AGENDA

State and Public School Life and Health Insurance Board
Drug Utilization and Evaluation Committee

April 07, 2014

1:00 p.m.

EBD Board Room – 501 Building, Suite 500

I.	*Call to Order*	*Kat Neill, Chairman*
II.	*Approval of February 7, 2014 Minutes*	*Kat Neill, Chairman*
III.	*Delivery Coordination Sub-Committee Report*	*David Keisner, UAMS*
IV.	*Pulmonary Hypertension Review*	*Jill Johnson, UAMS*
V.	*2015 Reference Price Review*	*David Keisner, UAMS*
VI.	*Immunization Coverage*	*Eric Crumbaugh, UAMS*
VII.	*Rheumatoid Arthritis PA criteria*	*Jill Johnson, UAMS*
VIII.	*2nd Review of drugs-Savella, Astagraf, Delzicol, Asacol*	*Jill Johnson, UAMS*
XI.	*New Drugs*	*Jill Johnson, UAMS*
X.	*EBD Report*	*Michele Hazelett, Chief Health Services Officer*

Upcoming Meetings

August 4th

NOTE: All material for this meeting will be available by electronic means only asepse-board@dfa.arkansas.gov

Notice: Silence your cell phones. Keep your personal conversations to a minimum. Observe restrictions designating areas as "Members and Staff only"

State and Public School Life and Health Insurance Board Clinical and Fiscal Drug Utilization and Evaluation Committee
Minutes
April 7, 2014

The State and Public Life and Health Insurance Board, Drug Utilization and Evaluation Committee (DUEC) met on Friday, April 7, 2014 at 1:00 p.m., in the EBD Board Room, 501 Woodlane, Little Rock, AR.

Members present:
Dr. Jill Johnson
Dr. Kat Neill - Chairman
Dr. Joe Stallings (teleconference)
Larry Dickerson
Dr. Hank Simmons – Vice Chairman
Connie Bennett
Dr. John Kirtley
Scott Pace

Members absent:
Dr. William Golden
Dr. Matthew Hadley
Mark McGrew

Michele Hazelett, Chief Health Services Officer, Employee Benefits Division

OTHERS PRESENT
Jill Johnson, Dwight Davis, David Keisner,, UAMS College of Pharmacy; John Kirtley, State Board of Pharmacy; Sherry Bryant, Janna Keathley, Stella Greene, Tammy McGill, Alicia Langston, Lori Eden, EBD; Pam Lawrence, AHH; Connie Bennett Catamaran; Marc Watts, ASEA; Warren Tyes, Merck; Ronda Walthall, AHTD; Ro Summers, ACHI; Frances Bauman, N. Nordisk; Charlene Kaiser, Amgen; Kanita Collins, Health Advantage; Barry Fielder, Qual Choice; Mark Chambers, Compsych; Treg Long, American Cancer Society; Sharon Jackson, GSK; Bridgett Johnson, Pfizer; Tony Orr, Brian Strickland, Gilead; Eric Crumbaugh, APA; Phillip Kenner, Acorda; Michael Cussia, Daichi Sankyo

CALL TO ORDER
Meeting was called to order by Dr. Kat Neill, Chairman.

APPROVAL OF MINUTES

The motion was made by Dr. Neill to approve the February 7, 2014 minutes. Simmons made the motion to approve. Dickerson seconded. All were in favor.

Minutes Approved.

DELIVERY OF COORDINATION WORK GROUP REPORT: *by Dr. David Keisner, UAMS*

Dr. Keisner reports the Delivery Coordination Work Group recently met for review and discussed Pulmonary Hypertension. The committee recommended for 2015 to cover the generic sildenafil Tier 1 with PA criteria. Adcirca, Viagra, Cialis, Levitra, and Staxyn will be excluded.

Dickerson motioned to approve the recommendations. Pace seconded. All were in favor.

Motioned Approved.

2015 REFERENCE PRICE REVIEW: *by Dr. David Keisner, UAMS*

Keisner reported on reference pricing for 2015. Many reference price meds have high co-pays. There is a potential that reference pricing could put the plan at financial risk due to the follow:

- When the members meets their max out-of-pocket there is no cost for the med
- Reference pricing does not apply to the Bronze Plan
- The Bronze Plan gained 11,000 members in 2013 and 15,000 in 2014

The top two (2) meds on the Bronze Plan in terms of cose is Nexium and Dexilant. These are referenced priced on Gold and Silver.

Dickerson motioned utilizing our policy to put meds in reference pricing and exclude Tier 2 & 3 meds, and when the meds qualify for Tier 1 they will be added to the plan. For current reference price meds when they qualify for Tier 1 they will be added to the plan also. Simmons seconded. All were in favor.

Motioned Approved.

Pace motioned to exclude the brand name if there is a generic available. If the generic is no longer available the brand name is made available. Simmons seconded. All were in favor.

Motioned Approved.

IMMUNIZATION COVERAGE: *by Dr. Eric Crumbaugh, UAMS*

Dr. Crumbaugh reported on Immunization coverage. The pharmacy Association has worked with the State Health Department on the Tetanus Vaccination. The member can receive the vaccination at their physician's office with a co-pay or at the pharmacy, and pay the full out-of-pocket expense. The member can request to be reimbursed. In 2012 there were over 48,000 cases of Pertussis. In 2013 there were 466 cases reported. The Pneumonia vaccination is similar. These immunizations would be valuable to the plan. In addition, this would also contribute to utilization.

Pace motioned to include coverage in our benefits for all ACIP recommended vaccinations to be available on the pharmacy benefit. Plan will request as a part of the benefit that each vaccine administered be reported to the immunization registry. In addition, internally continue to monitor the cost. Dickerson seconded. All were in favor.

Motioned Approved.

RHEUMATOID ARTHRITIS PA CRITERIA: *by Dr. Jill Johnson, UAMS*

Dr. Johnson reported on the change for Rheumatoid Arthritis. The recommended PA Criteria is:

- Does the patient have the diagnosis of rheumatoid arthritis?
- Has the patient reached the optimal dose of methotrexate 25-30 mg weekly and maintained for at least for 8w together with hydroxychloroquine and sulfasalazine 2-4g/d? Or does the patient have a contraindication to methotrexate?
- If the patient has a methotrexate contraindication, has the patient received leflunomide 20 mg daily as the first-line alternative to methotrexate?
- Does the patient have untreated chronic hepatitis B or Heart Failure (NYHA ckass III/IV and with an ejection fraction of <50%?

2ND REVIEW OF DRUGS: *by Dr. Jill Johnson, UAMS*

Current Coverage	Recommendation
Savella	**Exclude:** Communication to users 90 days

Astagraf	**Exclude:** Tier 1 generic is less expensive
Delzicol	**Cover: T2**
Asacol HD	**Continue to Exclude**
Apriso	**Covered at Tier 3:** Add qty limits 120 for 30 days
Pentasa	**Exclude**
Lialda	**Exclude**

Dr. Simmons motioned to approve the recommendations with 90 day member communication. Pace seconded. All were in favor.

Motioned Approved

NEW DRUGS: *by Dr. Jill Johnson, UAMS*

Johnson reported on new drugs. The review covered products released January 13, 2014 – March 10, 2014.

1. Potassium – for hypokalemia.

   Dickerson motioned to approve on Tier 1. Dr. Simmons seconded. All were in favor.

   ## Motion Approved.

2. Adasuve Inhalation – Tx of acute agitation associated with schizophrenia or bipolar I disorder.

   Dickerson motioned to exclude. Dr. Simmons seconded. All were in favor.

   ## Motion Approved.

3. Duavee tab - Prevention of post menopausal osteoporosis and hot flashes.

   Dr. Neill motioned to exclude. Dickersol seconded. All were in favor.

