



## ***The Bulletin of Medicaid Drug Utilization Review in Iowa***

### ***DUR Commission Members***

Larry Ambroson, R.Ph.

Gregory Barclay, M.D.

Casey Clor, M.D.

Brett Faine, Pharm.D.

Mark Graber, M.D., FACEP

Craig Logemann, R.Ph., Pharm.D.,  
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Susan Parker, Pharm.D.

Laurie Pestel, Pharm.D.

Sara Schutte-Schenck, D.O., FAAP

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### ***DUR Professional Staff***

Pamela Smith, R.Ph.

DUR Project Coordinator

## **Commission Welcomes New Member**



Gregory P. Barclay is the newest addition to the DUR Commission. Dr. Barclay is the President and Medical Director of Barclay and Associates, P.C. in Ames, Iowa. Dr. Barclay received his medical degree from the University of Kentucky College of Medicine and completed his residency training in psychiatric medicine at the Naval Regional Medical Center in San Diego, California. He is certified by the American Board of Psychiatry & Neurology, is a Fellow in the American Psychiatric Association, is a Governing Board member of the American Society of Adolescent Psychiatry, and is a member of the Legislative Affairs Committee of the Iowa Psychiatric Society. Dr. Barclay was appointed to the DUR Commission in 2011; his first term will expire in June 2015.

## **Annual Call for New Commission Members**

**Attention Physicians and Pharmacists:  
Are you looking for a new professional opportunity?**

CMS requires state Medicaid programs to have a drug utilization review (DUR) program consisting of prospective DUR, retrospective DUR, and an educational program. The goal of the DUR program is to ensure appropriate medication therapy, while permitting appropriate professional judgment to individualize medication therapy. In Iowa, the DUR Board is referred to as the Iowa Medicaid DUR Commission. The Iowa DUR Commission is composed of four Iowa licensed physicians and four Iowa licensed pharmacists who serve up to two, four-year terms, as well as a representative from the Department of Human Services. The Commission meets on the first Wednesday six months of the year from 9:30 a.m. to 1:30 p.m.

The DUR Commission is currently seeking a Physician and Pharmacist who serve Medicaid Members to join the committee. Any Physician or Pharmacist interested in serving in this capacity should send a resume or curriculum vitae, as well as a letter indicating their interest to Pam Smith at the address shown below. Candidates that would like more information about the Commission or who would like to speak to a present Commissioner are encouraged to call.

**The deadline for applications is March 30, 2012.  
Term begins July 1, 2012**

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## New Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis from the AACE<sup>1</sup>

The American Association of Clinical Endocrinologists (AACE) updated its guidelines for the treatment of postmenopausal osteoporosis recently. The goals in the treatment of osteoporosis are to 1) prevent fractures by improving bone strength and reducing the risk of falling and injury; 2) to relieve symptoms of fractures and skeletal deformity; and 3) to maximize physical function.

Candidates for pharmacologic treatment of postmenopausal women include those with the following: 1) a hip or spine fracture (either clinical spine fracture or radiographic fracture) (Grade A); 2) a T-score of -2.5 or below at the spine, femoral neck, or total hip (Grade A); and 3) A T-score between -1.0 and -2.5 at high 10-year risk of fracture with use of the FRAX tool ([www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX)) where treatment is considered cost-effective if the 10-year risk is 3% or more for hip fracture or 20% or more for major osteoporosis-related fracture (Grade A).

Medications approved by the FDA for prevention or treatment of osteoporosis include bisphosphonates (alendronate, ibandronate, risedronate, and zoledronic acid), calcitonin, denosumab, estrogen, raloxifene, and teriparatide. All of these drugs reduce bone absorption except for teriparatide, which has anabolic effects on bone. The AACE recommends alendronate (*Fosamax*), risedronate (*Actonel*), zoledronic acid (*Reclast*), or denosumab (*Prolia*) as first-line agents due to their efficacy in reducing the risk of vertebral, nonvertebral, and hip fractures. Ibandronate (*Boniva*) is a second-line agent, as it has only been shown to reduce the risk of vertebral fractures. Raloxifene (*Evista*) is recommended as a second or third-line agent, while calcitonin (*Miacalcin*) is recommended as the last-line therapy. Teriparatide (*Forteo*) should be reserved for patients with very high fracture risk or inadequate response with bisphosphonate therapy. Estrogen is approved by the FDA for the prevention of postmenopausal osteoporosis. Once considered the treatment of choice for postmenopausal osteoporosis, estrogen should only be considered for women at significant risk of osteoporosis and for whom non-estrogen medications are not considered to be appropriate.

The guidelines also recommend a “drug holiday” by discontinuing bisphosphonate therapy after an extended period of treatment. This concept is based on the persistent antifracture effects lasting one year or longer after discontinuation. This may decrease the risk of rare adverse events, such as atypical fractures that may be associated with reduced bone turnover or osteonecrosis of the jaw. A drug holiday may be considered in patients with mild osteoporosis after four to five years of bisphosphonate therapy. Patients at a high risk for fracture may take a one to two-year drug holiday after 10 years of bisphosphonate therapy. Bone mineral density and bone turnover markers should continue to be monitored throughout the drug holiday, and treatment should be resumed if the patient experiences a fracture, substantial bone density loss, or increases in bone turnover markers. While a drug holiday is recommended, there are no studies available to support the validity of this recommendation.

