GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Georgia Department of Community Health

DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health
2 Peachtree Street – 5th Floor Board Room
Atlanta, Georgia 30303

December 4, 2014

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

DRUG UTILIZATION REVIEW BOARD MEETING
AGENDA
2 Peachtree Street – 5th Floor Board Room
Atlanta, Georgia 30303
Thursday, December 4, 2014
9:30 a.m. to 1:30 p.m.

CALL TO ORDER	*Joseph Bona, MD, Chair*
COMMENTS FROM THE DEPARTMENT	*Linda Wiant, PharmD, Pharmacy Director*
MINUTES FROM PREVIOUS MEETING	*Chair*
ADVOCATE COMMENTS SESSION	*Chair*
ADJOURNMENT OF OPEN SESSION	*Chair*
EXECUTIVE SESSION	*Steve Liles, PharmD, Goold*
RECONVENING OF OPEN SESSION	*Chair*
CLINICAL REVIEWS	*Tara R. Cockerham, PharmD, NorthStar* *Emily Baker, PharmD, BCPS, NorthStar*
➢ **Manufacturers' Forum**	*Afzal Mistry, PharmD, NorthStar*

➢ **New Drug Reviews**
- ●Eloctate
- ●Grastek, Oralair, Ragwitek
- ●Myalept
- ●Zykadia
- ●Hetlioz

➢ **Class Reviews**
- ●Sedative Hypnotics
- ●Granulocyte Colony Stimulating Factors

➢ **Utilization Trends**

➢ **Drug Information**
- ●Drug Update Newsletter
- ●Horizon Watch Report
- ●Patent Expiration Report
- ●Clinical Compass Newsletter

FUTURE AGENDA ITEMS	*Chair*
ADJOURNMENT	*Chair*
LUNCH	

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Department of Community Health
Drug Utilization Review Board (DURB)
MINUTES
Thursday, September 18, 2014

MEMBERS PRESENT

Joseph R. Bona, M.D., MBA, Chair
Osgood (Drew) A. Miller, R.Ph., Vice-Chair
Mia Avery, Pharm.D.
Ann R. Damon, Pharm.D.
Gurinder J.S. Doad, M.D.
Traci Ferguson, M.D.
Deborah W. Fincher, M.S., R.Ph.
M. Celeste Fowler, Pharm.D.
Thomas B. Gore, M.D.
John Greeson, M.D., MBA
Edwina L. Jones, Pharm.D., MBA
Robyn Lorys, Pharm.D.
J. Russell May, Pharm.D.
Donald A. Paul, M.D.
Brent L. Rollins, R.Ph., Ph.D.
Robert E. Shervette III, M.D.
Mary Virginia "Ginny" Yates, Pharm.D.

MEMBERS ABSENT

Staff
Linda Wiant, Pharm.D., Pharmacy Director, Pharmacy Services
Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Rose Marie Duncan, MBA, Program Associate, Pharmacy Services

NorthStar HealthCare Consulting
Emily Baker, Pharm.D., BCPS, MHA, MBA, President
Tara R. Cockerham, Pharm.D., Clinical Programs Director

Catamaran
Kelly Coleman, Account Manager
Talmahjia “Tami” Sweat, Pharm.D., Clinical Systems Product Manager

Goold Health Services
Steve Liles, Pharm.D., Sr. Director, Pharmacy Services
Doug Martin, Pharm.D., Pharmacy Project Manager

Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its third meeting for the calendar year on September 18, 2014. The Chair, Joseph R. Bona, M.D., MBA, called the meeting to order at 9:33am.

Comments from the Department

Linda Wiant, Pharm.D., Pharmacy Director, Pharmacy Services, commented on the following items:

1. Procurements – Rebate will be out mid-October for a 7/1/15 start date; PBM will be posted January/February 2015 with a start date of 7/1/16; Other procurements – CMOs, GMCF for a 7/1/16 start date.
2. Flu Vaccines – The Department began covering flu vaccines through pharmacies on 8/1/14.

Minutes from the Previous Meeting

Dr. Bona asked for corrections or changes to the minutes from the June 5, 2014 meeting. There were no corrections. A motion was made (Thomas B. Gore, M.D.), seconded (Ann R. Damon, Pharm.D.), and carried to approve the minutes as written.

Consumer Comments Session

Consumer comments were presented to the Board from the following:

- Kate McGinnis, R.N., Neonatal nursing student-Emory School of Nursing – Synagis prophylaxis.
- Suzanne Staebler, DNP, APRN, NNP-BC, FAANP, Associate Professor-Emory School of Nursing, Neonatal Nurse Practitioner-Emory School of Medicine – Restrictions in the new RSV Guidelines.
- Tara Cockerham, Pharm.D., provided an overview of written comments received by two pediatricians regarding the new RSV guidelines.

Disclosure forms were completed by Kate McGinnis, R.N., and Suzanne Staebler, DNP, APRN, NNP-BC, FAANP, and were reviewed by the Department.

Respiratory Syncytial Virus (RSV) Guidelines Update

Tara Cockerham, Pharm.D., reviewed the American Academy of Pediatrics guidelines for Synagis prophylaxis use and compared the differences of the 2014 vs. 2012 guidelines.

Guest Expert Speaker

Harry Keyserling, M.D., spoke on RSV disease and the new guidelines. He addressed questions from the Board and the Board commented on the following:

- Cystic Fibrosis patients – study didn't show a benefit.
- Neuromuscular disease – ex. rare congenital muscle problems – no studies in this group; expert opinion would consider these infants as high risk.
- Hall Study – powerful study but doesn't show difference in hospitalization rates; no comparison of no prophylaxis vs. intervention.
- Recommendation for prophylaxis – base on risk factors of gestational and chronological age; cut point 29 weeks; severity of disease.
- New guidelines – very evidence based.

- Other Medicaid plans – still evaluating on whether to follow the guidelines; most will take to their P&T or DURB.
- With new guidelines, there would be a reduction in patients treated (nationally ~50,000; 40% reduction-2012 guidelines).
- Prior Authorizations – criteria applied through a series of questions handled by the Call Center; pharmacist review to determine if denied appropriately; 1st level appeal-reviewed by pharmacist at NorthStar; 2nd level appeal – reviewed at the Department.
- Risks for patients not getting Synagis – not a treatment but prophylaxis; some infants would get 1st dose in hospital.
- Synagis effectiveness – given prophylactically; does not prevent RSV infection; it prevents progression to severe disease; in one controlled study-prevented hospitalizations and ICU admissions by 50%.
- Appeals process – DCH can provide a peer-to-peer review; specific diagnoses can be put into criteria on the front end; clinical judgment is used in the appeal process.

It was moved (Thomas B. Gore, M.D.) and seconded (Robyn Lorys, Pharm.D.) to approve the 2014 AAP guidelines for administration of Synagis. The motion carried.

Adjournment of Open Session

The DUR Board voted to close the open meeting pursuant to the Open Meeting Act of Georgia Section 50-14-1 – 50-14-6 and pursuant to Federal Law Section 1396R-8B3D. The individuals recorded in attendance with the Board members were from the Department of Community Health, Goold Health Services, NorthStar HealthCare Consulting, and Catamaran. A motion was made by Thomas B. Gore, M.D., and seconded by J. Russell May, Pharm.D., to adjourn the open session and approve the closed session. There was a unanimous vote approving the closed session. The Chairman, Dr. Joseph R. Bona, adjourned the open session at approximately 10:24 am, at which time members took a break then reconvened for the executive (closed) session.

Executive Session

The Executive Session was held from 10:35am to 11:20am.

Reconvening of Open Session

The DUR Board reconvened for the open session at 11:23am.

Manufacturers' Forum

Tara Cockerham, Pharm.D., reviewed information regarding the Manufacturers' Forum that was provided in the Manufacturer Information section in the DUR Board binder. A total of eight (8) manufacturers participated and provided information regarding the following drugs discussed at the September 2014 DURB meeting:

Manufacturers	Drugs
Novartis	Zortress
Bristol Myers Squibb	Sprycel
Pfizer	Duavee
AstraZeneca	Farxiga
Astellas	Astagraf XL, Xtandi
Fresnius	Velphoro

Kaleo	Evzio
Takeda	Colcrys

There were no questions or comments. The next forum will be held on Thursday, November 6, 2014 from 9am-5pm at the NorthStar Healthcare Consulting office: 1121 Alderman Drive, Suite 112, Alpharetta, GA 30005.

New Drug Reviews

Clinical information for the following new drugs, in the market six months or more, was presented for discussion and recommendations. The complete detailed drug summary is in the New Drugs for Review section of the DUR Board binder.