   ## Motion Approved.

4. Farxiga 5 mg & 10 mg – Tx of type 2 diabetes.

   Dickerson motioned to exclude. Dr. Neill seconded. All were in favor.

   Motion Approved.

5. Copaxone 40 mg inj – for MS.

   Dickerson motioned to exclude. Dr. Neill seconded. All were in **favor.**

   Motion Approved.

6. Velphoro 500 mg – For control of serum phosphorus levels for chronic kidney disease.

   Dickerson motioned to exclude. Dr. Simmons seconded. All were in favor.

   Motion Approved.

7. Zohydro ER caps – Tx of severe pain.

   Dr. Pace motioned to exclude. Dr. Kirtley seconded. All were in favor.

   Motion Approved.

8. Anoro Ellipta – Tx of emphysema/COPD.

   Dr. Pace motioned to place where Spiriva and LABAs are. Place a TD edit to avoid overlapping days supply with Spiriva, Tudorza, Foradil, Serevent, & Arcapta. Dr. Simmons seconded. All were in favor.

   Motion Approved.

9. Luza Cream – Tx for tinea, pedia, tinea cruris, and tinea corporis.

   Dr. Neill motioned to exclude. Dr. Simmons seconded. All were in favor.

   Motion Approved.

10. Nuvigil 200 mg – Tx of Narcolepsy.

    Dr. Simmons motioned to approve on Tier 2 with PA and QL. Dickerson seconded. All were in favor.

    Motion Approved.

11. Vimizim – Tx of mucopolysaccharidosis.

    Dr. Neill motioned to exclude. Dickerson seconded. All were in favor.

    Motion Approved.

12. Aptiom tabs – Tx of partial – onset seizures.

    Dr. Simmons motioned to exclude. Dickerson seconded. All were in favor.

    Motion Approved.

13. Radiogardase cap – Tx of radiation exposure.

    Dr. Neill motioned to approve on Tier 3. Dickerson seconded. All were in favor.

    Motion Approved.

14. Kuvan Powder – Tx of phenylketonuria (PKU) .

    Dickerson motioned to exclude. Dr. Neill seconded. All were in favor.

    Motion Approved.

15. AIF #2 Drug Cream Prep Kit, Vopac Cream, Vopac GB Cream, Falesssa Kit, Lidolog Kit, Marlido Kit, Baclofen cream compounding kit, Lidocaine compounding kit, Naproxen cream compounding kit, Tramadol cream compounding kit, Bupivilog kit, Multi-Specialty Kit.

    Dickerson motioned to exclude all according to kit policy. Dr. Neill seconded. All were in favor.

    Motion Approved.

16. Zinc Gluconate inj – Hospital product.

    Dr. Hadley motioned to exclude from pharmacy. Dr. Simmons seconded. All were in favor.

    Motion Approved.

17. Lupaneta Kit –Tx of Endometriosos.

Dickerson motioned to exclude. Dr. Neill seconded. All were in favor.

Motion Approved.

18. Pennsaid Solution – Tx for osteoarthritis of the knee.

    Dickerson motioned to exclude. Dr. Simmonsl seconded. All were in favor.

    Motion Approved.

19. Dermanic – For dietary management .

    Dickerson motioned to exclude. Dr. Neill seconded. All were in favor.

    Motion Approved.

20. Vitapearl Caps - Prenatal vitamin.

    Dr. Simmons motioned to exclude. Dr. Neill seconded. All were in favor.

    Motion Approved.

21. Citranatal Caps – Prenatal vitamin.

    Dr. Simmons motioned to exclude. Dr. Neill seconded. All were in favor.

    Motion Approved.

22. Vitafol-Nan tabs – Prenatal vitamin.

    Dickerson motioned to exclude. Dr. Pace seconded. All were in favor.

    Motion Approved.

23. Tretten inj – For routine prophylaxis of bleeding in patients with cogential Factor XIII A-subunit deficiency.

    Covered under medical side.

24. Karbinal ER Susp – For allergic rhinitis, allergic conjunctivitis, mild allergic skin manifestations.

    Dr. Simmons motioned to exclude. Dr. Neill seconded. All were in favor.

Motion Approved.

25. Ferivafa Caps – vitamin

    Dickerson motioned to exclude. Dr. Neill seconded. All were in favor.

    Motioned Approved.

26. Lavare Wound Gel wash – wound cleanser

    Dr. Neill motioned to exclude. Dr. Simmons seconded. All were in favor.

    Motioned Approved.

EBD REPORT: *by Michele Hazlett, EBD Health Services Officer*

Hazlett thanked the committee for all their hard work. Hazlett reported the Delivery of Coordination Work Group will be reviewing meds that could be medical or pharmacy.

Dr. Kirtley motioned to approve Dulera on Tier 2 contigent based on the price. Dr. Neill seconded. All were in favor.

Dickerson inquired about coupons. Dr. Kirtley reported the task force will be reviewing coupons.

Meeting Adjourned.

IBD drugs

Mesalamine 3/7/14— **Oral: Propose to Cover Delzicol (least costly for Tx and maint), Apriso (w/#120 QL/30d).** Exclude Pentasa, Exclude Asacol HD, Exclude Lialda.

Rectal: Propose to Cover Canasa sup, mesalamine 4g enema. Exclude Rowasa & SF Rowasa, mesalamine kit (with the cleansing wipes).

BRAND NAME	GENERIC NAME	EBD Tier After 4/23/13	ROUTE	Dose for UC	Freq /day	AWP Medispan	AWP
Oral Products							
APRISO (QD)	MESALAMINE, capsule ER 24h, 0.375g	3	ORAL	UC maint: 1.5g qd (4 caps once daily) MAINTENANCE ONLY	1	$385.63/ #120 (30d)	$385.63/ 30d
ASACOL HD (TID)	MESALAMINE, 800mg Tab DR	ex	ORAL	UC tx: 4.8g TDD X6w (1.6g TID; 2tabs TID) TREATMENT ONLY	3	$989.28/ #180(30d)	$1384.99/ 6w
DELZICOL (QID)	MESALAMINE, 400mg Capsule, DR	ex	ORAL	UC tx: 2400mg TDD X 6w (800mg TIDX6w; 2caps TID) UC maint: 1600mg TDD (400mg QID; 1cap QID)	4	Tx$477.36/ #180(30d) Maint$318.24/#120	$668.30/ 6w $318.24/30d
LIALDA (QD)	MESALAMINE, 1.2g tab DR	2	ORAL	UC tx: 2.4-4.8g TDD X8w (2.4-4.8g qd X8w; 2-4capsQD) UC maint: 2.4g TDD (2.4g qd; 2 tabs qd)	1	$972.67/ #120 (4.8gqd) (2.4gqd)	$1361.74/ 6w $486.34/ 30d
PENTASA (QID)	MESALAMINE, 250mg Cap ER	2	ORAL	UC tx: 4g TDD (1g QID; 4 caps QID) UC Maint: 4g TDD (1gQID)	4	$491.23/ #240 (#240 is a 15ds) $982.46/30ds	$1375.44/ 6w $982.46/30d $982.46/30ds
PENTASA (QID)	MESALAMINE, 500mg Cap ER	2	ORAL	UC tx: 4g TDD (1gQID; 2 caps QID) UC Maint: 4g TDD (1g QID)	4	$491.23/ #120 $982.46/30ds 982.46/30ds	$1375.44/ 6w $982.46/30d $982.46/30d
Asacol	Mesalamine	DCd					
Rectal Products							
CANASA	MESALAMINE, 1000 mg, supp	3	RECTAL	UC 1g qd X 3-6w	$774.34/ #30	$1084.08/6w	
MESALAMINE	MESALAMINE, 4g enema	1	RECTAL	UC tx, at bedtime X 3-6w	$24.42/ 4g (60mL)	$1025.64/ 6w	
MESALAMINE	MESALAMINE, 4g enemaW/CLEANSING WIPES	1	RECTAL	UC tx, at bedtime X 3-6w	$171.05/ 4g (1)	$7184.10/ 6w	
ROWASA	MESALAMINE W/CLEANSING WIPES	3	RECTAL	UC tx, at bedtime X 3-6w	$360.56/4g(1)	$15143.52/6w	
SFROWASA	MESALAMINE	3	RECTAL	UC tx, at bedtime X 3-6w	$46.83/ 4g 60mL)	$1787.94/ 6w	

"TDD" is total daily dose, not the frequency of administration.