Currently, alendronate and *Miacalcin* are the preferred osteoporosis agents on the PDL ([www.iowamedicaidpdl.com](http://www.iowamedicaidpdl.com)).

The complete guidelines can be found at the following link:  
<https://aace.com/sites/default/files/OsteoGuidelines2010.pdf>

### References:

1. Watts, N, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Postmenopausal Osteoporosis. *Endocrine Practice* 2010;16(Suppl 3).

## FDA Update

- The FDA issued a drug safety communication notifying healthcare professionals and the public of a possible increased risk of blood clots with birth control pills containing drospirenone. The statement was prompted by a review of data from two studies recently published in the *British Medical Journal* that reported a greater risk of VTEs (DVTs and PEs) in women who took drospirenone-containing birth control pills compared with women who took birth control pills containing levonorgestrel. A two- to three-fold greater risk of VTEs was reported. Healthcare professionals are being advised to continue to follow the recommendations in the drug labels when prescribing oral contraceptives that contain drospirenone. The known benefits and potential risks should be discussed with patients, and patients should be educated about the signs and symptoms of DVT and PE. Brand names of drospirenone-containing products include *Yaz* (generics *Gianvi* and *Loryna*), *Yasmin* (generics *Ocella*, *Syeda*, and *Zarah*), *Beyaz*, and *Safyral*.
- The FDA has announced new safety recommendations for high-dose simvastatin. The changes in the labeling information for the drug are being made because the 80mg dose has been associated with an elevated risk of muscle injury or myopathy, particularly during the first 12 months of treatment. The risk of muscle injury is greatest during the first year of treatment, is often the result of interactions with certain other medications, and is associated with a genetic predisposition for simvastatin-related muscle injury. The FDA recommends simvastatin 80mg be used only in patients who have been taking this dose for 12 months or more and have not experienced any muscle toxicity. The agency is advising health care professionals not to start new patients on this dose and to prescribe alternative LDL cholesterol-lowering drugs for patients who do not meet their LDL-cholesterol goal on the 40mg dose of simvastatin. Simvastatin is marketed as *Zocor* and is also available in generic formulations. It is also available in combination with ezetimibe (*Vytorin*) and in combination with niacin (*Simcor*)

## New and Updated Drug Prior Authorization Criteria (changes italicized)

**Colchicine (Colcrys®):** Prior authorization is not required for colchicine (Colcrys®) for the treatment of acute gout for three (3) tablets per 60-day period. Prior authorization is required for colchicine (Colcrys®) for the treatment of chronic hyperuricemia/gout prophylaxis or Familial Mediterranean fever. Payment will be considered under the following conditions: 1) Chronic hyperuricemia/gout prophylaxis following a trial and therapy failure at a therapeutic dose with allopurinol or probenecid. A quantity limit of sixty (60) tablets per thirty (30) days will be applied, when criteria for coverage for chronic hyperuricemia or gout prophylaxis are met. 2) Familial Mediterranean fever. A maximum quantity limit of 120 tablets per thirty (30) days will be applied for this diagnosis. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

**Fingolimod (Gilenya™):** Prior authorization is required for Gilenya™. Payment will be considered under the following conditions: 1) A diagnosis of relapsing forms of multiple sclerosis, AND 2) A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated. A quantity limit of thirty (30) tablets per thirty (30) days will be applied, when criteria for coverage are met.

**Vitamins, Minerals, and Multiple Vitamins:** Prior approval is not required for 1) *prescribed multi-vitamins with or without iron* or 2) *vitamin D supplements for patients under 12 months of age* or 3) a prescription product primarily classified as a blood modifier, if that product does not contain more than three vitamins/minerals or for products principally marketed as prenatal vitamin-mineral supplements.

**Medicaid Statistics for Prescription Claims  
from January 1, 2011 to March 31, 2011\***

Number of claims paid: 1,152,083

Average amount paid per claim: \$59.60

Total dollars paid: \$68,667,751.57

Average amount paid per claim, brand: \$220.43

Percent controlled substances: 18.42%

Average Amount paid per claim, generic: \$11.60

<b>Top Drugs by Number of Prescriptions</b>	<b>Top Drugs by Dollars Spent</b>	<b>Top Therapeutic Class by Dollars Spent</b>
<i>ProAir HFA</i> \$45.18/RX	<i>Synagis 100mg/ml</i> \$3,126,191 \$1,926.18/RX	Antipsychotics – Atypicals \$11.7 million
Hydrocodone/APAP 5-500 \$4.83/RX	<i>Concerta 36mg</i> \$1,368,629 \$241.89/RX	Stimulants – Amphetamines – Long Acting \$4.6 million
Cheratussin Syrup AC \$5.98/RX	<i>Abilify 5mg</i> \$1,209,194 \$454.24/RX	Stimulants – Methylphenidate- Long Acting \$3.9 million
<i>Lexapro 20mg</i> \$96.06/RX	<i>Concerta 54mg</i> \$941,573 \$212.64/RX	RSV Prophylaxis \$3.4 million
Tramadol HCL 50mg \$6.41/RX	<i>Abilify 10mg</i> \$946,938 \$468.78/RX	Anticonvulsants \$3.4 million

\*All dollars reported are Pre-Rebate