Therapeutic Class	Drugs	Presenter
Estrogen-Selective Estrogen Receptor Modifiers	*Duavee*	Emily Baker, Pharm.D., BCPS
Antidiabetics, Non-Insulin	*Farxiga*	Emily Baker, Pharm.D., BCPS
Antineoplastics, Enzyme Inhibitor for Acute Lymphocytic Leukemia (ALL) and Chronic Myelogenous Leukemia	*Iclusig*	Emily Baker, Pharm.D., BCPS
Dermatologic, Antifungals	*Luzu*	Emily Baker, Pharm.D., BCPS
Phosphate Binder Agents	*Velphoro*	Emily Baker, Pharm.D., BCPS
Analgesics, Opioid Long-Acting	*Zohydro ER*	Emily Baker, Pharm.D., BCPS

The Board discussed the drug information, provided comments, and raised questions on the following:

- Farxiga – hyperkalemia differences between agents may be structural; expensive
- Iclusig – preferred vs. non-preferred status
- Luzu – expensive
- Velphoro – discoloration of feces
- Zohydro ER – no tamper resistant technology; place in therapy in chronic pain; concerns with long term dosing; confusion over dosing with short-acting; cautions in liver/kidney disease

The Board voted and made recommendations for all new drug reviews noted in the Board's Recommendations to the Department.

Non-Supplemental Rebate Drugs – New Clinical Information Review

Clinical updates to the Supplemental Rebate categories were listed in the Supplemental Rebate section of the DURB binder and presented to the Board by Dr. Tara Cockerham. The following therapeutic categories had updates:

Drug Class/Name
Antibiotics, Fluoroquinolones
Antibiotics, Macrolides
Antibiotics, Tetracyclines
Antifungals, Oral
Antihistamines, Oral
Antihypertensives, Calcium Channel Blockers
Antivirals, Genital Herpes Simplex
Antivirals, Influenza Agents
Contraceptives
Dermatologics, Acne Products
Dermatologics, Antivirals, Herpes Labialis
Dermatologics, Enzymes
Dermatologics, Genital warts
Dermatologics, Local Anesthetics
Gastrointestinal, Ulcer Drugs, H-2 Antagonists
Gastrointestinal, Ulcer Drugs, Proton Pump Inhibitors
Gout Agents
Hemostatics
Immunosuppressive Agents for Organ Transplant Rejection
Luteinizing-Hormone-Releasing Hormone (LHRH)/Gonadotropin-Releasing Hormone (GNRH) Agonist Analogs
Respiratory, Leukotriene Modifiers
Skeletal Muscle Relaxants

The Board commented on the following:

- Macrolides – pricing has increased but leave one as preferred.
- Nizatidine – preferred for renal patients; include in PA criteria

The Board voted and made recommendations for changes to the Non-Supplemental Rebate drugs noted in the Board's Recommendations to the Department.

Retrospective Drug Utilization Review (RDUR) Update

Emily Baker, Pharm.D., BCPS, reviewed information from the RetroDUR interventions' summaries and outcomes that was provided in the RDUR Update section of the DUR Board binder. The Board commented on the following: low response rate on the NSAIDs; high number of members receiving NSAID duplicative therapy; follow-up with diagnoses, which medications and if patients are still on the medication. Ideas for new interventions were: HIV-duplicative therapy; Onfi – appropriate use; Sovaldi – outcomes; Abilify – appropriate use and therapeutic duplication; Drug interactions-class 1.

Utilization Trend Review

Utilization trends for Georgia Medicaid Fee-for-Service were provided in detail in the Utilization Trends section of the DUR Board binder.

Drug Information

Information from the following was provided in detail in the Drug Information section of the DUR Board binder used for this meeting:

- Drug Update Newsletter
- Horizon Watch Report
- Patent Expiration Report
- Clinical Compass Newsletter

THERDOSE Overview

Tami Sweat, Pharm.D., provided an overview of the DUR edit, THERDOSE, which performs an ingredient-level examination of product strength consumed daily. The Board provided comments on the following: look at doses on the SSRIs and Antipsychotics; evaluate doses on racemic mixtures; ER vs. IR dosing; look at literature to determine max doses.

Future Agenda Items

There were no additional future agenda items noted.

Upcoming Meetings

The following upcoming meetings were published in the DURB binder:

- Drug Utilization Review Board
  2 Peachtree Street NW
  5th Floor Board Room
  Atlanta, Georgia 30303

  Thursday, December 4, 2014

- Manufacturers' Forum
  NorthStar Healthcare Consulting
  1121 Alderman Drive
  Suite 112
  Alpharetta, Georgia 30005

  Thursday, November 6, 2014

Disclosure Forms

Disclosure forms were received and reviewed by the Department for completeness for all Board members attending the meeting.

Board's Recommendations to the Department

After all clinical and financial evaluations and discussions, the DUR Board voted and presented the Department with the following recommendations for changes to the Preferred Drug List (PDL). All motions and votes are noted in Attachment A.

New Drugs and Non-Supplemental Rebate Classes

Drug Reviews

Estrogens-Selective Estrogen Receptor Modifiers

The DUR Board recommended ***Preferred*** status for ***Cenestin® (Oral) Tablet, Activella® (Oral) Tablet*** and ***Raloxifene (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Duavee® (Oral) Tablet, Estrace® (Oral) Tablet, Evista® (Oral) Tablet*** and ***Minivelle® (Transdermal) Patch***.

Antidiabetics – Non-Insulin

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Farxiga® (Oral) Tablet***.

Antineoplastics – Enzyme Inhibitors for Acute Lymphocytic Leukemia (ALL) and Chronic Myelogenous Leukemia (CML)

The DUR Board recommended ***Preferred*** status with ***Prior Authorization*** for ***Iclusig® (Oral) Tablet***.

Dermatologics - Antifungals

The DUR Board recommended ***Preferred*** status for ***Econazole (Topical) Cream*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Luzu® (Topical) Cream*** and ***Nystatin-Triamcinolone (Topical) Cream and Ointment***.

Phosphate Binder Agents

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Velphoro® (Oral) Tablet Chew***.

Analgesics – Opioid Long-Acting

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Zohydro® ER (Oral) Capsule***.

Antibiotics - Macrolides

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Ery-Tab® (Oral) Tablet, EES® 400 (Oral) Tablet, Erythrocin® (Oral) Tablet, Erythromcyin (Oral) Tablet, PCE® (Oral) Tablet, EES® 200 (Oral) Suspension, Erythromycin (Oral) Capsule, EryPed® 200 (Oral) Suspension*** and ***EryPed® 400 (Oral) Suspension***.

Antifungals - Oral

The DUR Board recommended ***Preferred*** status for ***Terbinafine (Oral) Tablet*** and ***Preferred*** status with ***Prior Authorization*** for ***Sporanox® (Oral) Solution***.

Antihistamines - Oral

The DUR Board recommended ***Preferred*** status for ***Levocetirizine (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** ***Arbinoxa® (Oral) Tablet and Liquid and Clarinex® (Oral) Syrup and Tablet***.

Antivirals – Genital Herpes Agents

The DUR Board recommended ***Preferred*** status for ***Acyclovir (Topical) Ointment*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Zovirax® (Topical) Ointment***.

Dermatologics – Genital Warts

The DUR Board recommended ***Preferred*** status for ***Aldara® (Topical) Cream*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Imiquimod (Topical) Cream***.

Gastrointestinal, Ulcer Drugs – Histamine-2 (H-2) Antagonists

The DUR Board recommended ***Non-Preferred*** status with ***Prior Authorization*** for ***Nizatidine (Oral) Capsule and Solution***, allowing access to renal patients through the prior authorization criteria.

Immunosuppressive Agents for Organ Transplant Rejection

The DUR Board recommended ***Preferred*** status for ***Sirolimus (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Rapamune® (Oral) Tablet***.

Skeletal Muscle Relaxants

The DUR Board recommended ***Non-Preferred*** status for ***Metaxalone (Oral) Tablet*** and ***Non-Preferred*** status with ***Prior Authorization*** for ***Carisoprodol Compound-Codeine (Oral) Tablet*** and ***Skelaxin® (Oral) Tablet***.

Conclusion

At the conclusion of the reconvened open session and no other business for discussion, there was a unanimous decision to adjourn the meeting. Chair Bona adjourned the meeting at 1:09pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY OF _____, 2014.