Milnacipran(Savella)
2nd Review
Jill Johnson, Pharm.D., BCPS
4/7/14

Currently:

DUEC-EBD Drug	Generic Name	Jill's notes/recommendations	DUEC Date	DUEC's final vote	Insurance Date	Insurance Board final vote
Savella	milnacipran	SSNRI for fibromyalgia; milnacipran vs placebo significant for FM composite. Pharmacists' Letter: no data except vs placebo. Need data vs TCAs, lyrica, cymbalta. T3 w/ QL of 100mg BID (2tab/day max); try TCAs first??	(not recorded)	T3 w QL of 100mg BID	(not recorded)	T3 w QL of 100mg BID

Proposed for new users (defined as non user for previous 90 days during automated lookback):

DUEC-EBD Drug	Generic Name	Jill's notes/recommendations	DUEC Date
Savella	milnacipran	T3 Step Therapy:120 day lookback for a 30ds each of any tricyclic antidepressant, venlafaxine, gabapentin, and cyclobenzaprine.	4/7/14

Evidence Review:

1. No comparative trials with milnacipran. All controlled trials on PUBMED to date (3/20/14) used placebo as the control arm.

2. HäuserW, Urrútia G, Tort S, ÜçeylerN,Walitt B. Serotonin and noradrenaline reuptake inhibitors (SNRIs) for fibromyalgia yndrome. Cochrane Database of Systematic Reviews 2013, Issue 1. Art. No.: CD010292. DOI: 10.1002/14651858.CD010292.

The SNRIs duloxetine and milnacipran provided a **small incremental benefit** over placebo in reducing pain. **The superiority of duloxetine and milnacipran over placebo in reducing fatigue and limitations of QOL was not substantial**. **Duloxetine and milnacipran were not superior to placebo in reducing sleep problems**. The dropout rates due to adverse events were higher for duloxetine and milnacipran than for placebo. The most frequently reported symptoms leading to stopping medication were nausea, dry mouth, constipation, headache, somnolence/dizziness and insomnia. Rare complications of both drugs may include suicidality, liver damage, abnormal bleeding, elevated blood pressure and urinary hesitation.

3. Saarto T, Wiffen PJ. Antidepressants for neuropathic pain. Cochrane Database of Systematic Reviews 2007, Issue 4. Art. No.: CD005454. DOI: 10.1002/14651858.CD005454.pub2.

This update has provided additional confirmation on the effectiveness of antidepressants for neuropathic pain and has provided new information on another antidepressant - **venlafaxine.** There is still limited evidence for the role of SSRIs. Whether antidepressants prevent the development of neuropathic pain (pre-emptive use) is still unclear. Both **TCAs and venlafaxine have NNTs of approximately three**. This means that for approximately every three patients with neuropathic pain who are treated with either of these antidepressants, one will get at least moderate pain relief. There is evidence to suggest that other antidepressants may be effective but numbers of participants are insufficient to calculate robust NNTs. SSRIs are generally better tolerated by

patients and more high quality studies are required.

From UpToDate:

Initial Treatment:

Patient education regarding the disease, the treatment approaches, good sleep hygiene, and the importance of treating comorbidities that may contribute to symptoms, including mood or sleep disorders .

●An exercise program, including aerobic conditioning, stretching, and strengthening

●Drug monotherapy for treatment of symptoms not relieved by nonpharmacologic measures

Patients not responsive to initial therapy — Many patients experience continued symptoms despite initial nonpharmacologic measures and treatment with a single drug at the maximum tolerated dose; we advise the continued use of several different treatment modalities in such patients, including both nonpharmacologic and pharmacologic treatment measures. The specific intervention depends upon symptoms, patient preferences regarding the types of therapies, available resources, and expertise. These interventions are not mutually exclusive and may include:

●Combinations of drugs

●Referral for a supervised physical medicine and rehabilitation evaluation and treatment program

●Referral for psychological interventions for pain management, including cognitive behavioral therapy and other interventions

●Consultation with one or more specialists, depending upon the specific expertise needed, such as a rheumatologist, physiatrist, psychiatrist, psychologist, or pain management specialist

●Assessment and care in a specialized multidisciplinary program, particularly for patients with disease refractory to other interventions or on chronic opioids

●Other treatments, including medications for which there is more limited evidence, and complementary and alternative measures, including “mind-body” therapies such as tai chi and yoga

TCAs:

A 2010 systematic review and meta-analysis provided an indirect comparison that suggested greater efficacy of amitriptyline compared with duloxetine and milnacipran in reducing pain, sleep disturbance, and fatigue, without differences in acceptability [35]. The strength of the conclusions was limited, to some degree, by the lower methodologic quality of the amitriptyline trials.

A 2009 meta-analysis comparing antidepressants for the treatment of fibromyalgia included 18 randomized trials of a variety of agents, finding evidence for efficacy of antidepressants for pain relief, fatigue, depressed mood, sleep disturbance, and improvement in health-related quality of life [36]. The effect sizes for tricyclic antidepressants were larger than those for selective serotonin reuptake inhibitors (SSRIs) (eg, fluoxetine) and for dual serotonin and norepinephrine reuptake inhibitors (SNRIs) (eg, duloxetine or milnacipran). However, the comparisons were largely indirect, and authors of the meta-analysis concluded that the data did not allow for “a definitive conclusion regarding the superiority of one class of antidepressants over another.” This meta-analysis did not include two additional **placebo-controlled** randomized trials also suggesting benefit with use of the SNRI, milnacipran, which were published subsequently [48,49].

Cyclobenzaprine:

A 2004 meta-analysis of five randomized trials included 312 patients [43]. Self-reported improvement (measured in three studies) was more likely in subjects receiving cyclobenzaprine than placebo (odds ratio 3.0, 95% CI 1.6-5.6); the absolute difference in the rate of improvement was 21 percent, suggesting that approximately five patients would need to be treated with cyclobenzaprine for one to improve. The degree of benefit relative to placebo was similar to that observed with amitriptyline in trials comparing the latter drug with placebo [44,45]. Pain decreased more in those who received cyclobenzaprine than placebo for four weeks, but the change in pain was not significantly different in active or placebo groups after 8 or 12 weeks. Changes in pain and in the number of tender points were not significantly different between the groups at any time.

●A randomized eight-week trial performed subsequent to the meta-analysis above and involving 36 patients found that use of very low-dosecyclobenzaprine (1 to 4 mg at bedtime) statistically significantly improved the symptoms of fibromyalgia, including pain, fatigue, and depression, compared with symptoms at baseline and with use of placebo, which did not result in significant improvement [52]. Significantly more patients who received the low-dose cyclobenzaprine had improved restorative sleep, based upon analysis of cyclic alternating pattern sleep by electroencephalography; the increase in nights with improved sleep by this measure correlated with improvements in fatigue and depression. The authors proposed that improvement in cyclic alternating sleep may be a biomarker for treatment efficacy.

