State and Public School Life and Health Insurance Board
Drug Utilization and Evaluation Committee Minutes
March 8, 2021

The State and Public Life and Health Insurance Board, Drug Utilization and Evaluation Committee (DUEC) met on Monday, March 8th, 2021 at 1:00 p.m., via teleconference.

Voting Members present:
Dr. Scott Pace, Vice-Chairman
Dr. Hank Simmons, Chairman
Dr. Keith McCain
Dr. John Kirtley
Laura Mayfield
Dr. Shane David

Non-Voting Members present:
Shalada Toles, EBD Deputy Director
Dr. Dwight Davis
Dr. Micah Bard
Dr. Jill Johnson

Voting Members absent:

Non-Voting Members absent:
Dr. Sidney Keisner

OTHERS PRESENT
Rhoda Classen, Janella DeVille, Mary Massirer, Shay Burleson, Drake Rodriguez, Laura Thompson, EBD; Frances Bauman, Nova Nordisk; Aaron Shaw, Marissa Keith, BI; Jessica Akins, Takisha Sanders, HA; Sherry Bryant, EBRx/EBD; Octavia DeYoung, EBRx; Elizabeth Montgomery, ACHI; Brent Flaherty, Judith Paslaski, Suzanne Woodall, MedImpact; James Chapman, Abbvie; Nima Nabavi, Amgen; Charlotte Downs, Trisha Grantham, AstraZeneca; Julie Grogan, UCB; Ronda Walthall, ARDOT; Mitch Rouse, TSS

CALL TO ORDER
Meeting was called to order by Dr. Hank Simmons, Chair, and he announced that we do have a quorum today.

APPROVAL OF MINUTES
The request was made by Dr. Simmons to approve the January 11th, minutes. Dr. Kirtley made the motion to approve. Dr. Simmons seconded; all were in favor.
Motion Approved.

I. Old Business

A. Second Review of Drugs: *Dr. Jill Johnson, UAMS*

Brand	Generic	Recommendation
(1) FAM-TRASTUZUMAB DERUXTECAN-NXKI	ENHERTU	Cover w/PA for gastric adenocarcinoma
(2) MOMETASONE FUROATE	SINUVA	Exclude from pharmacy, cover on medical
(3) IVOSIDENIB	TIBSOVO®	Exclude and revisit when placebo controlled trial OS data comes out

Dr. Kirtley made a motion to approve the recommendations as presented. Dr. Pace seconded. All were in favor.

Motion Approved.

New Business

A. New Drugs*: by Dr. Jill Johnson and Dr. Sidney Keisner, UAMS*

Brand	Generic	Recommendation
Non-Specialty Drugs		
(1) ALKINDI SPRINKLE	HYDROCORTISONE	Exclude, Code 13
(2) XARACOLL	BUPIVACAINE HCL	N/A Medical
(3) VAXELIS	DIP, PERT(A)TET/HEPB/POL/HIB/PF	N/A Medical
(4) WINLEVI	CLASCOTERONE	Exclude, Code 13
(5) KLISYRI	TIRBANIBULIN	Exclude, Code 13
(6) ASTRAZENECA COVID19 VAC(UNAPP)	COVID-19 VAC, AZD1222(ASTRA)/PF	Cover (pending FDA approval)
(7) JANSSEN COVID19 VACC(UNAPPROV)	COVID-19 VAC, AD26(JANSSEN)/PF	Cover
(8) GEMTESA	VIBEGRON	Cover (reference priced category)
Specialty Drugs		
(1) DOJOLVI	TRIHEPTANOIN	Exclude, Code 13
(2) CYSTADROPS	CYSTEAMINE HCL	Cover w/PA
(3) ORENITRAM ER	TREPROSTINIL DIOLAMINE	Exclude, Code 1 & 13
(4) ZAVESCA	MIGLUSTAT	Cover w/PA
(5) NYVEPRIA	PEGFILGRASTIM-APGF	Cover (subject to rebate contracts)
(6) OXLUMO	LUMASIRAN SODIUM	Exclude, Code 1
(7) DANYELZA	NAXITAMAB-GQGK	Exclude, Code 1 and 13
(8) ORLADEYO	BEROTRALSTAT HYDROCHLORIDE	Exclude, Code 13
(9) RIABNI	RITUXIMAB-ARRX	Cover (subject to rebate contracts)
(10) IMCIVREE	SETMELANOTIDE ACETATE	Exclude, Code 1
(11) ORGOVYX	RELUGOLIX	Exclude, Code 13
(12) ZOKINVY	LONAFARNIB	Exclude, Code 12

Dr. Simmons made a motion to approve the non-specialty drug recommendations as presented. Dr. McCain seconded. All were in favor.

