

**Drug Utilization Review (DUR) Board
Meeting Summary
September 6, 2012**

Agenda and Introduction

The Drug Utilization Review Board met on Thursday, September 6, 2012 from 9:00 A.M to 4:00 P.M., in Meeting Room 6, Concourse, Empire State Plaza, Albany, New York.

A. Background Materials

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:

- Arserver, Christiane, MD, Senior Regional Medical Director, Merck, Upper Gwynedd, PA
- Pearman, Leny G., RN, MS, CNS, Medical Liaison Consultant, Lilly USA, Indianapolis, IN
- Mar, Kirsten H., PharmD, BCPS, BCPP, Health Outcomes Liaison, Eli Lilly & Co, Dallas, TX

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

Januvia/Janumet

Testimony provided an overview of Januvia/Janumet including its use as add-on therapy and its ability to decrease HbA1C. The Board also heard testimony to the safety profile of Januvia/Janumet.

Forteo

Testimony provided a general overview of Forteo as the only anabolic osteoporosis agent approved in the United States. The Board also heard testimony regarding the indications for Forteo.

Duloxetine

Testimony provided an overview of duloxetine (Cymbalta) in treatment of diabetic neuropathic pain. The Board also heard results of a cohort retrospective study regarding patients initiated on duloxetine as well as other standard care treatments.

D. Presentations and Discussions:

The following speakers presented to the DUR Board:

- Catanzaro, Linda, PharmD, Clinical Assistant Professor Director, Pharmacotherapy Information Center Chair, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
- Coe, Holly, PharmD, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
- Hong, Irene, PharmD, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo
- Finnerty, Molly, MD, Director of the Bureau of Evidence Based Services & Implementation Science, NYS Psychiatric Institute, Office of Mental Health
- Lehmann, David, MD, PharmD, Professor of Medicine and Pharmacology, State University of New York Upstate Medical University
- Rivera, Christine A., Director, Uninsured Care Programs, New York State Department of Health
- Gonzalez, Charles John, MD, Associate Medical Director for Science and Policy/OMD, NYS Department of Health/AIDS Institute
- Naioti, John F., Jr., RPh, DUR Program Manager, NYS Department of Health

Treatment of Type 2 Diabetes – Diabetes Standard of Care

Dr. Catanzaro presented diabetes standards of care in the management of patients with diabetes mellitus (DM). This presentation was based on information published by the American Diabetes Association (ADA) and incorporated into federal Healthcare Effectiveness Data and Information Set (HEDIS) measures and NYS Department of Health Quality Assurance Reporting Requirements (QARR). Information presented included the incidence of HbA1C testing, lipid monitoring and/or treatment, nephropathy monitoring and/or treatment, annual influenza vaccination, and smoking cessation treatment.

Treatment of Type 2 Diabetes – Metformin

Dr. Catanzaro presented information on the treatment of Type 2 Diabetes (T2DM) considering metformin as optimal first-line pharmacologic therapy for patients without contraindications. Utilization within the Medicaid program was also examined along with safety and diagnosis information.

Treatment of Type 2 Diabetes – Glucagon-like Peptide-1 (GLP-1) Agonists

Dr. Catanzaro presented clinical information regarding the treatment of Type 2 Diabetes and place in therapy for glucagon-like peptide-1 (GLP-1) agonists. Guidelines were based on information from the American Association of Clinical Endocrinologists (AACE), American College of Endocrinology (ACE) consensus statement, National

Institute for Health and Clinical Excellence (NICE), and NYS DOH/UB Clinical Guidance Document. The presentation outlined use of GLP-1 medications as an alternative when other treatments cannot be used or tolerated or when weight loss is also essential. Utilization within the Medicaid program was also examined along with safety and diagnosis information.

Treatment of Diabetic Peripheral Neuropathy (DPN)

Dr. Coe presented clinical information regarding the treatment of diabetic peripheral neuropathy (DPN) including guidelines from the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE). Also presented were guidelines from the European Federation of Neurological Societies (EFNS) and the Oregon Health & Science University (OHSU) Drug Effectiveness Review Project. Utilization within the Medicaid program was also discussed, along with a cost comparison of treatment options.

Teriparatide (Forteo)

Dr. Hong presented clinical information associated with the treatment of osteoporosis with teriparatide (Forteo) including FDA indications, dosage and administration, and place in therapy. Medicaid program utilization was also examined considering cost effectiveness.

Prospective Anti-Retroviral (ARV) Interventions

Ms. Rivera and Dr. Gonzalez presented program and intervention information relating to the continuum of access to health related services through Medicaid and the HIV Uninsured Care Programs. The presentation included comprehensive planning and community involvement as well as information about the AIDS Institute.

Hepatitis-C Treatment in Hepatitis-C Treatment in Hepatitis-C Virus (HCV)/Human Immunodeficiency Virus (HIV) Co-Infection

Dr. Catanzaro presented information relating to Hepatitis-C treatment in HCV/HIV Co-Infection including recent FDA action regarding this treatment. Proper dosing to treatment naïve and treatment experienced patients, emphasis on safety and the usefulness of ProDUR edits were discussed.

Prescriber Education Program (PEP)

Dr. Lehmann presented the Prescriber Education Program (PEP) update that included a chart of the *Process for Optimal, Safe, Efficacious, and Fiscally Responsible Medication Use*. Dr. Lehmann discussed the partnership to integrate aspects of the public (Department of Health) and private (Managed Care) health care programs to improve population outcomes.