Inadequate response to tricyclics — In patients who do not respond to trials of low-dose tricyclics or who have intolerable side effects, we advise a trial of pregabalin, duloxetine, or milnacipran, depending upon the patient's symptoms. These medications may also be used as an alternative toamitriptyline for initial therapy.

●In patients who have more severe problems due to fatigue, we use a dual uptake inhibitor (eg, duloxetine or milnacipran) at breakfast. Duloxetine may be preferred in patients with depression requiring drug therapy, but, in such cases, care should be coordinated with a clinician with expertise in psychopharmacology of depression. In addition, regulatory factors may limit availability of one or the other agent (eg, there are differences between the US and Europe regarding which of these medications has regulatory approval for the treatment of mood disorders). (See 'Dual reuptake inhibitors' below and 'Duloxetine' below and 'Milnacipran' below.)

●In those patients with more severe problems with sleep, we use pregabalin taken at bedtime. Gabapentin is an acceptable alternative for patients for whom cost or regulatory constraints limit the availability of pregabalin. (See 'Anticonvulsants (alpha2-ligands)' below and 'Pregabalin' below and'Gabapentin' below.)

Targeted Immune Modulators
For RA
Jill Johnson, Pharm.D., BCPS
March 2014

Current:

EBRx PA criteria for Targeted Immune Modulators

If approved, the PA will be good for 1 year.

Rheumatoid Arthritis

1. Drug requesting:	↑ Infliximab (Remicade®)-must be used with methotrexate ↑ Etanercept (Enbrel®) ↑ Adalimumab (Humira®) ↑ Certolizumab pegol (Cimzia®) ↑ Golimumab (Simponi®) ↑ Tocilizumab (Actemra®) ↑ Anakinra (Kineret®) ↑ Abatacept (Orencia®) ↑ Rituximab (Rituxan®)
2. Does the patient have a diagnosis of rheumatoid arthritis?	↑ Yes ↑ No
3. Has the patient failed 3 months of DMARD therapy (examples: hydroxychloroquine, leflunomide, methotrexate, sulfasalazine, or minocycline)	↑ Yes ↑ No
4. Is the patient switching from one biologic to another? (If this is the case, the patient must have qualified for a biologic previously and have established RA requiring biologics.)	↑ Yes ↑ No
5. Does the patient have untreated chronic hepatitis B or Heart Failure (NYHA class III/IV and with an ejection fraction of ≤50%?	↑ Yes ↑ No If yes, TIMs are contraindicated.

Notes:
Early RA: The 2012 RA guidelines¥ recommend for DMARD combination therapy DMARD combination therapy.
Combinations including 2 drugs, most of which are methotrexate-based, with only a few exceptions (e.g., methotrexate & hydroxychloroquine, methotrexate, leflunomide, methotrexate& sulfasalazine, sulfasalazine & hydroxychloroquine), and triple therapy (methotrexate & hydroxychloroquine & sulfasalazine) including double and triple therapy in RA with moderate or high disease activity plus poor prognostic features. Anti-TNF biologic w/ or w/o methotrexate should be used in patients with high disease activity with poor prognostic features (except infliximab—it must be used with methotrexate).
Established RA: Three months of DMARD monotherapy should be exhausted before methotrexate, hydroxychloroquine, or leflunomide is added. If after 3 months of methotrexate or methotrexate/DMARD combination, then add a second non-methotrexate DMARD. (Triple therapy)
As an alternative to the above recommendation: After 3 months of methotrexate monotherapy or DMARD combination therapy, add or switch to an anti-TNF biologic, abatacept or rituximab.

Reference: ¥Singh JA, Furst DE, Bharat A, Curtis JR, et al. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2012 (May); 64(5): 625–639.

Proposed:

EBRx PA criteria for Targeted Immune Modulators

If approved, the PA will be good for 1 year.

Rheumatoid Arthritis				
	csDMARD (conventional synthetic)	**tsDMARD (targeted synthetic)**	**boDMARD (biologic originator)**	
	Methotrexate Sulfasalazine Leflunomide	**Tofacitinib** (targets JAK)**	**Adalimumab Certolizumab Etanercept Golimumab Infliximab Abatacept Rituximab* Tocilizumab Anakinra**	
1. Does the patient have the diagnosis of rheumatoid arthritis?				↑ Yes ↑ No (answer must be yes for access)
2. Has the patient reached the optimal dose of methotrexate 25-30mg weekly and maintained for at least for 8w together with hydroxychloroquine and sulfasalazine 2-4g/d? OR does the patient have a contraindication to methotrexate?				↑ Yes ↑ No (answer must be yes for access)
3. If the patient has a methotrexate contraindication, has the patient received leflunomide 20mg daily as the first-line alternative to methotrexate?				↑ Yes ↑ No (answer must be yes for access)
4. Does the patient have untreated chronic hepatitis B or Heart Failure (NYHA class III/IV and with an ejection fraction of ≤50%?				Yes ↑ No If yes, TIMs are contraindicated.
Note: Biologic DMARDs should all be used in combination with MTX.				
***FOR RITUXIMAB**				
NOTE: Rituximab is reserved for patients who have responded poorly to TNF blockers and not for csDMARDs.				
1. Does the patient have contraindications to other agents (recent history of lymphoma, latent tuberculosis with contraindications to the use of chemoprophylaxis, living in a TB-endemic region, or a previous history of demyelinating disease? (If so, rituximab may be used as 2nd line therapy after csDMARDs.)				↑ Yes ↑ No (answer must be yes for access)
****FOR TOFACITINIB**				
1. Has the patient failed 2 biologic DMARDS? Note: Long-term safety concerns supports this approach to make it 4th or 5th line. It may have higher serious infection rates, herpes zoster infections, TB and non-TB opportunistic infections, lymphocytopenia, anemia.				Yes ↑ No (answer must be yes for access)

Notes:

2013 EULAR Recommendations

1. Therapy with DMARDs should be started as soon as the diagnosis of RA is made.
2. Treatment should be aimed at reaching a target of remission or low disease activity in every patient.
3. Monitoring should be frequent in active disease (every 1–3 months); if there is no improvement by at most 3 months after the start of treatment or the target has not been reached by 6 months, therapy should be adjusted.
4. MTX should be part of the first treatment strategy in patients with active RA.
5. In cases of MTX contraindications (or early intolerance), sulfasalazine or leflunomide should be considered as part of the (first) treatment strategy.
6. In DMARD-naïve patients, irrespective of the addition of glucocorticoids, csDMARD monotherapy or combination therapy of csDMARDs should be used.
7. Low-dose glucocorticoids should be considered as part of the initial treatment strategy (in combination with one or more csDMARDs) for up to 6 months, but should be tapered as rapidly as clinically feasible.
8. If the treatment target is not achieved with the first DMARD strategy, in the absence of poor prognostic factors, change to another csDMARD strategy should be considered; when poor prognostic factors are present, addition of a bDMARD should be considered.
9. In patients responding insufficiently to MTX and/or other csDMARD strategies, with or without glucocorticoids, bDMARDs (TNF inhibitors*, abatacept or tocilizumab, and, under certain circumstances, rituximab†) should be commenced with MTX.
10. If a first bDMARD has failed, patients should be treated with another bDMARD; if a first TNF inhibitor therapy has failed, patients may receive another TNF inhibitor* or a biological agent with another mode of action.
11. Tofacitinib may be considered after biological treatment has failed.
12. If a patient is in persistent remission after having tapered glucocorticoids, one can consider tapering‡ bDMARDs§, especially if this treatment is combined with a csDMARD.
13. In cases of sustained long-term remission, cautious reduction of the csDMARD dose could be considered, as a shared decision between patient and physician.
14. When therapy needs to be adjusted, factors apart from disease activity, such as progression of structural damage, comorbidities and safety issues, should be taken into account.

