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**Drug Utilization Review Board Meeting
Meeting Agenda, Open Session
June 15, 2011, 10:00 a.m.**

Meeting Location

HP Enterprise Services ~ Capital and Cedar Crest Rooms
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, Kansas 66619

Board Members

Michael Burke, M.D, Ph.D. Dennis Grauer, Ph.D.
John Kollhoff, Pharm.D. Judy McDaniel Dowd, PA-C
Daniel Sutherland, R.Ph. Roger Unruh, D.O
Kevin Waite, Pharm.D.

KHPA Staff

Margaret Smith, M.D. Shea Robinson
Shelly Liby Kelley Melton, Pharm.D.

HP Enterprise Services / HID Staff

Karen Kluczykowski, R.Ph. Debra Quintanilla, R.N.
Lisa Todd, R.Ph. Nicole Churchwell, Pharm.D.

ACS Staff

Bethany Noble, C.Ph.T. Karen Powell, Pharm.D.

I. Call to Order

II. Announcements

III. Old Business

A. Review and Approval of April 13, 2011 Meeting Minutes

B. Acne Medications (Differin[®] (adapalene), Epiduo[®] (adapalene/benzyl peroxide), Azelex[®] & Finacea[®] (azelaic acid), Aczone[®] (dapsone), Retin-A[®] & Atralin[®] (tretinoin), Veltin[®] & Ziana[®] (tretinoin/clindamycin), and Tazorac[®] (tazarotene))

Currently, tretinoin topical agents for acne require prior authorization while other topical acne treatments do not. To ensure consistency, prior authorization criteria for all other agents in this class are being proposed. The prior authorization criteria being proposed reflect the current package inserts for these products.

- i. New Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

IV. New Business

A. Retinoids (Targretin[®] (bexarotene), Panretin[®] (alitretinoin), and Vesanoid[®] (tretinoin))

The retinoid agents currently require prior authorization. In April 2011 the DUR board requested this criteria be revised, the proposed revised prior authorization criteria match the current package inserts for these products.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

B. Rituxan[®] (rituximab)

Indications for Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA) were approved in April 2011 by the FDA, the prior authorization criteria is being revised to include the newly approved indications.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

C. Regranex[®] (becaplermin)

The package insert for Regranex was updated in March 2011 and the prior authorization criteria are being revised to reflect the current package insert.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

D. Topical Immunomodulators (Elidel[®] (pimecrolimus) and Protopic[®] (tacrolimus))

The current prior authorization criteria state that Protopic 0.1% ointment is approvable for patients 15 years of age or older. Revisions to the prior authorization criteria are being proposed to change the wording to 16 years of age or older to match the current prescribing information.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

E. Enbrel[®] (etanercept)

The current Enbrel prior authorization criteria require the prescriber to manually provide the specific diagnosis of plaque psoriasis since there is no corresponding ICD-9 code. We recommend using the general ICD-9 code for psoriasis (696.1) in the SmartPA rule to allow PA approval at the point-of-sale (POS).

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

*Public Comment is limited to five minutes per product; additional time will be allowed at the Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

**** This agenda is subject to change.**

F. Humira® (adalimumab)

The current Humira prior authorization (PA) criteria require the prescriber to manually provide the specific diagnosis of plaque psoriasis since there is no corresponding ICD-9 code. While PA approval at the point-of sale (POS) is not possible due to other PA requirements, we recommend using the general ICD-9 code for psoriasis (696.1) in the SmartPA rule for consistency among all agents used for the treatment of plaque psoriasis. Also the current prior authorization criteria for other biologics (e.g., Enbrel, Kineret, Remicade), do not allow for authorization of more than one biologic. The limitation of one biologic authorization is not in the current Humira PA criteria. We recommend adding this limitation to the Humira criteria.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

G. Remicade® (infliximab)

The current Remicade prior authorization (PA) criteria require the prescriber to manually provide the specific diagnosis of plaque psoriasis since there is no corresponding ICD-9 code. We recommend using the general ICD-9 code for psoriasis (696.1) in the SmartPA rule to allow PA approval at the point-of-sale (POS).