_____

Joseph R. Bona, M.D., MBA, Chair

CLINICAL REVIEW	

Motion/Recommendation: **Approve the 2014 American Acacemy of Pediatrics guidelines for the administration of Synagis.**

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.	√		√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 18, 2014

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ESTROGENS - SELECTIVE ESTROGEN RECEPTOR MODIFIERS	ACTIVELLA (ORAL) TABLET	NP	P	
	CENESTIN (ORAL) TABLET	NP	P	
	DUAVEE (ORAL) TABLE	NP/PA	NP/PA	
	ESTRACE (ORAL) TABLE	P	NP/PA	
	EVISTA (ORAL) TABLET	P	NP	
	MINIVELLE (TRANSDERM) 0ATCH TDSW	P	NP/PA	
	RALOXIFENE HCL (ORAL) TABLE	NPPA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA	√		√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)		√	√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	**0**	**0**

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 18, 2014

New Drug		Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTIDIABETICS - NON-INSULIN		FARXIGA (ORAL) TABLET	NP/PA	NP/PA		
	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.	√		√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)		√	√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 18, 2014

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments	
ANTINEOPLASTICS - ALL CML	ICLUSIG (ORAL) TABLET	P/PA	P/PA		
Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1 Avery, Mia, Pharm.D.	√		√		
2 Bona, Joseph R. M.D. - Chair			√		
3 Damon, Ann R., Pharm.D.				√	
4 Doad, Gurinder J.S., M.D.			√		
5 Ferguson, Traci, M.D.				√	
6 Fincher, Deborah W., M.S., R.Ph.		√	√		
7 Fowler, M. Celeste, Pharm.D.			√		
8 Gore, Thomas B., M.D.			√		
9 Greeson, John D., M.D., MBA			√		
10 Jones, Edwina L., Pharm.D., MBA			√		
11 Lorys, Robyn Pharm.D.				√	
12 May, J. Russell (Rusty)			√		
13 Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14 Paul, Donald A., M.D.				√	
15 Rollins, Brent L., R.Ph., Ph.D.			√		
16 Shervette III, Robert E., M.D.			√		
17 Yates, Mary Virginia "Ginny", Pharm.D.				√	
			12	**5**	**0**

16

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 18, 2014

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
DERMATOLOGIC, ANTIFUNGALS	ECONAZOLE NITRATE (TROPICAL) CREAM	NP/PA	P	
	LUZU (TROPICAL) CREAM	NP/PA	NP/PA	
	NYSTATIN-TRIAMCINOLONE (TROPICAL) CREAM	P	NP/PA	
	NYSTATIN-TRIAMCINOLONE (TROPICAL) OINT	P	NP/PA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.	√		√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)		√	√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	**0**	**0**

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 18, 2014

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
PHOSPHATE BINDER AGENTS	VELPHORO (ORAL) TAB CHEW	NP/PA	NPPA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)	√		√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	**0**	**0**

Drug Utilization Review Board

Motions - Votes - **New Drugs**

September 18, 2014

New Drug	Drug	PDL Status	Motion - Recommendations	Additional Comments
ANALGESICS, OPIOID LONG-ACTING	ZOHYDRO ER	NP/PA		

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA		√	√		
10	Jones, Edwina L., Pharm.D., MBA	√		√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

ANTIBIOTICS, FLUOROQUINOLONES

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

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ANTIBIOTICS, MACROLIDES

Drug	PDL Status	Motion - Recommendations	Additional Comments
E.E.S. 200 (ORAL) SUSP RECON	P	NP/PA	
E.E.S. 400 (ORAL) TABLET	P	NP/PA	
ERYPED 200 (ORAL) SUSP RECON	P	NP/PA	
ERYPED 400 (ORAL) SUSP RECON	P	NP/PA	
ERY-TAB (ORAL) TABLET DR	P	NP/PA	
ERYTHROCIN STEARATE (ORAL) TABLET	P	NP/PA	
ERYTHROMYCIN (ORAL) CAPSULE DR	P	NP/PA	
ERYTHROMYCIN (ORAL) TABLET	P	NP/PA	
PCE (ORAL) TAB PART	P	NP/PA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)	√		√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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ANTIBIOTICS, TETRACYLINES

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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	Board Members - Absent (Highlight, when present)

ANTIFUNGALS, ORAL

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	SPORANOX (ORAL) SOLUTION	NP/PA	P/PA	
	TERBINAFINE HCL (ORAL) TABLET	P/PA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.		√	√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA	√		√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

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ANTIHISTAMINES, ORAL

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	ARBINOXA (ORAL) LIQUID	P	NP/PA	
	ARBINOXA (ORAL) TABLET	P	NP/PA	
	CLARINEX (ORAL) SYRUP	P/PA	NP/PA	
	CLARINEX (ORAL) TABLET	P/PA	NP/PA	
	LEVOCETIRIZINE DIHYDROCHLORIDE (ORAL) TABLET	NP/PA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA		√	√		
11	Lorys, Robyn Pharm.D.	√		√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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ANTIHYPERTENSIVES, CALCIUM CHANNEL BLOCKERS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

25

ANTIVIRALS, GENITAL HERPES SIMPLEX

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	ACYCLOVIR (TOPICAL) OINT. (G)	NP/PA	P	
	ZOVIRAX (TOPICAL) OINT. (G)	P	NP/PA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)	√		√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.		√	√		
				17	0	0

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ANTIVIRALS, INFLUENZA AGENTS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

27

	Board Members - Absent (Highlight, when present)

CONTRACEPTIVES - PROGESTINS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

28

CONTRACEPTIVES - COMBOS - NON-ORAL

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

29

CONTRACEPTIVES - COMBOS- ORAL

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

30

CONTRACEPTIVES - BIPHASIC - ORAL

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

CONTRACEPTIVES - TRIPHASIC - ORAL

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

32

CONTRACEPTIVES EXT-CYCLE ORAL

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

33

DERMATOLOGICS, ACNE PRODUCTS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

34

DERMATOLOGICS, ANTIVIRALS - HERPES LABIALIS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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DERMATOLOGICS, ENZYMES

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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DERMATOLOGICS, GENITAL WARTS

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	ALDARA (TOPICAL) CREAM PACK	NP	P	
	IMIQUIMOD (TOPICAL) CREAM PACK	P	NP/PA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.	√		√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)		√	√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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DERMATOLOGICS, LOCAL ANESTHETICS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

GASTROINTESTINAL, ULCER DRUGS, H-2 ANTAGONISTS

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	NIZATIDINE (ORAL) CAPSULE 150 MG	P	NP/PA	
	NIZATIDINE (ORAL) CAPSULE 300 MG	P	NP/PA	
	NIZATIDINE (ORAL) SOLUTION 150MG/10ML	P	NP/PA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.	√		√		
9	Greeson, John D., M.D., MBA		√	√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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GASTROINTESTINAL, ULCER DRUGS, PROTON PUMP INHIBITORS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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GOUT AGENTS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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	Board Members - Absent (Highlight, when present)

HEMOSTATICS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

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IMMUNOSUPPRESSIVE AGENTS

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	RAPAMUNE (ORAL) TABLET	P	NP/PA	
	SIROLIMUS (ORAL) TABLET	NP/PA	P	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.		√	√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA	√		√		
11	Lorys, Robyn Pharm.D.					√
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

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LHRH-GNRH AGONIST ANALOGS

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

RESPIRATORY, LEUKOTRIENE MODIFIERS (BRONCHODIL, LT MODULATORS)

Motion: No PDL status change for the drugs in this class

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.			√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA			√		
11	Lorys, Robyn Pharm.D.		√	√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**	√		√		
14	Paul, Donald A., M.D.					√
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				16	**0**	**1**

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SKELETAL MUSCLE RELAXANTS (MUSCULOSKELETAL THERAPY AGENTS)

	Drug	PDL Status	Motion - Recommendations	Additional Comments
	CARISOPRODOL COMPOUND-CODEINE (ORAL) TABLET	P	NP/PA	
	METAXALONE (ORAL) TABLET	NP/PA	NP	
	SKELAXIN (ORAL) TABLET	NP	NP/PA	

	Board Members - Present (Strike out, when absent)	Motion Maker (√)	Seconded By (√)	VOTES YES (√)	NO (√)	ABSTAIN (√)
1	Avery, Mia, Pharm.D.			√		
2	Bona, Joseph R. M.D. - Chair			√		
3	Damon, Ann R., Pharm.D.		√	√		
4	Doad, Gurinder J.S., M.D.			√		
5	Ferguson, Traci, M.D.			√		
6	Fincher, Deborah W., M.S., R.Ph.			√		
7	Fowler, M. Celeste, Pharm.D.			√		
8	Gore, Thomas B., M.D.			√		
9	Greeson, John D., M.D., MBA			√		
10	Jones, Edwina L., Pharm.D., MBA	√		√		
11	Lorys, Robyn Pharm.D.			√		
12	May, J. Russell (Rusty)			√		
13	Miller, Osgood (Drew) A. R.Ph. - **Vice**			√		
14	Paul, Donald A., M.D.			√		
15	Rollins, Brent L., R.Ph., Ph.D.			√		
16	Shervette III, Robert E., M.D.			√		
17	Yates, Mary Virginia "Ginny", Pharm.D.			√		
				17	0	0

Drug Utilization Review Board Meeting			
September 18, 2014			
Therapeutic Class	Drug Name	Current PDL Status	DCH Decisions
Drug Reviews			
Estrogens-Selective Estrogen Receptor Modifiers			
	Duavee (Oral) Tablet	NP/PA	NP/PA
	Cenestin (Oral) Tablet	NP	P
	Activella (Oral) Tablet	NP	P
	Raloxifene (Oral) Tablet	NP/PA	P
	Estrace (Oral) Tablet	P	NP/PA
	Evista (Oral) Tablet	P	NP/PA
	Minivelle (Transdermal) Patch	P	NP/PA
Antidiabetics – Non-Insulin			
	Farxiga (Oral) Tablet	NP/PA	NP/PA
Antineoplastics – Enzyme Inhibitors for Acute Lymphocytic Leukemia (ALL) and Chronic Myelogenous Leukemia (CML)			
	Iclusig (Oral) Tablet	P/PA	P/PA
Dermatologics - Antifungals			
	Luzu (Topical) Cream	NP/PA	NP/PA
	Econazole (Topical) Cream	NP/PA	P
	Nystatin-Triamcinolone (Topical) Cream	P	NP/PA
	Nystatin-Triamcinolone (Topical) Ointment	P	NP/PA
Phosphate Binder Agents			
	Velphoro (Oral) Tablet Chew	NP/PA	NP/PA
Analgesics, Opioid Long-Acting			
	Zohydro ER (Oral) Capsule	NP/PA	NP/PA