***TNF inhibitors: adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, biosimilars (as approved according to a thorough approval process, such as by EMA and/or FDA).**

†The 'certain circumstances', which include history of lymphoma or a demyelinating disease, are detailed in the accompanying text.[1]

‡Tapering is seen as either dose reduction or prolongation of intervals between applications.

§Most data are available for TNF inhibitors, but it is assumed that dose reduction or interval expansion is also pertinent to biological agents with another mode of action.

DMARD, disease-modifying antirheumatic drug; EMA, European Medical Agency; EULAR, European League against Rheumatism; FDA, Food and Drug Administration; MTX, methotrexate; RA, rheumatoid arthritis; TNF, tumour necrosis factor.

References:

1. Smolen JS, Landewe R, Breedveld FC, et al. EULAR recommendations for the management of RA with synthetic and biological DMARDs: 2013 update. Ann Rheum Dis. 2014;73:492-509.
2. Moreland LW, O'Dell JR, et al. A randomized comparative effectiveness study of triple therapy versus etanercept plus methotrexate in early aggressive RA. TEAR Trial. Arthritis & Rheumatism. 2012;64(9):2824-2835.
3. O'Dell JR, Mikuls TR, et al. Therapies for active RA after methotrexate failure. N Engl J Med. 2013;369:307-18.
4. Van Vollenhoven RF, Ernestam S, Geborek P, et al. Addition of infliximab compared with addition of sulfasalazine and hydroxychloroquine to methotrexate in patients with early RA (Swefot trial): 1-y results of a randomized trial. Lancet. 2009;374:459-66.
5. Van Vollenhoven RF, Geborek P, Forslind K, et al. Conventional combination treatment versus biological treatment in methotrexate-refractory early RA: 2 y follow-up of the randomised, non-blinded, parallel-group Swefot trial. Lancet. 2012;379:1712-20.
6. Bathon JM, McMahon DJ. Making rational treatment decisions in RA when methotrexate fails. N Engl J Med. 369;4:384-85.

Delivery Coordination Proposal		
Drug	**Current Coverage**	**Proposed Coverage for 2015**
PDE5 antagonists		
sildenafil (generic Revatio)	T1	T1PA (PAH only)
Adcirca	T4	exclude
Viagra	T2PA	exclude
Cialis	T3PA	exclude
Levitra	T3PA	exclude
Staxyn	T3PA	exclude
Endothelin-receptor antagonists		
Tracleer	T4	T4PA
Letairis	T4	T4PA
Opsumit	tabled at last DUEC	T4PA
Guanylate cyclase stimulant		
Adempas	T4PA	T4PA
Prostacyclin analogues (pharmacy)		
Ventavis	T4PA	T4PA
Tyvaso	T4PA	T4PA
Prostacyclin Analogues(medical)		
Flolan	medical benefit (no PA required)	medical benefit (no PA required)
Remodulin	medical benefit (no PA required)	medical benefit (no PA required)

Reference Pricing

For many drug classes, a review of the medical literature reveals no evidence of clinical superiority between the many drug products available in that class. In other words, each of the products is thought to be as effective as any of the other products in that given category, and no single product stands out as being therapeutically superior. When this unique set of circumstances exists, reference pricing is put into place. In reference pricing a gold standard product is selected for the drug class. The gold standard product is as effective as all of the other drugs in the category, but it costs significantly less.

The cost per unit of the gold standard drug product would serve as the reference price for all of the other products in the class. This reference price is the maximum the plan will pay per unit (or pill) with the member responsible for the remaining cost.

One class of medications currently reference priced is proton pump inhibitors (PPI's). PPI's are commonly used to treat gastroesophageal reflux disease (GERD). The average plan cost, after the member copay, for omeprazole and pantoprazole (Generic Prilosec and Protonix) is $0.30 per pill. Omeprazole and pantoprazole are set at a Tier 1 copay and the plan will pay $0.30 per pill for all other medications in that class. The member is responsible for the remaining cost of the medication.

Reference pricing ensures our members will have access to effective medications while protecting the plan from the increasing price of prescription drug products. See below for a full list of medications that are reference priced.

	Tier 1	Tier 2	Tier 3	Tier 4
Antihyperlipidemic-HMG (Statins)	atorvastatin, lovastatin, pravastatin, simvastatin	Crestor 40mg*(PA)		
	***(RP) Reference Priced Antihyperlipidemic-HMG (Statins): Plan pays $0.30 per unit. Member is responsible for remaining cost.**	Altoprev, Crestor 5mg,10mg, 20mg, Lescol, Lescol XL, Lipitor, Mevacor, Pravachol, Zocor		
	losartan/HCTZ, irbesartan/HCTZ, irbesartan, losartan			
Angiotensin II Rec Antagonist (ARB)/Direct Renin Inhibitor (DRI)	***(RP) Reference Priced Angiotensin Receptor Blockers (ARB): Plan pays $0.81 per unit. Member is responsible for remaining cost.**	Amturnide, Atacand, **candesartan*(NG)**, Atacand HCT, candesartan cilexetil/HCTZ, Avalide, Avapro, Azor, Benicar, Benicar HCT, Cozaar, Diovan, Diovan HCT, valsartan/HCTZ, Edarbi, Edarbyclor, Exforge, Exforge HCT, Hyzaar, Micardis, **telmisartan*(NG)**, Micardis HCT, Tekturna, Tekturna HCT, Teveten, Teveten HCT, Twynsta, **telmisartan/amlodipine*(NG)**		

Antidepressant (SNRIs)	venlafaxine, venlafaxine XR capsule			
Antidepressant (SNRIs)	***(RP) Serotonin norepinephrine reuptake inhibitors (SNRIs): Plan pays $0.75 per unit. Member is responsible for remaining cost.**	Cymbalta, **duloxetine*(NG)**, Effexor XR, venlafaxine extended release ***tablets***		
Antidepressants (SSRIs)	sertraline, fluoxetine, paroxetine, citalopram, fluvoxamine			
	***(RP) Selective serotonin reuptake inhibitors (SSRIs): Plan pays $0.30 per unit. Member is responsible for remaining cost.**	Lexapro, escitalopram, Luvox CR, fluvoxamine ER, Paxil ER, paroxetine ER, Pexeva		
Sedative Hypnotics	zolpidem, zolpidem CR			
	***(RP) Reference Priced Sedatives/Hypnotics: Plan pays $0.15 per unit. Member is responsible for remaining cost.**	Ambiem, Ambien CR, Lunesta, Rozerem, Sonata, zaleplon		
Proton Pump Inhibitors	omeprazole 10mg, omeprazole 20mg, omeprazole 40mg, pantoprazole 20 & 40 mg		Zegerid powder packets	
	***(RP) Reference Priced Proton Pump Inhibitors: Plan pays $0.30 per unit. Member is responsible for remaining cost.**	Aciphex, **rabeprazole*(NG)**, Dexilant, lansoprazole, Nexium, omeprazole/sodium bicarb capsule,Prevacid, Prevacid 24hr *OTC,* Prilosec, Prilosec *OTC,* omeprazole *OTC,* Protonix, Zegerid capsule		
Overactive Bladder Agents	oxybutynin (extended release and immediate release)			
Overactive Bladder Agents	***(RP) Reference Priced Overactive Bladder Agents: Plan pays $2.12 per unit. Member is responsible for remaining cost.**	Detrol, tolterodine, Detrol LA, tolterodine (extended release), Ditropan, Ditropan XL, Enablex, Oxytrol Patch, Sanctura, trospium, Sanctura XR, trospium ER, Vesicare		
Nasal Products	azelastine, flunisolide, fluticasone			
	***(RP) Reference Priced Nasal Steroids: Plan pays up to $26.00 for a one month supply. Member is responsible for remaining cost.**	Beconase, Beconase AQ, Flonase, Nasonex, mometasone, Nasacort AQ, triamcinolone, Rhinocort AQ, budesonide		