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

H. Amevive® (alefacept)

The current Amevive prior authorization (PA) criteria require the prescriber to manually provide the specific diagnosis of plaque psoriasis since there is no corresponding ICD-9 code. While PA approval at the point-of sale (POS) is not possible due to other PA requirements, we recommend using the general ICD-9 code for psoriasis (696.1) in the SmartPA rule for consistency among all agents used for the treatment of plaque psoriasis.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

I. Forteo® (teriparatide)

Forteo has a new indication for treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. The prior authorization criteria are being revised to reflect this new indication.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

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J. Weight Loss Drugs (Xenical® & Alli® (orlistat) and Adipex-P® (phentermine))

The criteria for orlistat and phentermine allow for approval in pediatric patients (orlistat \geq 12 years) as long as the Body Mass Index (BMI) and other criteria are met. BMI is reported for people over 20 years of age and Body Mass Index percentiles for age are typically reported for those 2-20 years of age. While PA approval at the point-of sale (POS) is not possible due to other PA requirements, we recommend adding the ICD-9 for BMI that is greater than or equal to the 95th percentile for age (V85.54) to the BMI criteria to better assess overweight or obese pediatric patients who might be eligible for these medications. The current package insert for phentermine states that the safety and effectiveness in pediatric patients has not been established therefore it is being recommended the age criteria for phentermine be changed from \geq 16 years of age to \geq 17 years of age.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

K. Long-Acting Opioids (Butrans® (buprenorphine), Duragesic® (fentanyl), Embeda® (morphine/naltrexone), Opana ER® (oxymorphone), Kadian® (morphine), Avinza® (morphine), MS Contin® (morphine), Oramorph® (morphine))

Hydromorphone ER (Exalgo) and Oxycodone SR (Oxycontin, generics) were incorporated into the Meperidine/Hydromorphone/Oxycodone SR proposal and Tramadol ER (Ultram ER, generics, Ryzolt) was incorporated into the Narcotics/Tramadol/Skeletal Muscle Relaxants proposal. This was an operational change to improve efficiency and allow claims for these agents to flow through a single rule incorporating all clinical criteria and audit limits.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

L. Demerol® (meperidine), Dilaudid® (hydromorphone), Exalgo® (hydromorphone ER) and OxyContin® (oxycodone)

The long-acting opioid criteria were incorporated into the Meperidine/Hydromorphone/Oxycodone SR criteria to apply to hydromorphone ER (Exalgo) and oxycodone SR (OxyContin, generics).

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

M. Narcotics, Tramadol, and Skeletal Muscle Relaxants

The long-acting opioid criteria for Tramadol ER (Ultram ER, generics, Ryzolt) were incorporated into the Narcotics/Tramadol/SMR criteria along with the Preferred Drug List (PDL) criteria for Muscle Relaxants. This was an operational change to improve efficiency and allow a claim to flow through a single rule incorporating all clinical criteria, audit limits, and PDL requirements.

- i. Revised Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

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N. Arcalyst® (rilonacept)

Arcalyst is an interleukin-1 blocker indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). The other agent in this class, Ilaris® (canakinumab) was approved for prior authorization in October 2009 by the DUR board, to remain consistent among the class prior authorization criteria for Arcalyst is being proposed.

- i. New Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

O. Makena® (hydroxyprogesterone)

Multiple limits are being proposed for Makena including: quantity limits, diagnosis restrictions and prior authorization criteria. Quantity limits will ensure that the proper length of therapy is being used; prior authorization criteria are being proposed to ensure women have the indicated risk factors for preterm labor for use of Makena. Diagnosis restrictions are also being proposed to ensure women have the indicated risk factor for preterm labor for use of Makena since these restrictions can be implemented quicker than prior authorization criteria.

- i. Quantity Limits, Diagnosis Restrictions & New Clinical PA Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

P. Pradaxa® (dabigatran)

Quantity and day supply limits based upon the current package insert are being proposed for Pradaxa.

- i. Day Supply Limits & Quantity Limits
- ii. *Public Comment
- iii. Board Discussion/Action

Q. State Fiscal Year 2012 Retro-DUR Intervention Topic Selection

The DUR board needs to select 2-3 topics for Intervention in SFY 2012, the remaining topics will be selected at the October DUR board meeting.

- i. Intervention Topic Selection
- ii. *Public Comment
- iii. Board Discussion/Action

V. Public Comment

VI. Adjourn

**Lunch will be provided for DUR Board Members
NEXT MEETING: October 12, 2011**

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