Antibiotics - Macrolides			
	Ery-Tab (Oral) Tablet	P	NP/PA
	EES 400 (Oral) Tablet	P	NP/PA
	Erythrocin (Oral) Tablet	P	NP/PA
	Erythromycin (Oral) Tablet	P	NP/PA
	PCE (Oral) Tablet	P	NP/PA
	Erythromycin (Oral) Capsule	P	NP/PA
	EryPed 200 (Oral) Suspension	P	NP/PA
	EryPed 400 (Oral) Suspension	P	NP/PA
Antifungals - Oral			
	Terbinafine (Oral) Tablet	P/PA	P
	Sporanox (Oral) Solution	NP/PA	P/PA
Antihistamines - Oral			
	Levocetirizine (Oral) Tablet	NP/PA	P
	Arbinoxa (Oral) Tablet	P	NP/PA
	Arbinoxa (Oral) Liquid	P	NP/PA
	Clarinex (Oral) Syrup	P/PA	NP/PA
	Clarinex (Oral) Tablet	P/PA	NP/PA
Antivirals – Genital Herpes Agents			
	Acyclovir (Topical) Ointment	NP/PA	P
	Zovirax (Topical) Ointment	P	NP/PA
Dermatologics – Genital Warts			
	Aldara (Topical) Cream	NP	P
	Imiquimod (Topical) Cream	P	NP/PA
Gastrointestinal, Ulcer Drugs – Histamine-2 (H-2) Antagonists			
	Nizatidine (Oral) Capsule	P	NP/PA

	Nizatidine (Oral) Solution	P	NP/PA
Immunosuppressive Agents for Organ Transplant Rejection			
	Sirolimus (Oral) Tablet	NP/PA	P
	Rapamune (Oral) Tablet	P	NP/PA
Skeletal Muscle Relaxants			
	Metaxalone (Oral) Tablet	NP/PA	NP
	Carisoprodol Compound-Codeine (Oral) Tablet	P	NP/PA
	Skelaxin (Oral) Tablet	NP	NP/PA

NP = non-preferred/ P = preferred/ PA = prior authorization

Clinical Review

The Department of Community Health will follow the 2014 American Academy of Pediatrics Policy Statement on the Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection for Synagis prior authorization criteria.

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Manufacturers' Forum
Manufacturer Presentations

Dates: November 6, 2014

Location: NorthStar HealthCare Consulting
1121 Alderman Drive
Suite 112
Alpharetta, Georgia 30005

Attendees
Department of Community Health
Linda Wiant, PharmD, Director, Pharmacy Services

NorthStar HealthCare Consulting
Tara R. Cockerham, PharmD, Clinical Programs Director
Emily Baker, PharmD, BCPS, MBA, MHA, President
Afzal Mistry, PharmD, Clinical Pharmacist

Catamaran
Talmahjia "Tami" Sweat, PharmD, Director, Clinical Management-Public Sector

Drug Summary Documents
Please note that relevant, electronic materials that were provided by manufacturers were forwarded to the Drug Utilization Review Board (DURB). The manufacturers presenting at the Forum referred the audience and the readers of the materials to the prescribing information for additional information on the drug, especially in regards to safety.

Drug Presentations

I. Merck
Ashlie Singletary, PharmD, Medical Affairs Director
Lisa Bishop, Account Executive

Grastek® (Timothy grass pollen allergen extract)

One-Page Product Summary for GRASTEK® (Timothy Grass Pollen Allergen Extract) Tablet for Sublingual Use 2800 BAU

Before prescribing GRASTEK, please read the accompanying Prescribing Information, including the Boxed Warning about severe allergic reactions. For additional copies of the Prescribing Information, please call 800-672-6372, visit hcp.grastek.com, or contact your Merck representative.

Indications and Usage: GRASTEK is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. GRASTEK is approved for use in persons 5 through 65 years of age. GRASTEK is not indicated for the immediate relief of allergic symptoms.

Dosage and Administration: GRASTEK is for sublingual use only. Dosing is one GRASTEK tablet daily. Administer the first dose of GRASTEK in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. After receiving the first dose of GRASTEK, observe the patient for at least 30 minutes to monitor for signs or symptoms of a severe systemic or a severe local allergic reaction. If the patient tolerates the first dose, the patient may take subsequent doses at home. Administer GRASTEK to children under adult supervision.

Initiate treatment at least 12 weeks before the expected onset of each grass pollen season and continue treatment throughout the season. For sustained effectiveness for one grass pollen season after cessation of treatment, GRASTEK may be taken daily for 3 consecutive years (including the intervals between the grass pollen seasons). The safety and efficacy of initiating treatment in season have not been established. In the clinical trials, treatment interruptions for up to 7 days were allowed. Prescribe auto-injectable epinephrine to patients prescribed GRASTEK and instruct them in the proper use of emergency self-injection of epinephrine.

Clinical Studies

The efficacy of GRASTEK in the treatment of allergic rhinitis with or without conjunctivitis in Timothy grass pollen allergic subjects 5 years of age and older, with or without mild asthma, was evaluated during the first grass pollen season in 2 trials of approximately 24 weeks treatment duration. The sustained effect of GRASTEK was evaluated in one trial conducted over 5 grass pollen seasons. All 3 trials were randomized, double-blind, parallel group, multicenter clinical trials. Subjects had a history of grass pollen induced rhinitis with or without conjunctivitis and sensitivity to Timothy grass pollen as determined by specific testing (IgE). Subjects with a clinical history of symptomatic allergies to non-grass pollen allergens that required treatment during the grass pollen season were excluded. Subjects initiated GRASTEK or placebo approximately 12 weeks prior to the pollen season. Efficacy was established by self-reporting of rhinoconjunctivitis daily symptom scores (DSS) and daily medication scores (DMS). The sums of the DSS and DMS were combined into the Total Combined Score (TCS) which was averaged over the entire grass pollen season.

First Season Efficacy and Sustained Effect

Adults and Children: This placebo-controlled clinical trial evaluated 1501 subjects 5 through 65 years of age (approximately 80% were 18 years and older) comparing GRASTEK (N=752) and placebo (N=749) for approximately 24 weeks. In this study, approximately 25% of subjects had mild, intermittent asthma and 85% of all subjects were sensitized to other allergens in addition to grass pollen. Subjects treated with GRASTEK had a decrease in TCS throughout the grass pollen season compared to placebo-treated subjects (23% improvement compared to placebo, 95% confidence interval [CI] [-36.0, -13.0]). Similarly, TCS was decreased compared to placebo during the peak grass pollen season (29% improvement compared to placebo, 95% CI [-39.0, -15.0]). **Children:** This double-blind clinical trial of approximately 24 weeks duration evaluated 344 pediatric subjects 5 to 17 years of age who were treated with either GRASTEK or placebo once daily. In this study, 26% of subjects had mild intermittent asthma and most subjects (89%) were sensitized to other allergens in addition to grass pollen. Pediatric subjects treated with GRASTEK had a decrease in TCS throughout the grass pollen season compared to placebo-treated subjects (26% improvement compared with placebo, 95% CI [-38.2, -10.1]).

Adult Subjects ≥18 Years: The sustained effect of GRASTEK was measured in a 5-year double-blind study. The study included 634 randomized subjects between 18 and 65 years of age who received either GRASTEK or placebo for 3 consecutive years and were then observed for 2 subsequent years. Subjects treated with GRASTEK had a decrease in TCS throughout the grass pollen season during the 3 years of active treatment. This effect was sustained during the first year grass pollen season post-GRASTEK (27.2% improvement compared to placebo, 95% CI [-39.9, -12.4]), but not in the second year. GRASTEK also demonstrated improvement in TCS for treatment year 1 (34.2% improvement compared to placebo, 95% CI [-42.0, -26.3]), treatment year 2 (40.9% improvement compared to placebo, 95% CI [-51.8, -29.5]), and treatment year 3 (34% improvement compared to placebo, 95% CI [-45.5, -21.4]).