ADHD Medications	amphetamine salts*(QL), dextroamphetamine*(QL), methylphenidate*(QL), methylphenidate ER*(QL), modafinil*(PA)*(QL), pemoline*(QL), amphetamine - dextroamphetamine SR*(QL)	Nuvigil*(PA, QL), Strattera*(QL)	Adderall XR*(QL), Concerta*(QL), Daytrana*(QL), Dexedrine*(QL), Focalin*(QL), Focalin-XR*(QL), Metadate CD*(QL), ER*(QL), Provigil* (PA), Ritalin Tablet, LA*(QL), SR, Vyvanse*(QL)	
	***(RP) Long Acting Amphetamines: Plan pays $2.50 per unit. Member is responsible for remaining cost.**	Long Acting Amphetamines are ***reference priced*** for members 26 years of age or older; ****Quantity Limits*** will still apply to ***reference priced*** long acting amphetamines. Adderall XR*(QL), amphetamine salts*(QL) extended release, Dexedrine*(QL), dextroamphetamine*(QL) extended release, Vyvanse*(QL)		

***(RP) Reference Priced Anticonvulsants: Plan pays $0.35 per unit. Member is responsible for the remaining cost.**	Lyrica (**Note:** The generic drug gabapentin will remain at a Tier 1 copay.)

Bisphosphonates, a class of medications used to treat osteoporosis, will be reference priced. Alendronate (generic Fosamax) will remain covered with a Tier-1 coapayment for up to a months supply. The plan will pay $0.10 per unit for all other bisphosphonates (Actonel, Boniva, Atelvia and generic ibandronate) with the member responsible for any remaining cost.

DUEC JAN 13 - MAR 10, 2014

GPI	DRUG NAME	PRICING (AWP)	INDICATION	SIMILAR THERAPIES ON	Connie Notes	Consultant Notes	DUEC Vote	IB Vote
79700030000445	Potassium chloride CR 20meq	$0.63/tab	For hypokalemia	Several generic options at similar price	New dosage strength.	T1		
59154020008**	Adasuve Inhalation 10mg	$174/10mg inhalation	For treatment of acute agitation associated with schizophrenia or bipolar I disorder		Only available through a restricted program to specially certified healthcare settings. NOT FOR OUTPATIENT USE. Must only be administered by healthcare professional	Exclude. Code 13. Allen MH, Feifel D, et al. Efficacy and safety of loxapine for inhalation in the treatment of agitation in patients with schizophrenia: a randomized, double-blind, placebo-controlled trial. Journal of Clinical Psychiatry. 2011; 72(10): 1313-1321. • Randomized, double-blind, placebo-controlled study; n=129 patients with schizophrenia or schizoaffective disorder randomized to receive loxapine 5mg, loxapine 10mg, or placebo. Primary outcome: absolute change from baseline on excitatory component of the Positive and Negative Syndrome Scale (PANSS-EC). Secondary outcomes: Clinical Global Impression-Improvement Scale (CGI-I), Behavioral Activity Rating Scale (BARS), and time to first rescue medication. Results: Primary outcome- statistically significant change in PANSS-EC score for loxapine 10mg (-8.56) compared to placebo (-4.98) (p=0.0002), difference for 5mg (-6.71) was not statistically significant (p=0.088). Secondary outcomes- Scores on CGI-I at 2 hours showed statistically significant effects of the 10mg (p=0.0003) and 5mg (p=0.0067); difference from placebo for change from baseline on the BARS scores at 2 hours after inhalation was statistically significant for 10mg (p<0.0001), but not the 5mg dose group; at the 24-hr assessment 33% of patients in placebo group required rescue medication, compared with 11% of loxapine 5mg and 15% in loxapine 10mg group. Safety: Most frequently reported adverse events were dysgeusia, sedation, and dizziness. No patients withdrew due to adverse events. Kwentus J, Riesenberg RA, et al. Rapid acute treatment of agitation in patients with bipolar I disorder: a multicenter, randomized, placebo-controlled clinical trial with inhaled loxapine. Bipolar Disorders. 2012; 14(1):31-40. • Randomized, double-blind, placebo-controlled trial; n=314 patients with bipolar disorder received one, two, or three doses of inhaled loxapine 5mg, 10mg, or placebo. Primary outcome: change from baseline in the PANSS-EC score 2 hours after dose 1. Secondary outcome: absolute CGI-I score 2 hours after dose 1. Results: primary outcome- statistically significant difference for 5mg (-8.1, p<0.0001) and 10mg (-9.03, p<0.0001); secondary outcome- 66% of 5mg group rated as very much or much improved (p<0.001) and 74% of 10mg group (p<0.0001) compared to placebo. NNT= 2.58 for 5mg and 2.14 for 10mg. Most common adverse events were sedation, dysgeusia, and dizziness. No serious AEs or deaths. Lesem MD, Tran-Johnson TK, et al. Rapid acute treatment of agitation in individuals with schizophrenia: multicentre, randomised, placebo-controlled study of inhaled loxapine. British Journal of Psychiatry. 2011; 198(1):51-8. • Randomized, double-blind, placebo-controlled study; n=344 patients with schizophrenia received one, two, or three doses of inhaled loxapine 5mg, 10mg, or placebo. Primary outcome: change from baseline in the PANSS-EC score 2 hours after dose 1. Secondary outcome: CGI-I score 2 hours after one dose. Results: primary outcome- highly statistically significant difference for 5mg (-8, p=0.0004) and 10mg (-8.5, p<0.0001) compared to placebo (-5.5); secondary outcome- mean CGI-I score statistically significant for 5mg (2.3, p=0.0015) and 10mg (2.1, p<0.0001) compared to placebo (2.8). Most common adverse events were		
249950021003**	Duavee tab 0.45-20 mg	$133.50/30 days	Pairs estrogen with bazedoxifene rather than progestin for the prevention of post-menopausal osterporosis and hot flashes			Exclude. Code 13. It has not been compared to Prempro or premarin + raloxifene. Silverman SL, Christiansen C, et al. Efficacy of bazedoxifene in reducing new vertebral fracture risk in postmenopausal women with osteoporosis: results from a 3-year, randomized, placebo-, and active-controlled clinical trial. Journal of Bone & Mineral Research. 2008; 23(12):1923-34. • N=7,492 women randomized to receive bazedoxifene 20mg, bazedoxifene 40mg, raloxifene 60mg, or placebo. Primary endpoint: incidence of new vertebral fractures after 36 months. Secondary endpoints: nonvertebral fractures, BMD, bone turnover markers. Results: primary endpoint- risk reduction of new vertebral fractures: bazedoxifene 20mg- 42% (HR, 0.58; 95% CI, 0.38-0.89), bazedoxifene 40mg- 37% (HR 0.63; 95% CI, 0.42-0.96), raloxifene 60mg-42% (HR 0.58; 95% CI, 0.38-0.89). No statistically significant differences among bazedoxifene and raloxifene treatment groups. Secondary endpoints- no significant differences in incidence of nonvertebral fractures between treatment groups; however, in a posthoc analysis of a subgroup of women at higher fracture risk, bazedoxifene 20mg showed a 50% and 44% reduction in nonvertebral fracture risk relative to placebo (p=0.02) and raloxifene (p=0.05). Small but statistically significant differences in BMD response at the total hip between bazedoxifene and raloxifene treatment groups (p<0.01). Incidence of VTEs was higher in the active treatment groups compared with the placebo group (bazedoxifene 20mg, 0.7%, NNH= 250; bazedoxifene 40mg, 0.6%, NNH= 333; raloxifene 60mg, 0.5% NNH=500; placebo 0.3%) . No significant difference in incidence of breast cancer among treatment groups. Silverman SL, Chines AA, et al. Sustained efficacy and safety of bazedoxifene in preventing fractures in postmenopausal women with osteoporosis: results of a 5-year, randomized, placebo-controlled study. Osteoporos Int. 2012; 23: 351-363. • 2 year extension of previous study. N= 4216 women. Raloxifene arm discontinued after 3 years, and subjects receiving bazedoxifene 40mg were transitioned to 20mg after 4 years. Primary endpoint: incidence of new vertebral fractures. Secondary endpoint: non-vertebral fractures, changes in BMD, and bone turnover markers. Results: total of 2503 subjects completed the 5 year study (40% lost to f/u). Primary endpoint- incidence of new vertebral fractures: BZA 20mg (4.5%), BZA 40/20mg (3.9%), and placebo (6.8%), p<0.05. Secondary endpoints- no significant difference in non-vertebral fracture incidence, however, in subgroup of higher-risk women, BZA 20mg reduced risk versus placebo (37%, p=0.06), and combined		