Psychiatric Services and Clinical Knowledge Enhancement Systems (PSYCKES)

Dr. Finnerty presented the Psychiatric Services and Clinical Knowledge Enhancement Systems update. Dr. Finnerty presented to the Board information demonstrating the quality indicator sets used by the PSYCKES program, indicator sets under

development, and new strategies by the program that support physician decision making.

Election of Chair and Vice-Chair

The DUR Board held election of officers for the upcoming term. Dr. Seana O'Mara was elected Chair and Dr. John McIntyre was elected Vice-Chair.

E. DUR Board Discussion:

The DUR Board discussed the various diabetes standards of care measures related to proper therapy and how these measures compared to care within the Medicaid population.

The DUR Board discussed utilization of metformin as optimal first-line pharmacologic therapy for patients without contraindications. The Board considered adherence to FDA-approved uses and recommended guidelines for metformin as initial treatment for T2DM.

The DUR Board discussed the utilization of GLP-1 agonists and the necessity of diagnosis requirement to ensure reimbursement for covered uses only. The Board considered the appropriate place in therapy for the GLP-1 agonist category.

The DUR Board considered treatment of diabetic peripheral neuropathy (DPN) and the lack of significant differences in pain reduction between duloxetine, pregabalin, and gabapentin. The discussion also included the estimated cost of using either duloxetine or pregabalin versus either tricyclic anti-depressants (TCA) or gabapentin.

The DUR Board discussed the treatment of osteoporosis with teriparatide (Forteo) and the use in treatment of osteoporosis in patients at high risk for fracture. The Board also discussed duration of therapy, cost effectiveness, and appropriate use in comparison to bisphosphonates.

The DUR Board discussed prospective anti-retroviral interventions including the AIDS Drug Assistance Program (ADAP) and the goal of uninterrupted access to safe combinations of antiretroviral medications. The Board also discussed drug therapy criteria for providing the safest and most effective treatment.

The DUR Board discussed hepatitis-C treatment in HCV/HIV co-infection and the number of beneficiaries with HCV/HIV co-infection who have received antiretroviral drugs that should not be co-administered with boceprevir or telaprevir. The Board also considered the number of beneficiaries with HCV/HIV co-infection who have received telaprevir without the appropriate dose increase when co-administered with efavirenz.

The Board discussed a DUR informational letter response sent to the Department of Health by a provider stating an opinion that the Medicaid program made its decisions on drug therapies based on the cheapest price. Mr. Naioti stated that he took exception to the provider's statement, and stated that during his tenure at the Department of Health,

DUR Board and P&T Committee recommendations are evidence-based and in the best interest of treatment for the beneficiaries for whom they are responsible.

F. DUR Board Action:

Treatment of Type 2 Diabetes – Diabetes Standard of Care

The DUR Board took the following action(s) regarding Diabetes Standard of Care:

Targeted educational outreach to prescribers through NYS Medicaid Prescriber Education Program (NYSMPEP) diabetes initiative including:

- Continue key message promoting recommended HbA1C monitoring.
- Bulletin promoting recommended annual lipid screening or treatment with a statin as warranted.
- Bulletin promoting recommended annual nephropathy screening or treatment with ACEI or ARB.
- Bulletin promoting recommended annual influenza vaccination.
- Bulletin promoting documentation of tobacco use and resources for smoking cessation.

Treatment of Type 2 Diabetes – Metformin

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

- Step therapy with metformin +/- insulin prior to initiation of other antidiabetic agents unless documented contraindication.
- Targeted educational outreach to prescribers through NYSMPEP, promoting the use of metformin as first-line therapy in the treatment of T2DM consistent with clinical guidelines.

Treatment of Type 2 Diabetes – Glucagon-Like Peptide-1 (GLP-1) Agonists

The DUR Board took the following action(s) regarding GLP-1 agonist therapy:

- Prior authorization requirement with lack of covered diagnosis in medical history.
- Step therapy with metformin plus another oral antidiabetic agent prior to a GLP-1 agonist.

Treatment of Diabetic Peripheral Neuropathy (DPN)

The DUR Board took the following action(s) regarding Diabetic Peripheral Neuropathy therapy:

- Step therapy with a TCA **OR** gabapentin prior to duloxetine and pregabalin (for treatment of DPN).

Teriparatide (Forteo)

The DUR Board took the following action(s) regarding teriparatide (Forteo) therapy:

- Step therapy with a preferred oral bisphosphonate.
- Quantity limit of 1 unit (2.4 mL) per 30-day period.
- Lifetime quantity limit of 25 months of therapy.

Prospective Anti-Retroviral (ARV) Interventions

The DUR Board took the following action(s) regarding prospective anti-retroviral interventions:

Adopt ADAP ARV clinical parameters for ProDUR program as follows:

- No ARV active ingredient duplication.
- No more than five ARVs concurrently excluding boosting with ritonavir (dose limit 600 mg. or less) and cobicistat.
- No more than two Protease Inhibitors concurrently.

Update ARV ProDUR edits to severity level 1 as needed.

Hepatitis-C Treatment in Hepatitis-C Virus (HCV)/Human Immunodeficiency Virus (HIV) Co-Infection

The DUR Board took the following action(s) regarding Prospective Anti-Retroviral Interventions:

- Add prospective DUR edit for boceprevir with any HIV Protease Inhibitor (PI) or Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI).
- Add prospective DUR edit for telaprevir with any HIV PI other than atazanavir/ritonavir and any NNRTI other than efavirenz
- Set minimum quantity limit of telaprevir at nine tablets per day for beneficiaries receiving efavirenz.

The Board adopted a resolution to accept as public record the statement made by Mr. Naioti regarding decisions of the Department being evidence-based and in the best interest of treatment for the beneficiaries of the program.

The meeting adjourned at 1:40 P.M.