SELECTED IMPORTANT SAFETY INFORMATION ABOUT GRASTEK

WARNING: SEVERE ALLERGIC REACTIONS

- **GRASTEK can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction.**
- **Do not administer GRASTEK to patients with severe, unstable or uncontrolled asthma.**
- **Observe patients in the office for at least 30 minutes following the initial dose.**
- **Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.**
- **GRASTEK may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction.**
- **GRASTEK may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.**

- GRASTEK is contraindicated in patients with severe, unstable, or uncontrolled asthma; a history of any severe systemic allergic reaction; a history of any severe local reaction after taking any sublingual allergen immunotherapy; a history of eosinophilic esophagitis; or hypersensitivity to any of the inactive ingredients [gelatin, mannitol and sodium hydroxide] contained in this product.
- GRASTEK can cause systemic allergic reactions including anaphylaxis which may be life-threatening and severe local reactions, including laryngopharyngeal swelling, which can compromise breathing and be life-threatening. Educate patients to recognize the signs and symptoms of these allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur. Allergic reactions may require treatment with epinephrine.
- Prescribe auto-injectable epinephrine to patients receiving GRASTEK. Instruct patients to recognize the signs and symptoms of a severe allergic reaction, and in the proper use of emergency auto-injectable epinephrine. Instruct patients to seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with GRASTEK. Review the epinephrine package insert for complete information.
- Administer the initial dose of GRASTEK in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases and prepared to manage a life-threatening systemic or local allergic reaction. Observe patients in the office for at least 30 minutes following the initial dose of GRASTEK.
- Patients who have persistent and escalating adverse reactions in the mouth or throat should be considered for discontinuation of GRASTEK.
- Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue GRASTEK and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.
- GRASTEK has not been studied in patients with moderate or severe asthma or any subjects who required daily medication to treat asthma. Immunotherapy with GRASTEK should be withheld if the patient is experiencing an acute asthma exacerbation.
- GRASTEK has not been studied in subjects who are receiving concomitant allergen immunotherapy. Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.
- Stop treatment with GRASTEK to allow complete healing of the oral cavity in patients with oral inflammation (e.g., oral lichen planus, mouth ulcers or thrush) or oral wounds, such as those following oral surgery or dental extraction.
- The most common adverse reactions reported in clinical studies for subjects 18 through 65 years of age treated with GRASTEK vs placebo included oral pruritus (26.7% vs 3.5%), throat irritation (22.6% vs 2.8%), ear pruritus (12.5% vs 1.1%) and mouth edema (11.1% vs 0.8%).
- The most common adverse reactions for GRASTEK vs placebo in clinical studies for pediatric subjects between 5 and 17 years of age included oral pruritus (24.4% vs 2.1%), throat irritation (21.3% vs 2.5%), and mouth edema (9.8% vs 0.2%).
- Because systemic and local adverse reactions with immunotherapy may be poorly tolerated during pregnancy, GRASTEK should be used during pregnancy only if clearly needed.

Questions and Answers
Q: Will physician provide first dose or write a prescription to bring to office for first dose?
A: Samples are provided to physician for first dose.

Q: What percentage of patients have allergy due to grass?
A: Approximately 1 of 3 allergic rhinitis patients are symptomatic due to grass allergy.

Q: What is considered place in therapy for Grastek and Ragwitek?
A: For patients that only have allergy to grass or ragweed.

Q: Are there any head-to-head studies vs. injections planned?
A: No.

Q: Are physicians requesting prior authorization before administering first dose?
A: Yes, generally.

Q: Are only allergists prescribing?
A: Yes, except in rural areas where patients do not have access to allergist then some primary care physicians are prescribing.

Ragwitek™ (Short Ragweed pollen allergen extract)

One-Page Product Summary for RAGWITEK™ (Short Ragweed Pollen Allergen Extract) Tablet for Sublingual Use 12 Amb a 1-U

Before prescribing RAGWITEK, please read the accompanying Prescribing Information, including the Boxed Warning about severe allergic reactions. For additional copies of the Prescribing Information, please call 800-672-6372, visit hcp.ragwitek.com, or contact your Merck representative.

Indications and Usage: RAGWITEK is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. RAGWITEK is approved for use in adults 18 through 65 years of age. RAGWITEK is not indicated for the immediate relief of allergic symptoms.

Dosage and Administration: RAGWITEK is for sublingual use only. Dosing is one RAGWITEK tablet daily. Administer the first dose of RAGWITEK in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. After receiving the first dose of RAGWITEK, observe the patient for at least 30 minutes to monitor for signs or symptoms of a severe systemic or a severe local allergic reaction. If the patient tolerates the first dose, the patient may take subsequent doses at home.

Initiate treatment at least 12 weeks before the expected onset of ragweed pollen season and continue treatment throughout the season. The safety and efficacy of initiating treatment in season have not been established. Prescribe auto-injectable epinephrine to patients prescribed RAGWITEK and instruct them in the proper use of emergency self-injection of epinephrine.

Clinical Studies
The efficacy of RAGWITEK in the treatment of ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, was investigated in two double-blind, placebo-controlled clinical trials in adults 18 through 50 years of age. Subjects received RAGWITEK or placebo for approximately 12 weeks prior to the start of the ragweed pollen season and throughout the ragweed pollen season. Subjects with asthma who participated in clinical trials had asthma of a severity that required, at most, a daily low dose of an inhaled corticosteroid. Approximately 16% of subjects had mild asthma at baseline. Subjects with a clinical history of symptomatic allergies to non-short ragweed pollen allergens that required treatment during the ragweed pollen season were excluded from both trials. Efficacy was established by self-reporting of rhinoconjunctivitis daily symptom scores (DSS) and daily medication scores (DMS). The sums of the DSS and DMS were combined into the Total Combined Score (TCS) which was averaged over the peak ragweed pollen season. Also, the average TCS over the entire ragweed pollen season was assessed.

Trial 1: This trial evaluated subjects 18 through 50 years of age comparing RAGWITEK (n=187) and placebo (n=188). Approximately 22% of subjects had mild asthma and 85% were sensitized to other allergens in addition to short ragweed. A decrease in TCS during the peak ragweed season for subjects treated with RAGWITEK was demonstrated (26% improvement compared to placebo, 95% confidence interval [CI] [-38.7%, -14.6%]). Subjects treated with RAGWITEK also showed a decrease in the average TCS from the start of and throughout the entire ragweed pollen season (26% improvement compared to placebo, 95% CI [-37.6, -13.5]).

Trial 2: This trial evaluated subjects 18 through 50 years of age comparing RAGWITEK (n=194) and placebo (n=198). Approximately 17% of subjects had mild asthma and 78% were sensitized to other allergens in addition to short ragweed. A decrease in TCS during the peak ragweed season for subjects treated with RAGWITEK was demonstrated (24% improvement compared to placebo, 95% CI [-36.5, -11.3]). Subjects treated with RAGWITEK also showed a decrease in the average TCS from the start of and throughout the entire ragweed pollen season (27% improvement compared to placebo, 95% CI [-38.8, -14.1]).

SELECTED IMPORTANT SAFETY INFORMATION ABOUT RAGWITEK

WARNING: SEVERE ALLERGIC REACTIONS

- **RAGWITEK can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction.**
- **Do not administer RAGWITEK to patients with severe, unstable or uncontrolled asthma.**
- **Observe patients in the office for at least 30 minutes following the initial dose.**
- **Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.**
- **RAGWITEK may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction.**
- **RAGWITEK may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.**

- RAGWITEK is contraindicated in patients with severe, unstable, or uncontrolled asthma; a history of any severe systemic allergic reaction; a history of any severe local reaction after taking any sublingual allergen immunotherapy; a history of eosinophilic esophagitis; or hypersensitivity to any of the inactive ingredients [gelatin, mannitol and sodium hydroxide] contained in this product.
- RAGWITEK can cause systemic allergic reactions including anaphylaxis which may be life-threatening and severe local reactions, including laryngopharyngeal swelling, which can compromise breathing and be life-threatening. Educate patients to recognize the signs and symptoms of these allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur. Allergic reactions may require treatment with epinephrine.
- Prescribe auto-injectable epinephrine to patients receiving RAGWITEK. Instruct patients to recognize the signs and symptoms of a severe allergic reaction and in the proper use of emergency auto-injectable epinephrine. Instruct patients to seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with RAGWITEK. Review the epinephrine package insert for complete information.
- Administer the initial dose of RAGWITEK in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases and prepared to manage a life-threatening systemic or local allergic reaction. Observe patients in the office for at least 30 minutes following the initial dose of RAGWITEK.
- Patients who have persistent and escalating adverse reactions in the mouth or throat should be considered for discontinuation of RAGWITEK.
- Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue RAGWITEK and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.
- RAGWITEK has not been studied in subjects with moderate or severe asthma. Immunotherapy with RAGWITEK should be withheld if the patient is experiencing an acute asthma exacerbation. Reevaluate patients who have recurrent asthma exacerbations and consider discontinuation of RAGWITEK.
- RAGWITEK has not been studied in subjects who are receiving concomitant allergen immunotherapy. Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.
- Stop treatment with RAGWITEK to allow complete healing of the oral cavity in patients with oral inflammation (e.g., oral lichen planus, mouth ulcers or thrush) or oral wounds, such as those following oral surgery or dental extraction.
- The most common adverse reactions reported in subjects 18 years of age and older treated with RAGWITEK vs placebo included throat irritation (16.6% vs 3.3%), oral pruritus (10.9% vs 2.0%), ear pruritus (10.4% vs 1.1%), oral paraesthesia (10.0% vs 4.0%), mouth edema (6.1% vs 0.5%), and tongue pruritus (5.1% vs 0.5%).
- Because systemic and local adverse reactions with immunotherapy may be poorly tolerated during pregnancy, RAGWITEK should be used during pregnancy only if clearly needed.

Questions and Answers

Q: Will a pediatric indication be sought?
A: Most likely not.