277000402003**	Farxiga 5mg & 10mg	$346.80/30 days	For Type 2 diabetes.	Invokana 300mg = $346.80/30 days	This is the second SGLT2(blocks the reabsorption of glucose by the kidney, increases glucose excretion, and lowers blod glucose levels).	Exclude. Code 13. Summary: Dapagliflozin has been shown to lower HbA1c as monotherapy and as add-on therapy to different anti-diabetic agents in patients with type 2 diabetes. It has added benefit of weight loss and reduced hypoglycemic events. It has an increase in signs and symptoms of UTIs and genital infections. There is currently only one non-inferiority trial and no data addressing how dapagliflozin effects microvascular complications or cardiovascular outcomes.		
6240003010E540	Copaxone inj 40mg/ml - syringe	$5,568/box of 12/4 week supply	For MS - dosage formulation for 3 times a week dosing	Copaxone 20mg/ml syringe - once daily dosing AWP = $6,072/box of 30 syringes	Specialty Drug	Exclude. Code 13. There are no data to suggest Copaxone 40mg TIW works any better than 20mg qd. Also, generics for the 20mg daily should be available starting in May 2014.		
52800080100520	Velphoro 500mg chw tab (sucroferric oxyhydroxide)	$1,026/bottle of 90	For the control of serum phosphorus levels in patients with chronic kidney disease on dialysis	Renvela - max dose of 14Gm/day (or 18 tabs)- $2,278/30 days. Renvela packets covered T3 w/QL.	Makers of Velphoro claims advantage of lowering pill burden than the current standard of care - Renvela	exclude. Code 13. Velphoro has not been proven to be more effective than any other agent in this class and it is considerably more expensive. Velphoro markets the product as having a lower pill burden, but if you look at the doses that are comparable in their clinical trial vs. sevelamer, this is not the case.		
651000301069**	Zohydro ER caps (10, 15, 20, 30, 40, or 50mg)	$7 - $8.58/cap	Hydrocodone extended-release cpasule used to manage pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. First extended-release dosage form of hydrocodone and is not combined with an analgesic such as acteaminophen. THIS IS NOT AN ABUSE DETERRENT FORMULATION		Catamaran coverage criteria: patient is 18 or older, AND diagnosis of severe pain requiring continuous, around-the-clock opioid analgesic for an extended period of time (at least 2 weks) AND, patient has not been adequately controlled with immediate release opioids or adjuvant non-opioid pain medications AND has tried and failed, or is unable to tolerate two of the following generic extended-release opioid products AND patient does not have any contraindications to therapy including: significant respiratory	Exclude. Code 13.		

44209902958020	Anoro Ellipta Inhalation(umeclidinium/vilanterol)	$336/inhaler	Once daily dosing of 2 bronchodilators: a long-acting muscarinic antagonist (LAMA) and a long acting beta agonist (LABA) for emphysema/COPD	The only other muscarinic antagonist/beta agonist combo inhaler, Combivent Respimat(T2)requires 4 times/day dosing AWP = $316	Anoro is name of medication combo and Ellipta is the name of the inhalation device	Place where Spiriva and LABAs are. Place a TD edit to avoid overlapping days supply with Spiriva, Tudorza, Foradil, Serevent, Arcapta.		
901540480037**	Luzu Cream(luliconazole cream)	$456/60gm tube	Topical antifungal for treatment of tinea pedia, tinea cruris, and tinea corporis.	Clotrimazole cream (T1)$3.30/45gm. Econazole (T1)$100/85gm	Drug company states "first topical azole antifungal agent approved to treat tinea cruris and tinea corporis with a 1-week, once-daily treatment regimen"	EXCLUDE. 60X7.6=$456/tube? Not compared to clotrimazole or miconazole. For tinea corporis, pedis, cruris. Has been compared only to placebo or vehicle. Code 13.		
61400010000335	Nuvigil 200mg	$20/tab			new dosage strength	Place where other strengths of Nuvigil are.		
30907030052020	Vimizim(elosulfase)	$1,280/5ml vial	Orphan drug for the treatment of mucopolysaccharidosis IVA (Morquio A syndrome) - given by IV infusion		Specialty Drug	Exclude from pharmacy benefit. Available in Medical Benefit?		
726000241003**	Aptiom tabs (200, 400,600, or 800mg tabs) - eslicarbazepine	$720/30 tabs - once daily dosing of 800mg tabs. Max dose = 1200mg/day	Adjunctive treatment of partial - onset seizures	Oxcarbazepine (T1)1200mg/day = $300/mo	Eslicarbazepine is converted to eslicarbazepine, which is the active ingredient. Eslicarbazepine is also the active metabolite of oxcarbazepine.	Exclude. Not compared to oxcarbazepine (its metabolite). If cover, require 2 meta-analyses (indirect comparisons) were not available to the UAMS Library in Full text. Will need to get interlibrary loan. Overall, 325 pts were enrolled (intent-to-treat population); 223 (68.6%) patients completed 1-year of treatment. ESL median dose was 800 mg once-daily. Compared to baseline period of the double-blind study completed prior to this OLE study, median sz frequency decreased by 32% in w 1–4, and between 37% and 39% thereafter. The responder rate (seizure reduction ≥ 50%) was 37% during w 1–4 and thereafter ranged bw 38%- 42% per 12-w interval. Proportion of sz-free pts/12-w interval ranged bw 5%-11%. Improvements from baseline in several QOL in Epilepsy Inventory-31 (QOLIE-31) and Montgomery Asberg Depression Rating Scale (MADRS) scores were observed. AEs were reported by 83% of patients. AEs occurring in ≥10% of patients were dizziness, headache and somnolence. AEs were usually of mild-moderate intensity.		
93000072100120	Radiogardase cap 0.5gm	$123/bottle of 36	Treatment of radiation exosure			T3. Prussian blue insoluble is indicated for treatment of patients with known or suspected internal contamination with radioactive cesium and/or radioactive or non-radioactive thallium to increase their rates of elimination. It does not treat complications of radiation exposure. Causes constipation.		
30908565103020	Kuvan Powder 100mg packet	$38.74/100mg packet	For treatment of phenylkitonuria(PKU)	100mg packet same price as 100mg tab $38.74	Specialty Drug	Exclude. Code 1. Sapropterin dihydrochloride indicated for PKU which can lead to neurocognitive development & growth difficulties. Oral form of tetrahydrobiopterin (BH4). Trials have measured phenylalanine levels, not rates of mental retardation or neurocognitive delays. ONe trial showed improvement in autism spectrum disorders, however, no other trials are published on this. Dose was 20mg/kg/day (assume 27kg), or $3200/d. In 2008, we tabled awaiting a geneticist's opinion. For now we do not cover it		