Motion Approved.

Dr. Kirtley made a motion to approve the specialty drug recommendations as presented. Dr. David seconded. All were in favor.

Motion Approved.

Dr. Johnson: On the second review drugs, I just want to clarify the third drug (Tibsovo) that we had questions on. We voted to exclude this drug. Sidney's notes state that we do want to continue to exclude for one of the indications but covered with a PA for refractory relapsed AML.

Dr. Simmons: The intent of the original vote was to exclude the drug for untreated AML. I suggest at this point that we consider a second vote for covering Tibsovo for relapsed AML.

Dr. Pace: My only question is if that was the recommendation out of the EBRx P&T committee or is that just the reinterpretation of data after questioning?

Dr. Bard: This drug was reviewed twice since the last DUEC in the EBRx P&T committee. It was reviewed in January and again in February. In January, the data wasn't out yet, but in February the data came out so the decision changed.

Dr. Simmons made a motion to cover this drug for relapsed AML. Dr. McCain seconded. All were in favor.

Motion Approved.

Dr. Simmons made a motion to adjourn the meeting. Dr. Kirtley seconded. All were in favor.

Meeting Adjourned.

***New Drug Code Key:**

1	Lacks meaningful clinical endpoint data; has shown efficacy for surrogate endpoints only.
2	Drug's best support is from single arm trial data
3	No information in recognized information sources (PubMed or Drug Facts & Comparisons or Lexicomp)
4	**Convenience Kit Policy** - As new drugs are released to the market through Medispan, those drugs described as "kits will not be considered for inclusion in the plan and will therefore be excluded products unless the product is available solely as a kit. Kits typically contain, in addition to a pre-packaged quantity of the featured drug(s), items that may be associated with the administration of the drug (rubber gloves, sponges, etc.) and/or additional convenience items (lotion, skin cleanser, etc.). In most cases, the cost of the "kit" is greater than the individual items purchased separately.
5	**Medical Food Policy** - Medical foods will be excluded from the plan unless two sources of peer-reviewed, published medical literature supports the use in reducing a medically necessary clinical endpoint. A medical food is defined below: A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), is "a food which is formulated to be consumed or administered eternally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food. Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition, and all foods fed to sick patients are not medical foods. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who is seriously ill or who requires use of the product as a major component of a disease or condition's specific dietary management.
6	**Cough & Cold Policy** - As new cough and cold products enter the market, they are often simply re-formulations or new combinations of existing products already in the marketplace. Many of these existing products are available in generic form and are relatively inexpensive. The new cough and cold products are branded products and are generally considerably more expensive than existing products. The policy of the ASE/PSE prescription drug program will be to default all new cough and cold products to "excluded" unless the DUEC determines the product offers a distinct advantage over existing products. If so determined, the product will be reviewed at the next regularly scheduled DUEC meeting.
7	**Multivitamin Policy** - As new vitamin products enter the market, they are often simply re-formulations or new combinations of vitamins/multivitamins in similar amounts already in the marketplace. Many of these existing products are available in generic form and are relatively inexpensive. The new vitamins are branded products and are generally considerably more expensive than existing products. The policy of the ASE/PSE prescription drug program will be to default all new vitamin/multivitamin products to "excluded" unless the DUEC determines the product offers a distinct advantage over existing products. If so determined, the product will be reviewed at the next regularly scheduled DUEC meeting.
8	Drug has limited medical benefit &/or lack of overall survival data or has overall survival data showing minimal benefit
9	Not medically necessary
10	Peer -reviewed, published cost effectiveness studies support the drug lacks value to the plan.
11	**Oral Contraceptives Policy** - OCs which are new to the market may be covered by the plan with a zero dollar, tier 1, 2, or 3 copay, or may be excluded. If a new-to-market OC provides an alternative product not similarly achieved by other OCs currently covered by the plan, the DUEC will consider it as a new drug. IF the drug does not offer a novel alternative or offers only the advantage of convenience, it may not be considered for inclusion in the plan.
12	Other
13	Insufficient clinical benefit OR alternative agent(s) available