II. Greer
Richard Lankow, PhD
Laura H Beveridge, MEd, RRT

Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass mixed pollens allergen extract)
ORALAIR® is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for grass species. The US FDA approved ORALAIR in April, 2014. In the US ORALAIR is indicated for use in persons 10 through 65 years of age.

ORALAIR is taken daily on a pre- and co-seasonal schedule starting approximately 4 months before the expected start of the grass pollen season and continuing through the season.
Allergic rhinitis is a common condition, affecting up to 40% of Americans. Data shows that rhinitis is associated with a range of inflammatory conditions, including allergic asthma, allergic conjunctivitis and other comorbidities. Immunotherapy for allergic rhinitis has been used for more than 100 years. The most common form of allergy immunotherapy is delivered by subcutaneous injection of sterile preparations of allergen extracts (SCIT). Recently large-scale clinical trials, including those with ORALAIR, have demonstrated the efficacy and safety of allergen immunotherapy administered via the sublingual route (SLIT).
Grass Pollen is a major cause of allergic rhinitis affecting 25-40% of the population. Most grass-allergic patients are exposed to and sensitized to multiple grass species. Because of that ORALAIR is prepared from pollen from 5 common allergenic grass species that exhibit cross-reactivity to a wide range of grass species found throughout the US.

ORALAIR Clinical Experience: ORALAIR clinical development trials included more than 2,500 subjects in 6 placebo-controlled trials. Five studies included adults age 18 to 65 and one study included a pediatric population age 5 to 17. In the U.S. ORALAIR is indicated for use in patients age 10 to 65. Allergic rhinitis clinical trials for ORALAIR were conducted before and during the months when grass pollen is released. The trials evaluated Rhinoconjunctivitis Total Symptom Score (RTSS), which rates the severity of 4 nasal symptoms and 2 eye symptoms. In addition, subjects are allowed access to symptomatic medications including oral and ocular antihistamines, nasal steroids, and oral steroids. The use of those medications is tracked and reported as Rescue Medication Score (RMS). Clinical trials with ORALAIR showed mean improvements in symptom scores and rescue medication use compared with placebo ranging between 27% and 39%. The World Allergy Organization (WAO) notes that in allergic rhinitis clinical trials treatments may be considered clinically relevant if improvement over placebo reaches 20% or greater. Recent meta-analyses of published trials reported comparable reductions in symptom scores for allergic rhinitis drugs of approximately 5% for leukotriene receptor antagonists, 7% for antihistamines, and 17% for intranasal steroids.

In both adults and children, the most common adverse events were generally local and included oral pruritus, throat irritation, and mouth edema. Post-marketing safety studies in >800 adults and >900 children/adolescents showed a similar profile of adverse events. These local adverse events are transient are most common in the first week of treatment.

ORALAIR is currently marketed in 30 countries and was first approved in 2008. The product has been prescribed to more than 170,000 patients including 55,000 pediatric patients. Spontaneous reports to pharmacovigilance have identified 12 instances that could be classified as anaphylaxis. Of those 10 cases were related to intake of ORALAIR tablets with 8 reactions occurring with the first dose of the product. All cases resolved without the administration of epinephrine.

Questions and Answers
Q: Are there any head to head trials compared to injectable therapy planned?
A: No.

Q: If patient has Timothy grass allergy, what % of these patients will have cross reactivity to other grasses?
A: Approximately 85%.

III. Amgen
Tammy G Curtice, PharmD, MS, MBA, Sr Regional Medical Liaison

Neupogen (filgrastim)

Indications and Usage
- **Febrile Neutropenia:** NEUPOGEN® (filgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever.
    - A complete blood count and platelet count should be obtained prior to chemotherapy, and twice a week during NEUPOGEN® therapy to avoid leukocytosis and to monitor the neutrophil count.
- **Induction or Consolidation Chemotherapy:** NEUPOGEN® is indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia (AML).
- **Cancer Patients Receiving Bone Marrow Transplant:** NEUPOGEN® is indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation. It is recommended that complete blood counts (CBCs) and platelet counts be obtained at a minimum of 3 times per week following marrow infusion to monitor the recovery of marrow reconstitution.
- **Peripheral Blood Progenitor Cell Collection and Therapy:** NEUPOGEN® is indicated for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
- **Patients with Severe Chronic Neutropenia (SCN):** NEUPOGEN® is indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. It is essential that serial CBCs with differential and platelet counts, and an evaluation of bone marrow morphology and karyotype be performed prior to initiation of NEUPOGEN® therapy. The use of NEUPOGEN® prior to confirmation of SCN may impair diagnostic efforts and may thus impair or delay evaluation and treatment of underlying condition, other than SCN, causing the neutropenia.

Clinical Experience of Cancer Patients Receiving Myelosuppressive Chemotherapy
- In a phase 3 clinical trial of 210 patients with small cell lung cancer, patients received SC administration of NEUPOGEN® (4 – 8 ug/kg/day, days 4 to 17) or placebo after receiving standard dose chemotherapy with cyclophosphamide, doxorubicin, and etoposide (CAE).
- The primary end-point was incidence of infection, as manifested by febrile neutropenia.
- Secondary analyses were also performed to examine both incidence of hospitalization and IV antibiotic use.
- Treatment with NEUPOGEN® resulted in a clinically and statistically significant reduction in the incidence of infection, as manifested by febrile neutropenia ($p< 0.001$).
- The incidence of at least one infection over all cycles of chemotherapy was 76% (84/111) for placebo-treated patients, versus 40% (40/99) for NEUPOGEN®-treated patients ($p < 0.001$).
- The requirements for in-patient hospitalization and antibiotic use were also significantly decreased during the first cycle of chemotherapy; incidence of hospitalization was 69% (77/111) for placebo-treated patients in cycle 1, versus 52% (51/99) for NEUPOGEN®-treated patients ($p = 0.032$).
- The incidence of IV antibiotic usage was 60% (67/111) for placebo treated patients in cycle 1, versus 38% (38/99) for NEUPOGEN®-treated patients ($p = 0.003$).
- The mean duration of severe neutropenia in cycle 1 was reduced from 6 days (range 0 – 10 days) for patients receiving placebo to 2 days (range 0 – 9 days) for patients receiving NEUPOGEN® ($p<0.001$).
- The mean duration of neutropenia in cycle 1 was 5.64 ± 2.27 days for patients receiving placebo versus 2.44 ± 1.90 days for patients receiving NEUPOGEN®.
- Administration of NEUPOGEN® resulted in an earlier ANC nadir following chemotherapy than was experienced by patients receiving placebo (day 10 vs. day 12).
- Mean duration of dosing of NEUPOGEN® was 10-11 days.
    - Retrospective studies support duration of dosing per the label to provide outcomes that are consistent with pivotal trials.

Questions and Answers
Q: Which indication is Neupogen primarily used for?
A: Primarily used for all other indications except febrile neutropenia.

Neulasta (pegfilgrastim)

Indication

- Neulasta® is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Dosage and Administration

- 6 mg administered subcutaneously once per chemotherapy cycle
- Do not administer between 14 days before and 24 hours after chemotherapy

Phase 3 Pivotal Trials

- Neulasta was evaluated in three randomized, double-blind, controlled studies. Study 1 (Green2 et al-fixed dose Neulasta) and study 2 (Holmes3 et al-weight-adjusted Neulasta dose) were active-controlled studies that employed doxorubicin 60 mg/m2 and docetaxel 75 mg/m2 administered every 21 days for up to 4 cycles for the treatment of metastatic breast cancer (high-risk stage II or stage II/IV).
- Without G-CSF support, similar chemotherapy regimens have been reported to result in a 100% incidence of severe neutropenia (ANC < 0.5 x 109/L) with a mean duration of 5-7 days and a 30% - 40% incidence of febrile neutropenia (FN). The efficacy of Neulasta was demonstrated by establishing comparability to filgrastim-treated patients in the mean days of severe neutropenia.
- In both study 1 and 2 patients were randomized to receive either a single subcutaneous (s.c.) injection of pegfilgrastim or daily s.c. injections of filgrastim 5 □g/kg/day on day 2 of each cycle, approximately 24 hours after completion of chemotherapy.
- A single injection of pegfilgrastim each chemotherapy cycle resulted in grade 4 neutropenia duration that was both clinically and statistically similar to that observed after a mean of 11 daily injections of filgrastim.
- The third pivotal study (Vogel et al) employed docetaxel 100 mg/m2 administered every 21 days (up to 4 cycles) for the treatment of metastatic or non-metastatic breast cancer. In this study, 928 patients were randomized to receive a single 6 mg subcutaneous injection of Neulasta or placebo on day 2 of each chemotherapy cycle. The primary measure was met in this study by demonstrating that the incidence of febrile neutropenia (defined as temperature ≥ 38.2° C & ANC ≤ 0.5 x 109) was lower for Neulasta-treated patients as compared to placebo-treated patients (1% vs 17%, respectively, p < 0.001). Secondary endpoints, examining the incidence of hospitalizations (1% vs 14%) as well as antiinfective use (2% vs 10%) were lower for the Neulasta-treated patients compared to the placebo-treated group.

Questions and Answers

Q: What is the advantage of Neulasta?
A: Longer acting so dosing is only required once per chemotherapy cycle.