85100032102130	Tretten inj	$15.96/vial. Each vial contains 2000-3125 IU/vial)	For the routine prophylaxis of bleeding in patients with congential Factor XIII A-subunit deficiency.	na/z	Catamaran recommends no UM due to drug used for condition in specific popluation where barrier to therapy may result in adverse event	Exclude from Pharmacy Benefit. N/A Medical. Recombinant Factor 13, A-subunit. N/A Medical. Once monthly injection.		
41200010151120	Karbinal ER Susp 4mg/5ml (carbinoxamine maleate ER susp)	$51/120ml bottle	Extended release formulation of carbinoxamine for alergic rhinitis, allergic conjunctivitis, mild allergic skin manifestations	Carbinoxamine solution 4mg/ml = $21/120 ml Carbinoxamine 4mg tab = $0.65/tab (T1)		Exclude. Code 13. Multiple other antihistamines are available. Indicated for: Seasonal and perennial allergic rhinitis, Vasomotor rhinitis, Allergic conjunctivitis due to inhalant allergens and foods, Mild, uncomplicated allergic skin manifestations of urticaria and angioedema, Dermatographism, As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled, Amelioration of the severity of allergic reactions to blood or plasma.		
2nd Review								
	Asacol HD					handout.		
	Delzicol					"		
	Savella					Handout.		
	Astagraf					David Keisner		
No review								
90219905303700	AIF #2 Drug Cream Prep Kit	$1,109	Gabapentin-flurbiprofen-cyclobenzaprine-lidocaine-dexamethasone compounding kit			Exclude. Kit Policy. Code 4.		
90219902353750	Vopac Cream	$487/kit	Ketoprofen-lidocaine compounding kit			Exclude. Kit Policy. Code 4.		
90219903503720	VOPAC GB Cream	$487/kit	Ketoprofen-lidocaine-gabapentin compounding kit			Exclude. Kit Policy. Code 4.		
25990003406420	Falessa Kit	$130/box	levonorgest-eth estrad-FA kit			Exclude. Code 13, 4. There are 6 generic products (although without FA). Levonorgestrel 0.1 mg + folic acid 1mg (as 2 types of folic acid, Folic Acid (Vitamin B9) 400mcg, Levomefolate Glucosamine 600mcg)		
22109902906420	Lidolog Kit	$473/kit	triamcinolone inj/lidocaine inj kit			Exclude. Kit Policy. Code 4.		
69990002156420	Marlido Kit	$550/kit	lidocaine inj/bupivacaine inj kit			Exclude. Kit Policy. Code 4.		
90070015003720	Baclofen cream compounding kit	$292				Exclude. Kit Policy. Code 4.		
908500601037**	Lidocaine compounding kit	$289				Exclude. Kit Policy. Code 4.		
90210065003720	Naproxen cream compounding kit	$290				Exclude. Kit Policy. Code 4.		
90070070103720	Tramadol cream compounding kit	$293				Exclude. Kit Policy. Code 4.		
22109902876420	Bupivilog Kit	$580	Triamcinolone inj/bupivacaine kit			Exclude. Kit Policy. Code 4.		

22109902656420	Multi-Specialty Kit	$615	methylprednisolone inj/lidocaine inj kit			Exclude. Kit Policy. Code 4.		
7980002000200	Zinc gluconate inj 10mg/10ml		Hospital product			Exclude from pharmacy benefit. It is a hospital product.		
################	Ferivafa Caps	$5.47/capsule	Iron-C-FA-B12-Biotin-Cooper-Docusate capsules - multiple vitamin with iron	several generic options for less cost		Desi drug. Rx only supplement. Vit C, B12, Copper, Docusate. Not FDA-approved		
90943000004000	Lavare Wound Gel Wash	$1,725/100gm	Wound cleanser			Exclude, code 3. Mark, drug not on their website. Received ad from manufacturer. No clinical data.		
300899025064**	Lupaneta Kit	11.25mg + 90 norethindrone 5mg tabs = $3.085. 3.75mg + 30 norethindrone 5mg tabs = $1,028	leuprolide 1 month or 3 month injection & norethindrone 5mg tab for treatment of endometriosos	Lupron 11.25mg = $3,085 Lupron 3.75mg = $1,028. Norethindrone 5mg tabs = $2.65/tab	Specialty Drug	Ex. Kit policy. Code 4. No mechanism to keep up with brand kit increases over time. Currently the cost of the brand kit vs Leuprolide + generic norethindrone is the same.		
90210030302030	Pennsaid Solution 2%	$225/bottle	2 pumps to affected knee two times a day for osteoarthritis of the knee		New dosage strength. Pennsaid 1.5% currently set to reject.	Exclude, Code 13. 1.5% already on market (what we did in 2010 for 1.5%: The manufacturer has not provided sufficient data demonstrating any advantage of this drug over formulary alternatives. The product is less safe than available formulary alternatives. hepatotoxicity.Exclude) 2/19/14: CochSysRev shows topicals work better than placebo, some topicals work better than other topicals, but still no trials of any topical NSAIDs vs their orally available drugs for either efficacy or safety. Massey T, Derry S, Moore RA, McQuay HJ. Topical NSAIDs for acute pain in adults. Cochrane Database of Systematic Reviews 2010, Issue 6. Art. No.: CD007402. DOI: 10.1002/14651858.CD007402.pub2.		
81259990000400	Dermanic	$3.39/tab	Dietary management product			Exclude. Code 5, Medical Food Policy. Chromium 70mcg, Chromium Nicotinate 0.5mg, Folic Acid (Vitamin B9) 500mcg, Hydroxocobalamin 15mcg, Inositol 328mg [Inositol niacinate], Iron 1.5mg, Niacin (Vitamin B3) 1.5mg, Niacinamide 498mg, Zinc 69.5mg [N-Acetyl Cysteine]		
78512079000230	Vitapearl caps	$4/cap	prenatal vitamin	various generics available		Exclude. Code 7, Vitamin Policy. Ascorbic Acid (Vitamin C) 30mg, Biotin 300mcg [D-Biotin], Cholecalciferol 400IU, Cyanocobalamin (Vitamin B12) 8mcg, Dl-Alpha Tocopheryl Acetate (Vitamin E) 30IU, Docosahexaenoic Acid (DHA) 200mg, Folic Acid (Vitamin B9) 1.4mg, Iodine 150mcg [Potassium Iodide], Iron 30mg [Ferrous Fumarate], Niacin (Vitamin B3) 20mg [Niacinamide] [Nicotinamide], Pantothenic Acid (Vitamin B5) 10mg [Calcium Pantothenate (Vitamin B5)], Pyridoxine (Vitamin B6) 25mg, Riboflavin (Vitamin B2) 2mg, Thiamine Mononitrate (Vitamin B1) 1.7mg, Zinc 7.5mg [Zinc Oxide]		
78516047000130	Citranatal Caps	$3/cap	prenatal vitamin	various generics available		Exclude. Code 7. Vitamin Policy. Calcium 104mg [Calcium Citrate], Carbonyl Iron , Cholecalciferol 400IU, Dl-Alpha Tocopheryl Acetate (Vitamin E) 30IU, Docosahexaenoic Acid (DHA) 260mg [Algal Oil 650mg], Docusate Sodium 50mg, Ferrous Fumarate , Folic Acid (Vitamin B9) 1mg, Iron 27mg, Pyridoxine (Vitamin B6) 25mg		
78512050200320	Vitafol-Nano tabs	$3/tab	prenatal vitamin	various generics available		Exclude. Code 7. Vitamin Policy.		

A. Principles for Drug Placement--addition

The DUEC may exclude drugs from coverage for a variety of reasons coded below:

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 enterally 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