limit:

    - Initially 56 days, pending results of quantitative HCV RNA testing after 4 weeks of treatment.
    - Maximum 12 consecutive weeks over beneficiary lifetime, pending results of quantitative HCV RNA testing

The DUR Board took the following action(s) regarding boceprevir:

- Step therapy will be applied to guarantee 4 consecutive weeks of peginterferon and ribavirin therapy immediately before initiation of boceprevir

- Quantity limit: maximum 12 capsules per day, 360 capsules per 30 days

- Duration limit:

    - Initially 84 days, pending results of quantitative HCV RNA testing after 4 and 8 weeks of boceprevir treatment (i.e. weeks 8 and 12 of triple therapy)
    - Subsequent limit of 84 days, pending results of quantitative HCV RNA testing after 20 weeks of boceprevir treatment (i.e. week 24 of triple therapy
    - Maximum 44 consecutive weeks over beneficiary lifetime, pending results of quantitative HCV RNA testing if:
    - Prior peginterferon/ribavirin non responder
    - Compensated cirrhosis
    - Maximum 32 consecutive weeks over beneficiary lifetime, pending results of quantitative HCV RNA testing for all other beneficiaries

G. Additional Discussion

Mr. Naioti (DUR Manager) announced Marc Speert has resigned from the DUR Board, concluding eighteen years of participation, nine years as chair, and thanked him, on behalf of the Board, for his service.

The meeting adjourned at 3:30 p.m.