IV. AstraZeneca
Kathy J Berkowitz, APRN, FNP-BC, CDE, Senior Medical Science Liaison
Julie Huber, Regional Clinical Account Director
Rana Rittgers-Simonds, RD, Regional Account Director

Myalept (metreleptin)

Overview

MYALEPT is a recombinant analog of human leptin indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy (LD). There are currently no approved drugs for the treatment of metabolic abnormalities associated with LD. Current available therapies are directed toward treating the individual abnormalities, and include pharmacologic intervention with oral anti-hyperglycemic agents or insulin to target insulin-resistance and diabetes, and/or lipid-lowering agents (statins, fibrates, niacin, and fish oil).2 Those with more severe abnormalities often do not respond to these treatments due to the underlying pathophysiology as well as the profound nature of their metabolic abnormalities. With the evidence reported in the literature for shortened life expectancy in patients with LD, there is a significant unmet

medical need for a therapy that corrects the underlying pathophysiological consequences of the lipodystrophic state (i.e., leptin deficiency) and effectively improves the metabolic disorders in these patients. Native human leptin is a hormone predominantly secreted by adipose tissue that informs the central nervous system of the status of energy stores in the body. The metreleptin clinical development program for LD supporting the registration consists of an open-label, single-arm trial of MYALEPT completed at the National Institutes of Health (NIH) in LD patients.

Important Limitations of Use

- The safety and effectiveness of MYALEPT for the treatment of complications of partial lipodystrophy have not been established.
- The safety and effectiveness of MYALEPT for the treatment of liver disease, including non-alcoholic steatohepatitis (NASH), have not been established.
- MYALEPT is not indicated for use in patients with HIV-related lipodystrophy.
- MYALEPT is not indicated for use in patients without concurrent evidence of generalized lipodystrophy.

Boxed Warnings: Please refer to the MYALEPT Prescribing Information for Boxed Warnings associated with MYALEPT treatment: the development of neutralizing antibodies and T-cell lymphomas. **Contraindication:** MYALEPT is contraindicated in general obesity not associated with congenital leptin deficiency and hypersensitivity to metreleptin. **Dosing and Administration:** MYALEPT is administered as a subcutaneous injection once daily after lyophilized cake is reconstituted with bacteriostatic water for injection (BWFI) or preservative-free sterile water for injection (WFI). The recommended daily dosages in milligrams (mg) per kilogram (kg) of body weight are:

- Body weight 40 kg or less: starting dose 0.06 mg/kg/day, increase or decrease by 0.02 mg/kg to a maximum daily dose of 0.13 mg/kg
- Males greater than 40 kg body weight: starting dose 2.5 mg/day, increase or decrease by 1.25mg to 2.5mg/day to a maximum dose of 10 mg/day
- Females greater than 40 kg body weight: starting dose 5 mg/day, increase or decrease by 1.25mg to 2.5 mg/day to a maximum dose of 10 mg/day

Clinical Data

The efficacy of metreleptin for the treatment of metabolic disorders associated with inherited or acquired generalized in pediatric and adult patients was evaluated in the ongoing, long-term, open-label, single-arm NIH study. In the NIH study (N = 72), 48 (67%) patients were diagnosed with generalized lipodystrophy. Use of placebo control was not considered ethically justifiable based on results of a pilot study. Metreleptin showed clinically relevant reductions in glycated hemoglobin (HbA1c), fasting plasma glucose (FPG), and fasting triglycerides (TG) at month 4, 8 and 12 in the overall population. For patients diagnosed with generalized lipodystrophy (n = 48), as of the 11 July 2011 data cutoff in the long-term NIH study:

- The (mean ± SE) absolute change from baseline in HbA1c was -2.1 ± 0.3% at month 12 (n=50; mean baseline [SD]=8.2+ 2.2).
- The (mean ± SE) absolute changes in FPG were –48.3 ± 16.9 mg/dL at month 12 (n=52; mean baseline [SD]=169.9+ 88.5 mg/dL).
- The (mean ± SE) absolute changes in TG were –761.1 ± 245.6 mg/dL at month 12 (n=51; mean baseline [SD]=1015.6+ 1780.3mg/dL).

Distinguishing Characteristics

Myalept is the first and only recombinant analog of human leptin. Myalept exerts its function by binding to and activating the human leptin receptor (ObR), which belongs to the Class 1 cytokine family of receptors that signals through the JAK/STAT transduction pathway. In patients with generalized lipodystrophy, the deficiency of adipose tissue leads to hypertriglyceridemia and ectopic deposition of fat in non-adipose tissue such as liver and muscle, contributing to metabolic abnormalities including insulin resistance. Native leptin is a hormone predominately secreted by adipose tissue that informs the central nervous system of the status of energy stores in the body. In patients with generalized lipodystrophy, leptin deficiency, resulting from the loss of adipose tissue, contributes to excess caloric intake, which exacerbates the metabolic abnormalities.

Safety

- The total duration of exposure to metreleptin ranged from 3.6 months to approximately 11 years with a mean duration of 2.7 years.
- Six patients (13%) had 7 adverse reactions of hypoglycemia, 6 of which occurred in the setting of concomitant insulin use, with or without oral antihyperglycemic agents.

- Two patients (4%) had events of pancreatitis, both of whom had a medical history of pancreatitis.
- Adverse events (>5%) in patients who received at least 1 dose of metreleptin in the open-label NIH study (N=48) were: headache, 6(13%); hypoglycemia*, 6(13%); decreased weight, 6(13%); abdominal pain, 5(10%); arthralgia, 4(8%); dizziness, 4(8%); ear infection, 4(8%); nausea, 4(8%); ovarian cyst, 4(8%); upper respiratory tract infection, 4(8%); anemia, 3(6%); back pain, 3(6%); diarrhea, 3(6%); paresthesia, 3(6%); proteinuria, 3(6%); pyrexia, 3(6%); proteinuria, 3(6%); and pyrexia, 3(6%).
- Hypoglycemia events were assessed as mild, moderate, severe, or life threatening based on the protocol specified definitions: Mild: Documentation of low plasma glucose values with no symptoms; Moderate: Presence of clinical symptoms requiring ingestion of glucose, self-alleviated; Severe: Presence of neuroglycopenic symptoms requiring assistance from others for alleviation; Life threatening: Loss of consciousness and/or requiring intervention by administration of intravenous glucose or intramuscular glucagon.
- In patients with generalized lipodystrophy receiving MYALEPT in this study, less common adverse reactions included injection site erythema and urticaria (N=2 [4%]).

It is important to note, that LD patients may have multiple, and serious, pre-existing medical conditions. That, in combination with the relatively small numbers of patients included in the evaluations, can make interpretation of true incidence rates of adverse events (AEs), and their association with MYALEPT treatment, uncertain.

Questions and Answers
Q: How many people have generalized lipodystrophy?
A: Approximately 200-2,000 worldwide but a number of patients are not diagnosed. There are 28 patients in US on Myalept therapy.

Q: How many patients are in Georgia?
A: <6.

Q: Are other indications being sought?
A: Not at this time.

Q: What were the ages in the clinical trial?
A: Median was 15 years of age, range was 1-68 years of age and 73% were <18 years of age.

Q: Is there any outcomes data?
A: Not at this time.

V. Novartis

Deepak Singh, PharmD, National Account Scientific Director
Julia Compton, PharmD, Regional Account Scientific Director
Suzette Bannister, Senior Manager, Business Solutions

Zykadia (ceritinib)

Overview
- The recommended dose of Zykadia (ceritinib) is 750 mg orally once daily until disease progression or unacceptable toxicity. Administer Zykadia on an empty stomach (i.e., do not administer within two hours of a meal)
- Summarized below is the pivotal, Phase I, multicenter, non-randomized, open-label, dose escalation study which evaluated ceritinib, administered orally in adult patients with tumors characterized by genetic abnormalities in ALK. (Shaw et al. 2014; Felip et al. 2014)

Study Design
- Phase I, multicenter, non-randomized, open-label, dose escalation study evaluated ceritinib, administered orally in adult patients with tumors characterized by genetic abnormalities in ALK. In patients with NSCLC, demonstration of ALK rearrangement was required in ≥15% of tumor cells by break-apart fluorescence in situ hybridization (FISH) assay. Other eligibility criteria included ≥18 years of age, Eastern Cooperative Oncology Group (ECOG) performance status 0 to 2, and adequate end-organ function. Patients with asymptomatic untreated or treated central nervous system (CNS) metastases were eligible (Shaw et al. 2014).

- The primary objective was to determine the maximum tolerated dose (MTD) of ceritinib in adult patients with tumors harboring a genetic alteration in ALK. Secondary objectives were to characterize the safety and side effect profile, pharmacokinetic profile, and antitumor activity of ceritinib. In the dose-escalation phase, treatment comprised a single ceritinib dose followed by a three day pharmacokinetic evaluation period, and daily oral dosing in continuous 21-day treatment cycles. The starting dose was 50 mg per day. Expansion cohorts received the MTD of 750 mg per day (Shaw et al. 2014).

Results

- As of April 2014, a total of 246 patients with ALK-positive NSCLC have been treated with ceritinib 750 mg daily in the dose expansion portion of the study. Of these 246 patients, 83 were crizotinib naïve and 163 had been previously treated with crizotinib. Baseline characteristics were similar between those patients with and without prior crizotinib therapy (Felip et al. 2014).
- The median duration of follow-up was 10.2 months (0.1-24.1 months) in NSCLC patients previously treated with crizotinib, and 12.5 months (0.4-22.2 months) in crizotinib naïve patients (Felip et al. 2014).
- The overall response rate (ORR) for all patients with ALK+ NSCLC was 61.8% (95% CI: 55.4, 67.9) (Felip et al. 2014).
- Median duration of response (DOR) was 9.7 months (95% CI 8.3, 11.4) and median progression free survival (PFS) was 9.0 months (95% CI 6.9, 11.0) (Felip et al. 2014).
- ORR was 72.3% (95% CI: 61.4, 81.6) in crizotinib naive patients versus 56.4% (95% CI: 48.5, 64.2) in patients previously treated with crizotinib (Felip et al. 2014).
- Median PFS was 18.4 months (95% CI: 11.1, non-estimable) in crizotinib naïve patients versus 6.9 months (95% CI: 5.6, 8.7) in patients previously treated with crizotinib (Felip et al. 2014).
- Median time to response was 6.1 weeks (range: 3.0 to 42.1) for the 152 ALK-positive NSCLC patients with a confirmed complete response (CR) or partial response (PR). In the 60 crizotinib naïve patients with confirmed CR or PR, the median time to response was also 6.1 weeks (range: 3.0 to 42.1) (Felip et al. 2014).

Safety

- All patients treated at ceritinib 750 mg daily (n=255) experienced at least one adverse event, including 246 patients who experienced an adverse event suspected to be drug-related.
- Grade 3/4 adverse events and serious adverse events, suspected to be drug-related, were reported in 130 and 32 patients, respectively (Felip et al. 2014).
- The most common adverse events (all grades) included diarrhea (86.7%), nausea (82.7%), vomiting (61.6%), fatigue (42.7%), abdominal pain (38.4%), decreased appetite (37.3%), constipation (31.0%) and cough (28.6%) (Felip et al. 2014).
- Interstitial lung disease (ILD)/pneumonitis developed in 12 patients (4.7%), requiring discontinuation of ceritinib in three patients (1.2%). One case of ILD/pneumonitis was fatal. The remaining cases were managed by ceritinib dose adjustments and/or interruptions (Felip et al. 2014).

Questions and Answers

Q: When will results for the phase 3 trial be available?
A: 2016.

Q: Are other indications being sought?
A: Not at this time but being researched in other mutations.

Q: Is ceritinib being studied as initial treatment in NSCLC?
A: Yes.

Q: What other tumors exhibit ALK mutation?
A: The ALK mutation is rarely seen in a small percentage of breast cancer.

Manufacturers' Forum

ANNOUNCEMENT

NorthStar HealthCare Consulting
Georgia Department of Community Health

On behalf of the Georgia Department of Community Health (DCH) and in service to the Georgia Medicaid Fee-for-Service (FFS) Drug Utilization Review Board (DURB), NorthStar HealthCare Consulting (NHC), in conjunction with Catamaran, announces the Manufacturers' Forum occurring Thursday, February 5, 2015, with an overflow day on Tuesday, February 10, 2015 ***only*** if needed.

Date: **Thursday, February 5, 2015 from 9am-5pm EST**
Tuesday, February 10, 2015 from 9am-5pm EST (overflow day *only* if needed)

Location: **NorthStar HealthCare Consulting, 1121 Alderman Drive, Suite 112**
Alpharetta, GA 30005

Appointments: The Manufacturers' Forum is by appointment only. Appointments may be requested and will be scheduled ***after*** the Drugs Under Review are posted to the DCH website at **http://dch.georgia.gov/durb-meeting-information** approximately 30 days prior to the Forum. Manufacturers with drugs up for review at the current DURB meeting will be granted preference when seeking appointments. All requests for appointments must be made in writing to **GAMedicaid@nhc-llc.com** and include the drug name. New drug entities are generally not reviewed by the DURB until the drug has been on the market for at least 6 months.

Guidelines for Participation:

- To ensure equitable treatment of all manufacturers, individual manufacturer participation shall be limited to one 30-minute time segment per Forum. The presentation shall be limited to 20 minutes with 10 minutes for questions and answers.
- Manufacturer presentations may be audio-recorded for review after the Forum and the associated information shall be presented by NHC in summary fashion at regularly scheduled DURB meetings.
- For new drugs, manufacturers are highly encouraged to present all clinical information pertinent and relevant to current NHC clinical presentations to the DURB, to DCH drug benefit plan design as posted on the DCH website, and to other drugs within the class.
- For existing drugs, manufacturers are highly encouraged to present new clinical information since the drug was last reviewed by the DURB, especially clinical information related to comparisons of other drugs within the class.
- An electronic **one-page** summary (front only, font 10, not including references) of the presentation should be provided one week prior to the presentation via email to **GAMedicaid@nhc-llc.com** and please include a pronunciation guide of the drug's brand and generic names. The one-page summary along with relevant questions and answers related to the presentation will be provided to the DURB as well as published in the DURB meeting handout that is provided to the public at the meetings and on the DCH website at **http://dch.georgia.gov/durb-meeting-information**.

Comments and Inquiries:

- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **Preferred Drug List, Prior Authorization Criteria, Manufacturers' Forum or DURB** should submit these in writing to **GAMedicaid@nhc-llc.com**.
- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **supplemental rebates** should submit these in writing to **GAOffers@ghsinc.com**.
- Manufacturers with comments or inquiries related to Georgia Medicaid FFS **claims processing** or **drug benefit plan design** should submit these to the address or phone number below:

Catamaran, Inc.
Georgia Department of Community Health
Windward Fairways I, 3025 Windward Plaza Suite 200, Alpharetta, Georgia 30005
Phone: 770-776-2000 Fax: 770-776-2050

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Georgia Department of Community Health (GDCH)

Opportunities for Pharmaceutical Manufacturer Input on Clinical Recommendations and Clinical Management Strategies by the Drug Utilization Review Board

Clinical Information and Clinical Management Strategies relevant to the GDCH Medicaid Fee-For-Service program will be presented to the Drug Utilization Review Board (DURB) at each meeting through Catamaran by its vendor NorthStar HealthCare Consulting (NHC). Manufacturer input on recommendations is welcomed and appreciated using these opportunities. **Please note that new drug entities are generally not reviewed by the DURB until the drug has been on the market for at least 6 months.**

Ongoing Opportunity:

DUR Board Meeting Process: Drugs, therapeutic classes and/or supplemental rebate classes under review will be posted to the DCH website at **http://dch.georgia.gov/durb-meeting-information** approximately 30 days prior to the Manufacturers' Forum. Input specific to the drugs under review from manufacturers are made directly to NHC via **GAMedicaid@nhc-llc.com** and reported as appropriate by NHC at subsequent DURB meetings. NHC will pass relevant manufacturer-submitted electronic materials to the DURB members via a secure FTP site.

Upon review of information, and based on its expertise and discussions, the DURB makes recommendations to GDCH.

Presentation Opportunity:

Manufacturers' Forum: A forum prior to each relevant DURB meeting whereby manufacturers may present:

1) Clinical information relevant to a new drug on the market or a drug that is part of a therapeutic or supplemental rebate class under review by the DURB at the next meeting.

2) Clinical information relevant to ongoing NHC/Catamaran clinical management strategies (e.g. review of drug benefit plan designs, new drugs coming to market, new indications, etc.) as deemed necessary by NHC/Catamaran.

Please see the Manufacturers' Forum Announcement at **http://dch.georgia.gov/durb-meeting-information**.

Opportunity to Appeal to GDCH:

GDCH Review Process: DURB recommendations are reviewed by GDCH for final decisions. Manufacturers may request an appeal meeting for review directly with GDCH within 10 business days following DURB meetings. **Contact: Shirmary Hodges at (404) 656-4044 or shodges@dch.ga.gov**

Questions not addressed in this document may be sent to NorthStar HealthCare Consulting by e-mail: GAMedicaid@nhc-llc.com

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2015

Upcoming Meetings

Drug Utilization Review Board Meeting

2 Peachtree Street, N.W.

5th Floor Board Room

Atlanta, Georgia 30303

Thursday, March 26, 2015:	9:00am – 4:00pm
Thursday, June 4, 2015:	9:30am – 2:30pm
Thursday, September 24, 2015:	9:30am – 1:30pm
Tuesday, December 15, 2015:	9:30am – 1:30pm

Manufacturers' Forum

NorthStar HealthCare Consulting

1121 Alderman Drive

Suite 112

Alpharetta, Georgia 30005

Thursday, February 5, 2015:	9:00am – 5:00pm
Tuesday, February 10, 2010 (if needed)	9:00am – 5:00pm
Thursday, April 30, 2015:	9:00am – 5:00pm
Thursday, August 6, 2015:	9:00am – 5:00pm
Thursday, November 5, 2015:	9:00am – 5:00pm